Court File No. CV-19-00632601-00CP

ONTARIO
SUPERIOR COURT OF JUSTICE

B E T W E E N:

ROBERT DRYNAN

Plaintiff

- and -

BAUSCH HEALTH COMPANIES INC., BAUSCH HEALTH, CANADA INC., VALEANT CANADA GP LIMITED, VALEANT CANADA LIMITED and VALEANT CANADA LP

Defendants

(Proceeding under the *Class Proceedings Act, 1992,* S.O. 1992, c. 6)

STATEMENT OF DEFENCE

1. The Defendants, Valeant Canada LP and Bausch Health, Canada Inc., (the **Defendants**) deny each and every allegation set out in the Statement of Claim, except as hereinafter expressly admitted, and put the Plaintiff to the strict proof thereof.

2. The action has not been certified as against Bausch Health Companies Inc., Valeant Canada GP Limited, and Valeant Canada LP, as there was no basis in fact to support the existence of a common issue against these parties. These parties fully reserve their rights in all respects and say that this action should be dismissed against them, but do not respond further to the Statement of Claim given the Court's determination.

3. The Defendants have no knowledge of the allegations contained in paragraphs 12 and 13 of the Statement of Claim.

OVERVIEW

4. The Defendants have not engaged in any form of misleading, deceptive, or otherwise unfair advertising practices with respect to the COLD-FX® Products (as defined in the Statement of Claim) so as to be liable to class members, either generally or as alleged.

5. Contrary to the allegations in the Statement of Claim, the Defendants have never stated that COLD-FX® Products "prevent and cure" colds and flu. Rather, the COLD-FX® Products have been accurately and fairly advertised, labelled, and otherwise marketed as having a "clinically proven formula" or "clinically proven" ingredients to "help to relieve" symptoms of colds and flus or to "help to reduce" the frequency, severity, and duration of cold and flu symptoms by, amongst other things, boosting the immune system.

6. As natural health products (**NHP**s), the COLD-FX® Products have been approved for sale by Health Canada based on multiple clinical studies that demonstrate, both generally and to the satisfaction of Health Canada, that the COLD-FX® Products help reduce the frequency, severity and duration of cold and flu symptoms and provide other benefits specific to each COLD-FX® Product at issue. Contrary to the allegations in the Statement of Claim, clinical studies support the statements made in relation to the COLD-FX® Products.

7. The Defendants maintain that the COLD-FX® Products are effective to help reduce the frequency, severity, and duration of cold and flu symptoms, and provide other benefits that are specific to each COLD-FX® Product. Where a consumer is not satisfied with the Product, the consumer may seek a refund from the Defendants through their customer support line. Very few consumers have sought a refund, which reflects the COLD-FX® Products' efficacy.

THE COLD-FX® PRODUCTS

8. COLD-FX® is the brand name under which Bausch Canada markets a number of NHPs containing the proprietary active ingredient CVT-E002™. CVT-E002™ is an extract of Panax quinquefolius (commonly known as North American ginseng root). CVT-E002™ is rich in poly-furanosyl-pyranosyl-saccharides. Its quality is assured using a proprietary standardization technology called ChemBioPrint®.

9. Unlike natural ginseng, CVT-E002™ undergoes extensive quality control and quality assurance processes to ensure that appropriate raw material is obtained from selected suppliers and tested against established specifications. Additionally, the CVT-E002™ extract is tested for physiochemical properties (such as appearance, odor, pH, solubility, and bulk density); biological activity; and purity and safety (including moisture content, microbiological content, and contaminants such as pesticides and heavy metals).

10. At present, there are two main product lines for COLD-FX®: COLD-FX® Daily Support and COLD-FX® First Signs. These Products include different medicinal ingredients and are marketed differently as a result:

(a) COLD-FX® Daily Support is marketed for daily intake to help reduce the chance of contracting colds and flus throughout the cold and flu season. The only active ingredient in the COLD-FX® Daily Support product line is CVT-E002™.

(b) COLD-FX® First Signs is marketed for cold and flu symptom relief when used at the first signs of a cold or flu. The active ingredients in the COLD-FX® First Signs product line include CVT-E002™, Andrographis paniculata, zinc, echinacea, and

melatonin. COLD-FX® First Signs exists in both a day time and nighttime variation.

APPROVAL OF COLD-FX® BY HEALTH CANADA

A. Pathway for Approval

11. As NHPs, the COLD-FX® Products are regulated pursuant to the Natural Health Products Regulations, SOR/2003-196 under the *Food and Drugs Act*, RSC, 1985, c. F-27 (the **FDA**). The Natural and Non-prescription Health Products Directorate (previously the Natural Health Products Directorate) of Health Canada is responsible for implementing and overseeing the regulation of NHPs in Canada.

12. The Natural Health Product Regulations, which came into effect on January 1, 2004, were developed in response to the 1999 Standing Committee on Health's Report: "Natural Health Products: A New Vision" whose recommendations formed the basis for the creation of the current regulatory framework for these products, recognizing the unique features of NHPs that make them distinct from foods and pharmaceutical products.

