Amended March 31, 2006 pursuant to the Order of Madam Justice E.A. Arnold-Bailey

No. S87156
New Westminster Registry

IN THE SUPREME COURT OF BRITISH COLUMBIA

BETWEEN:

DIANNA LOUISE STANWAY

PLAINTIFF

AND:

WYETH CANADA INC., WYETH PHARMACEUTICALS, INC. WYETH HOLDINGS CANADA INC., WYETH CANADA, ~~WYETH-AYERST PHARMACEUTICALS INC.~~ WYETH-AYERST INTERNATIONAL INC. ~~WYETH LABORATORIES INC., WYETH PHARMACEUTICALS~~ and WYETH, ~~INC.~~

DEFENDANTS

Brought under the *Class Proceedings Act*, R.S.B.C. 1996, c. 50

AMENDED STATEMENT OF CLAIM

The Parties

1. The Plaintiff resides in Sechelt, British Columbia. She developed lobular and ductal breast cancer as a result of taking the Defendants' hormone therapy drug Premarin in combination with progestin. The Plaintiff purchased and used Premarin in British Columbia. She brings this claim on her own behalf, and on behalf of a class of similarly situated persons resident in British Columbia and elsewhere in Canada.

2. ~~The Defendant, Wyeth Canada Inc., is a pharmaceutical company which markets the prescription drugs Premarin and Premplus in British Columbia and across Canada. It is incorporated under the laws of Canada and has a registered office in British Columbia at 700~~

~~West Georgia Street, Vancouver, British Columbia. Wyeth Canada Inc. is a subsidiary or affiliate of the remaining Defendants, Wyeth Pharmaceuticals, Inc., Wyeth-Ayerst Pharmaceuticals Inc., Wyeth-Ayerst International Inc., Wyeth Laboratories Inc., Wyeth Pharmaceuticals, and Wyeth, Inc.~~ The Defendants, Wyeth Canada Inc. and Wyeth Holdings Canada Inc. are Canadian corporations that carry on business in Canada through a general partnership known as Wyeth Canada. Each of the Defendants, Wyeth Canada Inc., Wyeth Holdings Canada Inc. and Wyeth Canada has a registered office in British Columbia at 700 West Georgia Street, Vancouver, British Columbia. Wyeth Canada is a pharmaceutical business which markets the prescripton drugs Premarin and Premplus in British Columbia and Canada. Wyeth Canada Inc., Wyeth Holdings Canada Inc., Wyeth Pharmaceuticals Inc. and Wyeth-Ayerst International Inc. are wholly owned subsidiaries of the Defendant, Wyeth. The Defendants individually and jointly manufactured, tested, marketed, labelled, distributed, promoted, and sold Premarin and Premplus in British Columbia and elsewhere. The Defendants engaged in a joint enterprise for the promotion and sale of Premarin and Premplus in British Columbia and elsewhere.

Premarin and Premplus

3. Premarin is a form of the hormone estrogen. It was prescribed to women to treat the symptoms of menopause. It was also prescribed to women for long-term use to treat the post-menopausal effects of aging. Premarin was promoted by the Defendants as providing a number of health benefits including, but not limited to improvement in one's sense of well-being, reduced nervousness, reduced anxiety, reduced depression, reduced irritability, reduced fatigue, improved sleep, reduced memory loss, improved cognition, reduction in loss of bone density, decrease in osteoporosis, improved cardiovascular function, decrease in cardiovascular and coronary artery disease, prevention of Alzheimer's disease, and improved sexual function.

4. Premarin was usually prescribed together with the hormone progestin, such that women taking Premarin would usually also use medication with progestin. Premplus contains both estrogen and progestin in a single medication. It was used for the same purposes as Premarin and was prescribed such that women would receive both hormones from a single medication.

which the drugs were promoted. For the vast majority of women, the risks of using Premarin and Premplus outweigh the limited benefits. The symptoms of menopause can be alleviated with other, safer therapies. Premarin and Premplus should not be used except in limited circumstances for short durations and only where other therapeutic choices have been found inadequate.

7. The Plaintiff was prescribed and ingested Premarin together with progestin for approximately 8 years, beginning in 1995. In the summer of 2002, she became aware of recently published studies that linked the use of estrogen to a variety of health problems including breast cancer. She consulted with her physician who prescribed a graduated reduction of the hormone therapy. By in or about March 2003, the Plaintiff had stopped her use of Premarin and progestin. In May 2003, the Plaintiff had a mammogram which revealed the presence of a tumour. On or about May 27, 2003, she was diagnosed with ductal and lobular breast cancer.

8. The Plaintiff's breast cancer was caused or materially contributed to by the ingestion of Premarin.

9. At all material times, the Defendants owed the Plaintiff and all of the consumers of Premarin and Premplus a duty of care.

Negligence

10. The Defendants negligently marketed, tested, manufactured, labelled, distributed, promoted, sold, and otherwise placed Premarin and Premplus into the stream of commerce in British Columbia and elsewhere in Canada when they knew, or ought to have known that Premarin and Premplus were of limited efficacy and were unsafe, and that the risks of using Premarin and Premplus outweighed the benefits. The Defendants negligently marketed, labelled, distributed, promoted, and sold Premarin and Premplus in British Columbia and elsewhere in Canada with insufficient testing and medical evidence as to efficacy and safety.