13. Health Canada specified two different pathways for licensing NHPs: one for products making traditional health claims and one for products making modern health claims. Traditional health claims are limited to products used within a traditional system of medicine defined by Health Canada as medicine based on the sum total of knowledge, skills and practices – which are in turn based on the theories, beliefs and experiences indigenous to different cultures – used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness. In contrast, modern health claims are defined as claims based on evidence from a range of sources, including (but not limited to) clinical studies, animal and in

vitro studies, pharmacopoeias, textbooks, peer-reviewed published articles, and regulatory authority reports.

14. Pursuant to the Natural Health Product Regulations, NHPs are manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans; restoring or correcting organic functions in humans; or modifying organic functions in humans.

15. NHPs such as COLD-FX® are defined in the Natural Health Product Regulations as products: (a) whose medicinal ingredients exist in nature including herbal remedies, vitamins and minerals, probiotics, essential fatty acids, amino acids; (b) that are manufactured, sold or represented for uses for medicinal purposes (as opposed to being consumed as foods); and (c) that are safe for self-care use by consumers (*i.e.*, can be sold as over-the counter products without a prescription). By definition, NHPs are not drugs under the FDA. At no point have the COLD-FX® Products or their ingredients been advertised as "drugs" as referenced at paragraph 23 of the Statement of Claim.

B. Assessment of Efficacy, Quality and Safety

16. Prior to being marketed in Canada, a NHP must be assessed by Health Canada and found to be safe, effective and of high quality under their recommended conditions of use. The assessment process required the Defendants to submit a licensing application to Health Canada that specifies the medicinal ingredients, recommended use(s) or health claims, and evidence supporting the safety and efficacy of the product. A product licence is only granted if Health Canada deems the product to be safe, effective and of high quality for the recommended uses or claims.

17. The type and amount of supporting evidence required depends on a product's proposed health claim(s) and its overall risks. Evidence may include clinical trial data or references to published studies, journals, pharmacopoeias and traditional resources. Health Canada also maintains a list of "pre-cleared information" supporting the safety, efficacy or quality of medicinal ingredients or NHPs that Health Canada has reviewed and deemed acceptable based on supporting evidence.

18. When Health Canada determines that a product is safe, effective and of high quality, it issues a product licence along with an eight-digit Natural Product Number (**NPN**) or Homeopathic Medicine Number (DIN-HM), which must appear on the product label. Each of the COLD-FX® Products have been reviewed, approved, and assigned a product licence and NPN by Health Canada.

19. Each of the COLD-FX® Products were approved by Health Canada based on the evidence provided to support the Products' safety, efficacy and quality in light of the recommended uses and/or claims. The clinical studies and/or information provided to, or available to, Health Canada supported and continue to support the representations made in the COLD-FX® Products' advertising and labelling. The Defendants deny that this information or the results of these studies are speculative, uncertain, contradictory, highly qualified, and/or inconclusive, as alleged or otherwise. The Defendants plead that, at no point, were the results of the clinical studies on COLD-FX® concealed or misrepresented, knowingly or otherwise.

HEALTH CANADA'S REGULATION OF NHP ADVERTISING

20. The Marketed Health Products Directorate of Health Canada regulates advertising of NHPs. Health Canada is the national regulatory authority for advertisements of health products and it is committed to ensuring that advertisements of health products are not false, misleading

or deceptive. Only NHPs that have been approved for sale (*i.e.*, licensed) by Health Canada may be advertised. Additionally, all NHPs must meet specific labelling requirements.

21. A Product Licence outlines a NHP's Terms of Market Authorization (**TMA**), a document that includes the claims authorized by Health Canada. The authorization by Health Canada of a product's health claims is based on Health Canada's review of the evidence provided by the manufacturer as part of the product's licence application. Health Canada's approval of a health claim authorizes a company to make advertising statements consistent with – although not necessarily identical to – the product's approved claims as set out in the TMA. Depending on the NPN associated with the Product, there may be some variation across the Products' claims. For example, the COLD-FX® Daily Support Products (NPNs: 80002849; 80015586; 80069106) are licensed with the following claims:

(a) Helps reduce the frequency, severity and duration of cold and flu symptoms by boosting the immune system.

(b) Helps to increase production of certain types of cytokines that may signal and activate the immune system in high performing athletes.

(c) Helps to increase production of certain types of cytokines involved in the immune response in high performing athletes.

(d) Provides further reduction of cold and flu symptoms when taken with a flu shot.

(e) Further reduces the frequency, severity and duration of cold and flu symptoms when taken with a flu shot.

(f) Clinically proven to reduce the frequency, severity and duration of cold and flu symptoms in individuals over 65 by boosting the immune system.

(g) Clinically proven to be safe and efficacious against cold and flu symptoms in individuals over 65.

(h) COLD-FX® is safe and effective for reducing symptoms associated with acute respiratory tract infections.

(i) COLD-FX® helps reduce overall symptoms of sore throat, runny nose, sneezing, nasal congestion, malaise, fever, headache, hoarseness, ear-aches and cough.

22. By way of further example, the COLD-FX® First Signs Products (Daytime) (NPNs: 80052049 and 80052846) include the following claims:

(a) Helps reduce the frequency, severity and duration of cold and flu symptoms by boosting the immune system.

(b) Echinacea helps to relieve the symptoms and shorten the duration of upper respiratory tract infections. Zinc helps to maintain immune function.

(c) Ginger is traditionally used in Herbal Medicine as an expectorant and anti-tussive to help relieve bronchitis as well as coughs and colds.

(d) Echinacea is (traditionally) used in Herbal Medicine to help fight off infections, especially of the upper respiratory tract.

(e) COLD-FX® is safe and effective for reducing symptoms associated with acute respiratory tract infections.

(f) COLD-FX® helps reduce overall symptoms of sore throat, runny nose, sneezing, nasal congestion, malaise, fever, headache, hoarseness, earaches and cough.

(g) Take at first signs of a cold to help relieve cold symptoms and boost the immune system.

(h) Take at first signs of cold to help reduce the frequency of cold and flus.

(i) Helps to relieve the symptoms and shorten the duration of upper respiratory tract infections.

(j) Helps to relieve the symptoms of upper respiratory tract infections, such a sore throat, cough, runny nose, fatigue, fever and headache.

23. The Defendants plead that the labelling and advertising of the COLD-FX® Products are consistent with the approved health claims and the Natural Health Product Regulations, and deny that the COLD-FX® marketing is in breach of Ontario's *Consumer Protection Act* or Equivalent Consumer Protection Legislation, the *Competition Act*, the *Food and Drugs Act*, or Health Canada's advertising guidelines.

24. As described below, the Defendants rely on the statutory presumption of consistency and the regulated conduct defence. Health Canada has specifically authorized the Defendants to make the representations that are challenged by the Plaintiff.

THE PLAINTIFF'S CLAIM

25. The Plaintiff's claim arises from his purchase of COLD-FX® Daily Support on or around March 15, 2019, allegedly for the purpose of preventing the full onset of a cold once he began experiencing cold and flu symptoms. The Plaintiff alleges his symptoms continued to develop despite having taken COLD-FX® Daily Support.

26. The Plaintiff did not acquire the appropriate COLD-FX® Product for his medical concerns: he purchased COLD-FX® Daily Support rather than COLD-FX® First Signs, even though he claims to have already been exhibiting the signs of a cold or flu. To treat his symptoms and to minimize the effects of his cold, the Plaintiff should have taken COLD-FX® First Signs, which includes additional active ingredients to help alleviate symptoms. COLD-FX® First Signs was specifically introduced by the Defendants to provide consumers with a treatment option for exhibited symptoms.

27. The Defendants maintain that if COLD-FX® Daily Support was not effective as the Plaintiff claims, it is because this specific product is not intended to provide relief once an individual is already exhibiting cold and flu symptoms. Rather, as described above, COLD-FX® Daily Support is intended to be used throughout the cold and flu season to, as marketed, help to reduce the severity, frequency and duration of cold and flu symptoms by boosting the immune system.

28. The Plaintiff failed to identify and purchase the correct COLD-FX® product for his cold. As such, his claim that the COLD-FX® Product he purchased did not work was caused solely by his own actions, including a failure to consult a healthcare professional and/or read the information available in respect to the COLD-FX® Product he purchased. The Plaintiff did not see a doctor, consult a pharmacist or take any notes regarding the degree of symptoms he experienced, and as such, there is no objective record of his symptoms or how they compared to previous colds. The Plaintiff made no attempt to obtain a refund, nor did he contact the Defendants about a refund given his alleged dissatisfaction with COLD-FX® Daily Support.

NO FALSE, MISLEADING, OR UNCONSCIONABLE REPRESENTATIONS

29. The Defendants deny that any representations regarding the COLD-FX® Products were unsubstantiated, false, misleading, deceptive, or unconscionable, and further deny that any representations were made with reckless disregard as to the truth of these representations, or with knowledge that these representations were false or misleading, as alleged.

30. The Defendants further deny the Plaintiff's claim that the evidence submitted to Health Canada or otherwise relied upon for the purposes of obtaining a Product Licence does not support the advertised benefits of the COLD-FX® Products. To the contrary, the evidence provided to Health Canada on the safety, efficacy and quality of the COLD-FX® Products adequately supports the advertised statements regarding the COLD-FX® Products' efficacy, benefits, uses, and/or health claims, both generally and to Health Canada's satisfaction in its role as the regulator of NHPs and their advertising. In fact, Health Canada approved the claims in the COLD-FX® Products' TMA based on the submitted evidence.

31. Throughout the Statement of Claim, the Plaintiff has mischaracterized numerous Representations or listed Representations that have not been made by the Defendants. The Defendants deny that each and every alleged improper Representation in respect to each of the COLD-FX® Products:

(a) was stated in the language set out by the Plaintiff's in the Statement of Claim;

(b) was actually made, approved by, or otherwise in the control of the Defendants;

(c) supports finding that the Defendants engaged in false, misleading, and/or unconscionable practices; and/or

(d) forms a consumer and/or general impression, as alleged or otherwise.

32. Contrary to the allegations contained in the Statement of Claim, at no point have the Defendants marketed the COLD-FX® Products as being able to prevent or cure colds and flus. At no point did the Defendants represent that the COLD-FX® Products guarantee or warrant efficacy in every consumer with every use. The Defendants maintain that no reasonable person would have concluded or formed the general impression that the COLD-FX® Products were a cure for, or would instantly and/or totally relieve symptoms of, colds and flus, or that the Representations alleged deceive or tend to deceive.

33. Further, or in the alternative, the phrases “clinically proven” or “proven by science”, as part of the overall COLD-FX® promotional campaign: (a) are subjective in their meaning and general impression; (b) reflect the difference between COLD-FX® and other ginseng or NHP products, which proceed through the traditional health claims pathway and are therefore not based on any clinical data; (c) reflect the fact that there is clinical data and scientific research supporting the COLD-FX® Products’ claims; and (d) have only been used by the Defendants in the context of the claims set out in the Products’ TMA. The general and literal impressions conveyed by the Defendants’ marketing and labelling of the COLD-FX® Products are accurate.

34. Further, and contrary to the Plaintiff’s allegations, the Defendants have not represented that:

(a) The efficacy of COLD-FX® Products is “Proven by Science” or “clinically proven” to prevent and cure colds and flu, or help to cure colds and flus;

(b) Consumers should use COLD-FX® Products in place of “the flu shot or other proven prophylactics against, or treatments of, colds and flu”, or otherwise dissuaded consumers from taking other measures to prevent colds and flus. To

the contrary, the COLD-FX® Products are marketed as complementary to the flu shot;

(c) The COLD-FX® Products were "clinically proven to provide instant relief of symptoms at the first signs of a cold or flu" or "proven by science" to do so; and

(d) The COLD-FX® Products will provide the benefits advertised without adequate evidentiary support.

35. The Defendants specifically deny, as alleged, that any class members or reasonable person would have formed the general impression that any of the COLD-FX® Products:

(a) "were clinically proven to provide instant relief of symptoms at the first signs of a cold or flu";

(b) "have approval, performance characteristics, benefits, and qualities that they do not have"; or

(c) "are of a particular standard, quantity, and grade (including "clinically proven" and "Proven by Science") that they are not".

36. The Defendants deny that they failed to state material facts, or that they used exaggeration, innuendo or ambiguity as to material facts about the COLD-FX® Products, and further deny that they engaged in any behaviour that deceived or tended to deceive.

37. The Defendants deny that they had any knowledge, or that there is truth in the allegation that, but for these alleged misrepresentations, many consumers would not have purchased the COLD-FX® Products and/or would not pay the price charged for COLD-FX® Products, and put the Plaintiff to the strict proof thereof.

38. The Defendants deny that they made any false or misleading representations with respect to the COLD-FX® products in testimonials posted on the COLD-FX® website, on social media or otherwise. In any event, the Defendants deny that they are liable for the content of testimonials that are provided by third parties. The Defendants further deny that they are liable for any information provided by, or representations made by, retailers, pharmacists, or other third parties concerning the COLD-FX® Products, beyond what is included in the Products' label, advertising or packaging.

APPROVAL THROUGH THE REGULATORY REGIME

39. Simply put, the Defendants' marketing of the COLD-FX® Products is supported the materials reviewed by Health Canada that demonstrate the Products' safety, efficacy, and quality, which were the basis of Health Canada's approval of the Products as NHPs. Contrary to the Plaintiff's claims that the evidentiary support for COLD-FX® Products' safety and efficacy is unreliable, Health Canada determined that these studies and other information cited by the Defendants were sufficient to obtain approval for the COLD-FX® Products and the claims listed in the Products' respective TMAs.

40. The Defendants deny that the supporting evidence provided to Health Canada was inadequate for the reasons set out in the Statement of Claim, or otherwise. The Defendants put the Plaintiff to the strict proof of these allegations.

41. The Defendants rely on Health Canada's review and approval of the evidence supporting the COLD-FX® Products' health claims and advertising, as well as the regulatory regime through which that approval was provided. The Defendants plead that the Plaintiff's allegations in this action undermine the role of the governing regulatory bodies in this respect and rely on the statutory presumption of consistency and the regulated conduct defence.

42. In the alternative, if determined that the Defendants made any of the Representations as alleged in the Statement of Claim, the Defendants plead that these Representations were part of a holistic advertising campaign focussed on differentiating the COLD-FX® Products from other NHPs that do not have clinical support, and further plead that such Representations were not intended to, and in fact do not, convey the meanings alleged in the Statement of Claim.

43. In the further alternative, the Defendants state that any Representations not included in the Products' labelling and/or TMAs are mere puffery and are, in any event, not actionable. Moreover, as set out at paragraph 32 above, the Plaintiffs have reframed and/or misstated numerous Representations set out in the Statement of Claim. The Defendants state that any such Representation is also not actionable.

NO CLAIM UNDER CONSUMER PROTECTION LEGISLATION

A. No Liability Under Consumer Protection Legislation

44. The Defendants deny that they engaged in unfair practices under, or otherwise breached any provisions of, the *Consumer Protection Act*, 2002, S.O. 2002, c. 30 (the **Ontario CPA**) or Equivalent Consumer Protection Legislation (as defined in the Statement of Claim). The Defendants deny that the labelling or advertising of the COLD-FX® Products was in any way misleading or deceptive, whether under the CPA, Equivalent Consumer Protection Legislation, or otherwise.

45. The Defendants specifically deny that they knew or ought to have known that (a) consumers would be unable to receive a substantial or any benefit from the COLD-FX® Products; (b) the consumer transactions were excessively one-sided in favour of the Defendants;

and (c) the impugned representations, including testimonials regarding COLD-FX® Products, contained misleading statements that consumers were likely to rely on to their detriment.

46. The Defendants maintain that, where the Plaintiffs have accurately set out the impugned Representations in the Statement of Claim, these are supported by the TMA and COLD-FX® Products' licences, which Health Canada granted based on an assessment of supporting evidence, including clinical studies. The Defendants deny that they knowingly concealed or misrepresented the results of such clinical studies.

47. In addition, the Defendants deny that they are liable, jointly or severally, under Section 18(12) of the Ontario CPA or under Equivalent Consumer Protection Legislation for the alleged unfair practices concerning the COLD-FX® Products.

48. The Defendants further deny that any agency relationship existed or exists between either Defendant and the COLD-FX® Product retailers, distributors, or other "sales agents", as set out in the Statement of Claim or otherwise, as it relates to the matters pleaded in the Statement of Claim. The Defendants deny that they, or their alleged "sales agents", knew or ought to have known the nature of the alleged misrepresentations as stated at paragraph 74 of the Statement of Claim. The Defendants further deny that they or the alleged "sales agents" acted unconscionably, or engaged in unfair practices in any way.

49. The Defendants deny that any of the alleged misrepresentations are express warranties as alleged at paragraph 80 of the Statement of Claim, and put the Plaintiff to the strict proof thereof, in addition to the availability of damages resulting from breach of the same.

50. Further, the Defendants put the Plaintiff and class members to the strict proof of any loss, damages, or detriment on the basis that the return or restitution of the COLD-FX® Products purchased is no longer possible, as alleged.

B. "Equivalent" Consumer Protection Legislation

51. The Plaintiff has failed to plead the material facts necessary to satisfy the elements of the statutory causes of action for misleading advertising that vary across Equivalent Consumer Protection Legislation, and has not, in fact, even pleaded the relevant provisions of such legislation, including applicable privity and/or notice requirements. The Defendants put the Plaintiffs to the strict proof of demonstrating that the necessary elements of each statutory cause of action under the Ontario CPA and Equivalent Consumer Protection Legislation have been pleaded and met.

a. *The Ontario CPA*

52. The Defendants deny that the impugned representations are actually false, misleading or unconscionable within the meaning of sections 14, 15 and 17 of the Ontario CPA. The Defendants specifically deny that they did, said, or failed to do or say anything regarding the COLD-FX® Products that would be considered to be an unfair practice under the Ontario CPA. The Defendants deny that the Plaintiff is entitled to any remedy under section 18 of the Ontario CPA.

53. Contractual privity is necessary for the class members to recover under section 18 of the Ontario CPA. The Defendants deny that any agreement exists, directly or indirectly, between the Defendants and any consumer with respect to the COLD-FX® Products that would satisfy the statutory privity requirement.

54. As set out above, the Representations are not warranties, and the class members are not entitled to damages pursuant to the Ontario CPA on this basis, as alleged at paragraph 80 of the Statement of Claim. No provision with respect to breach of an express warranty under the Ontario CPA has been specifically pleaded.

55. The Defendants further deny that the Plaintiff complied with the notice requirements under section 18(3) of the Ontario CPA. The Defendants say that there is no basis, either pleaded or at law or in fact, to waive any notice requirements under the Ontario CPA.

b. *British Columbia's Business Practices and Consumer Protection Act, SBC 2004, c 2* (**British Columbia Statute**)

56. The Defendants deny that the impugned representations constitute deceptive or unconscionable acts or practices within the meaning of sections 4, 8 and 9 of the British Columbia Statute. The Defendants specifically deny that they did, said, or failed to do or say anything regarding the COLD-FX® Products that would be considered to be an unfair practice under the British Columbia Statute.

57. As set out above, the Representations are not warranties, and the class members are not entitled to damages pursuant to the British Columbia Statute on this basis as alleged at paragraph 80 of the Statement of Claim. No provision with respect to breach of an express warranty under the British Columbia Statute has been specifically pleaded.

c. *Alberta's Consumer Protection Act*, RSA 2000, c C-26.3 (**Alberta Statute**)

58. The Defendants deny that the impugned representations qualify as unfair practices within the meaning of section 6 of the Alberta Statute. The Defendants specifically deny that they did,

said, or failed to do or say anything regarding the COLD-FX® Products that would be considered to be an unfair practice under the Alberta Statute.

59. Contractual privity is necessary for the class members to recover under section 7 of the Alberta Statute. The Defendants deny that any agreement exists, directly or indirectly, between the Defendants and any consumer with respect to the COLD-FX® Products that would satisfy the statutory privity requirement. No equivalent provision has been pleaded regarding joint and several liability under the Alberta Statute.

60. As set out above, the Representations are not warranties, and the class members are not entitled to damages pursuant to the Alberta Statute on this basis, as alleged at paragraph 80 of the Statement of Claim. No provision with respect to breach of an express warranty under the Alberta Statute has been specifically pleaded.

61. The Defendants further deny that the Plaintiff complied with the notice requirements under section 7.1 of the Alberta Statute. The Defendants say that there is no basis, either pleaded or at law or in fact, to waive any notice requirements under the Alberta Statute.

d. *Saskatchewan's Consumer Protection and Business Practices Act, SS 2013, c C-30.2* (**Saskatchewan Statute**)

62. The Defendants deny that the impugned representations are unfair practices within the meaning of sections 6, 7 and 8 of the Saskatchewan Statute. The Defendants specifically deny that they did, said, or failed to do or say anything regarding the COLD-FX® Products that would be considered to be an unfair practice under the Saskatchewan Statute. The Defendants deny that the general impression conveyed by the impugned representations is misleading.

63. As set out above, the Representations are not warranties, and the class members are not entitled to damages pursuant to the Saskatchewan Statute on this basis, as alleged at

paragraph 80 of the Statement of Claim. No provision with respect to breach of an express warranty under the Saskatchewan Statute has been specifically pleaded.

64. Further, the Defendants maintain that they acted reasonably in the circumstances in conveying the alleged unfair practice, and took reasonable precautions and exercised due diligence to avoid the alleged unfair practice.

e. *Manitoba's Business Practices Act, CCSM c B120* (**Manitoba Statute**)

65. The Defendants deny that the impugned representations are unfair business practices within the meaning of sections 2, 3 and 5 of the Manitoba Statute. The Defendants specifically deny that they did, said, or failed to do or say anything regarding the COLD-FX® Products that would be considered to be an unfair practice under the Manitoba Statute. The Defendants deny that the general impression conveyed by the impugned representations supports finding that either Defendant engaged in unfair practices.

66. As set out above, the Representations are not warranties, and the class members are not entitled to damages pursuant to the Manitoba Statute on this basis, as alleged at paragraph 80 of the Statement of Claim. No provision with respect to breach of an express warranty under the Manitoba Statute has been specifically pleaded.

67. Further, the Defendants took reasonable precautions and exercised due diligence to avoid the alleged unfair practice. The Defendants maintain that the Plaintiff and class members did not make reasonable efforts to minimize any damage resulting from the alleged unfair business practices and to resolve the dispute with the Defendants before commencing the court action.

f. *Quebec's Consumer Protection Act, CQLR c P-40.1* (**Quebec Statute**)

68. The Defendants deny that the impugned representations are false or misleading within the meaning of the Quebec Statute under *Part II – Business Practices* or otherwise. The Defendants specifically deny that they did, said, or failed to do or say anything regarding the COLD-FX® Products that would be considered under the Quebec Statute to be a false or misleading representation, or that the COLD-FX® Products do not conform to their description in statements or advertisements. The Defendants deny that the general impression conveyed by the impugned representations supports finding that either Defendant engaged in unfair practices.

69. Contractual privity is necessary for the class members to recover under the Quebec Statute. The Defendants deny that any agreement exists, directly or indirectly, between the Defendants and any consumer with respect to the COLD-FX® Products. No equivalent provision has been pleaded regarding joint and several liability under the Quebec Statute.

70. As set out above, the Representations are not warranties, and the class members are not entitled to damages pursuant to the Quebec Statute on this basis, as alleged at paragraph 80 of the Statement of Claim. No provision with respect to breach of an express warranty under the Quebec Statute has been specifically pleaded.

g. *Prince Edward Island's Business Practices Act, RSPEI 1988, c B-7* (**PEI Statute**)

71. The Defendants deny that the impugned representations are unfair business practices or unconscionable consumer representations within the meaning of sections 2 and 3 of the PEI Statute. The Defendants specifically deny that they did, said, or failed to do or say anything regarding the COLD-FX® Products that would be considered to be an unfair practice under the PEI Statute.

72. Contractual privity is necessary for the class members to recover under section 4 of the PEI statute. The Defendants deny that any agreement exists, directly or indirectly, between the Defendants and any consumer with respect to the COLD-FX® Products that would satisfy the statutory privity requirement. No equivalent provision has been pleaded regarding joint and several liability under the PEI Statute.

73. As set out above, the Representations are not warranties, and the class members are not entitled to damages pursuant to the PEI Statute on this basis, as alleged at paragraph 80 of the Statement of Claim. No provision with respect to breach of an express warranty under the PEI Statute has been specifically pleaded.

74. The Defendants further deny that the Plaintiff complied with the notice requirements under section 4 of the PEI Statute. The Defendants say that there is no basis, either pleaded or at law or in fact, to waive any notice requirements under the PEI Statute.

h. *Newfoundland and Labrador's Consumer Protection and Business Practices Act, SNL 2009, c C-31.1* (**Newfoundland Statute**)

75. The Defendants deny that the impugned representations are unfair consumer practices or unconscionable acts within the meaning of sections 7, 8 and 9 of the Newfoundland Statute. The Defendants specifically deny that they did, said, or failed to do or say anything regarding the COLD-FX® Products that would be considered to be an unfair practice under the Newfoundland Statute. No equivalent provision has been pleaded regarding joint and several liability under the Newfoundland Statute.

76. Contractual privity is necessary for the class members to recover under section 10 of the Newfoundland Statute. The Defendants deny that any agreement exists, directly or indirectly,

between the Defendants and any consumer with respect to the COLD-FX® Products that would satisfy the statutory privity requirement.

77. As set out above, the Representations are not warranties, and the class members are not entitled to damages pursuant to the Newfoundland Statute on this basis, as alleged at paragraph 80 of the Statement of Claim. No provision with respect to breach of an express warranty under the Newfoundland Statute has been specifically pleaded.

i. *New Brunswick, Nunavut, Nova Scotia, Northwest Territories and Yukon Consumer Protection Statutes*

78. The Defendants deny that the New Brunswick, Nunavut, Nova Scotia, Northwest Territories and Yukon consumer protection statutes contain provisions concerning unfair or unconscionable practices that parallel or are equivalent to those in the Ontario CPA. Equivalent provisions have not been pleaded. In the alternative, the Defendants specifically deny that they did, said, or failed to do or say anything regarding the COLD-FX® Products that would be considered to be an unfair practice under these statutes.

79. The Defendants state that, to the extent recovery for unfair practices equivalent to those set out in the Ontario CPA are available to the Plaintiff and class members, contractual privity is necessary for the class members to recover under these statutes. The Defendants deny that any agreement exists, directly or indirectly, between the Defendants and any consumer with respect to the COLD-FX® Products that would satisfy the statutory privity requirement. No equivalent provision has been pleaded regarding joint and several liability under any of these statutes

80. As set out above, the Representations are not warranties, and the class members are not entitled to damages pursuant to these statues on this basis, as alleged at paragraph 80 of the Statement of Claim. No provisions with respect to breach of an express warranty under these

statues have been specifically pleaded. In regard to the New Brunswick Statute, the Defendants maintain that the alleged loss was not reasonably foreseeable at the time of the contract as liable to result from the breach.

NO CLAIM UNDER THE *COMPETITION ACT*

81. The Defendants deny that they are in breach of Section 52 of the *Competition Act,* R.S.C. 1985, c. C-34, and further deny that damages should be awarded pursuant to section 36 of the *Competition Act*.

82. As described herein, the Defendants deny that the labelling, advertising, or other marketing activities concerning the COLD-FX® Products were in any way false or misleading, or could be expected to deceive or mislead a reasonable person as to the COLD-FX® Products, whether pursuant to section 52 of the *Competition Act* or otherwise. The COLD-FX® Product labels were consistent with the Products' TMAs and were approved by Health Canada.

83. The Defendants further deny that the Plaintiff or any class members or members of the public would have formed the general and/or consumer impression set out in the Statement of Claim.

84. In the alternative, if the Defendants are found to have labelled or marketed the COLD-FX® Products in a manner that was false or misleading, which is not admitted but expressly denied, the Defendants did not act knowingly or recklessly in making the alleged misleading statements to the public. The Defendants further deny that the alleged misrepresentations were false or misleading in a material respect.

85. The Defendants deny that the Plaintiff or any class members suffered losses or damages as a result of the alleged unfair practices and corresponding breach of section 52, and further

deny that any investigation costs were incurred in connection with the matter. The Defendants put the class members to the strict proof thereof.

NO CLAIM UNDER THE *FOOD AND DRUGS ACT*

86. The Defendants deny that their conduct in any way violates the FDA or Health Canada's advertising guidelines for NHPs, as alleged or otherwise. The Defendants further deny that any cause of action is available to the class members under the FDA or the advertising guidelines.

NO UNJUST ENRICHMENT

87. The Defendants deny that either Defendant has been unjustly enriched from the marketing and sale of the COLD-FX® Products by way of the Defendants' sales revenues or otherwise, and further deny that the class members suffered any corresponding deprivation to the unjust enrichment alleged. The Defendants maintain that there was no deprivation as class members received products that performed in accordance with the Products' labelling.

88. In the alternative, if either Defendant is found liable for unjust enrichment (which is expressly denied), the Defendants plead that there is juristic reason for the alleged enrichment and corresponding deprivation. The Defendants deny that their alleged misconduct negates or renders void any such juristic reason, as alleged at paragraph 90 of the Statement of Claim or otherwise.

NO WAIVER OF TORT

89. The Defendants rely on the Plaintiff's position at the certification hearing that the Plaintiff's waiver of tort claim is no longer being pursued.

NO DAMAGES OR SPECIFIC PERFORMANCE

90. The Defendants deny that any losses, damages, or detriment were suffered by the Plaintiff or class members, as compensatory damages under section 18 of the Ontario CPA or Equivalent Consumer Protection Legislation, section 36 of the *Competition Act*, or by way of restitution or disgorgement, either as alleged or otherwise.

91. The Defendants say that, in the vast majority of cases, the COLD-FX® Products worked in a manner consistent with the scientific studies and clinical trials upon which they were approved by Health Canada, and thus the Products' ingredients and/or formula should be considered to be "clinically proven" or "proven by science" to deliver the effects of these Products as advertised.

92. At all times, the COLD-FX® Products had the characteristics, standards, benefits, and qualities that they were advertised to possess. The Defendants deny that the Plaintiff or any other class member purchased any COLD-FX® Products based on (a) an expected value that was more than the actual value acquired for the actual product or (b) characteristics subsequently determined by the purchaser to have been falsely or misleadingly advertised.

93. The Defendants put the Plaintiff and class members to the strict proof of demonstrating:

(a) the price paid for the COLD-FX® Products;

(b) when the purchases were made in relation to the alleged misrepresentation(s);

(c) the value of the COLD-FX® Products purchased; and

(d) the alleged "sales agent" from whom the Product was purchased.

94. In any event, the Defendants deny that restitution and/or disgorgement of the Defendants' profits is available to the class members, and put the Plaintiff to the strict proof thereof.

95. The Defendants further deny that the class members' value of the COLD-FX® Products, or the damages allegedly incurred by the Plaintiff or class members, if any, can be determined on a class-wide basis.

96. Further, no punitive or exemplary damages are warranted. The Defendants maintain that there is no basis to the Plaintiff's claim that the alleged misrepresentations are false or misleading, let alone unconscionable or demonstrative of a careless disregard for consumers' health, as pleaded or otherwise.

97. In the alternative, should the Defendants be found to have engaged in unfair practices with respect to the COLD-FX® Products (which is expressly denied), the Defendants plead that the damages sought by the class members are excessive, remote, or otherwise unrecoverable at law. Further, the Plaintiff and the class members have failed to mitigate their damages.

98. The Defendants deny that the Plaintiff, or any class member, is entitled to the specific performance sought, which would enjoin the Defendants from claiming that the efficacy of the COLD-FX® Products is "Proven by Science" or from making the other Representations, as set out in the Statement of Claim.

99. The Defendants plead that, as applicable, the class members' claims are statutorily barred and rely on:

(a) In Ontario, section 4 of the *Limitations Act*, RSO 2002, c. 24;

(b) In British Columbia, section 6 of *The Limitation Act*, SBC 2012, c. 13;

(c) In Alberta, section 3 of the *Limitations Act*, RSA 2000, c L-11;

(d) In Saskatchewan, section 5 of *The Limitation Act,* SS 2004, c. L-16.1;

(e) In Manitoba, section 6 of the *Limitations Act*, SM 2021, c 44.

(f) In Quebec, article 2925 of the *Civil Code of Quebec*;

(g) In New Brunswick, section 5 of the *Limitation of Actions Act*, SNB 2009, c. L-8.5;

(h) In Prince Edward Island, section 2 of the *Statute of Limitations,* RSPEI 1988, c. s-7;

(i) In Nova Scotia, section 2 of the *Limitation of Actions Act*, RSNS, c. 258;

(j) In Newfoundland and Labrador, section 5 of the *Limitations Act*, SNL, 1995, c. L-16.1;

(k) In Nunavut, section 2 of the *Limitation of Actions Act*, RSNWT (Nu) 1988, c L-8;

(l) In the Northwest Territories, section 2 of the *Limitation of Actions Act*, RSNWT 1988, c L-8; and

(m) In the Yukon, section 2 of the *Limitation of Actions Act*, RSY 2002, c. 139.

100. The Defendants ask that this action be dismissed with costs on a substantial indemnity basis.

October 21, 2022

NORTON ROSE FULBRIGHT CANADA LLP
222 Bay Street, Suite 3000
Toronto ON M5K 1E7

Randy Sutton LSO#: 50369C
Tel: 416.216.4046
randy.sutton@nortonrosefulbright.com
Justine Smith LSO#: 75276S
Tel: 416.216.1921
justine.smith@nortonrosefulbright.com
Jacob Medvedev LSO#: **84951W**
jacob.medvedev@nortonrosefulbright.com
Tel: 416-203-4460

Fax: 416.216.3930

Lawyers for the Defendants

TO:

TYR LLP
180 John Street
Toronto ON M5T 1X5

Sean Campbell
Tel: 416.527.3934
scampbell@tyrllp.com
James Bunting
Tel: 647.519.6607
jbunting@tyrllp.com
Carlos Sayao
Tel: 416.294.7800
csayao@tyrllp.com

Tel: 647.475.5669

Lawyers for the Plaintiff

Court File No. CV-19-00632601-0000

ROBERT DRYNAN
Plaintiff

-and-

BAUSCH HEALTH COMPANIES INC. et al.
Defendants

ONTARIO
SUPERIOR COURT OF JUSTICE

PROCEEDING COMMENCED AT
TORONTO

STATEMENT OF DEFENCE

NORTON ROSE FULBRIGHT CANADA LLP
222 Bay Street, Suite 3000
Toronto ON M5K 1E7

Randy Sutton LSO#: 50369C
Tel: 416.216.4046
randy.sutton@nortonrosefulbright.com
Justine Smith LSO#: 75276S
Tel: 416.216.1921
justine.smith@nortonrosefulbright.com
Jacob Medvedev LSO#: 84951W
Tel: 416-203-4460
jacob.medvedev@nortonrosefulbright.com

Fax: 416.216.3930

Lawyers for the Defendants