11. The Defendants were negligent in failing to adequately inform the Plaintiff and the other class members and their physicians of the limited efficacy of Premarin and Premplus. The

Defendants were negligent in failing to adequately inform the Plaintiff and other class members and their physicians of the risks of using Premarin and Premplus. The Defendants were negligent in failing to adequately inform the Plaintiff and the other class members and their physicians that there was little or no testing on the efficacy and safety of Premarin and Premplus. The Defendants were negligent in failing to adequately inform the Plaintiff and the other class members and their physicians that the testing that had been done by the Defendants and others indicated significant health risks associated with the use of Premarin and Premplus.

12. The Defendants were negligent in their marketing of Premarin and Premplus in that they irresponsibly over-promoted the long-term and widespread use of these drugs, thereby creating a market for these drugs which was far greater than the efficacy and safety of these drugs warranted. The Defendants improperly encouraged, through their sales and marketing efforts, the long-term use of these drugs as an effective and safe treatment for symptoms of aging in post-menopausal women. The Defendants knew, or ought to have known, that the risks of such long-term use outweighed the benefits. The Defendants knew or ought to have known that they were selling far more of these drugs than could reasonably be justified given the drugs' limited short-term benefits for only a limited patient population. The Defendants could have and ought to have taken reasonable steps, through warnings, and through sales and marketing efforts, to responsibly restrict the use of these drugs to a limited number of women in limited circumstances, and in particular, only to women who suffered severe symptoms of menopause, and who were not responsive to other therapies, and then only for short-term use.

13. The Defendants were negligent in over-promoting the illusory benefits of the drugs, and in making claims for the efficacy of these drugs which were not properly supported by testing and research. Although, Premarin and Premplus are of some benefit in reducing some symptoms of menopause and in reducing the incidence of osteoporosis, they do not offer the other benefits for which they were marketed and sold. Nevertheless, the Defendants repeatedly and actively portrayed these drugs as being effective at providing a host of health benefits even though research to support such claims was limited or non-existent or suggested otherwise. Through their sales and marketing efforts, the Defendants oversold the effectiveness of the drugs, and made claims regarding the efficacy of these drugs which were insufficiently supported by

research, while also failing to adequately disclose the safety risks of these drugs.

14. The Defendants have sought since the 1960's to build a market for estrogen "replacement" therapy and to promote the concept that women, as they age, should replace naturally receding levels of estrogen through the long-term use of estrogen medications and, in particular, Premarin and Premplus. The Defendants marketed Premarin, and later Premplus, with insufficient research as to the efficacy and safety of these drugs. Decades passed without the Defendants conducting adequate research into the efficacy and safety of these products when such research could and should have been conducted by the Defendants. It was only in 1991, when the United States National Institutes of Health commissioned the Women's Health Initiative ("WHI"), that a proper long-term research project was begun. Preliminary results of the WHI, announced in July 2002, found significantly increased risks of heart disease, strokes, blood cots, and breast cancer attributed to the hormone therapy. These preliminary results were considered so significant that the researchers recommended that the study be terminated immediately rather incur further risk to the women enrolled in the study.

15. The particulars of the Defendants' negligence include:

(a) placing Premarin and Premplus on the market when they knew or ought to have known that these drugs were of limited medical efficacy and that the risks of these drugs outweighed their benefits;

(b) making claims regarding the efficacy of Premarin and Premplus, and attributing benefits to Premarin and Premplus which were incorrect and insufficiently supported by research;

(c) failing to adequately test Premarin and Premplus or to conduct proper clinical trials prior to making the drugs available to potential consumers, including the Plaintiff;

(d) failing to adequately monitor and respond to incidents of side-effects related to Premarin and Premplus once the drugs were placed on the market;

(e) failing to conduct proper, timely and continuing research on the safety of Premarin and Premplus once the drugs were placed on the market;

(f) failing to provide the Plaintiff and class members and their physicians with any, or

any adequate, updated or current information respecting the risks of adverse reactions to the drugs as this information became available and known to the Defendants;

(g) failing to make available to the public, regulators, and to the medical and scientific communities internal company research and information regarding Premarin and Premplus which was inconsistent with, or which did not support, the Defendants' claims for the efficacy and safety of Premarin and Premplus;

(h) over-promoting Premarin and Premplus and creating a market for Premarin and Premplus which was far larger than the efficacy and safety of these drugs would justify;

(i) promoting or allowing Premarin and Premplus to be sold for long term use;

(j) failing to properly track sales patterns of Premarin and Premplus, such that the Defendant could monitor usage patterns of the drugs and act to prevent inappropriate long term use;

(k) failing to instruct its employees to properly evaluate, record and advise on complaints of side effects related to Premarin and Premplus;

(l) failing to adequately warn the Plaintiff and other class members and their physicians of the potentially harmful side-effects of Premarin and Premplus;

(m) failing to adequately inform the Plaintiff and other class members and their physicians that Premarin and Premplus should only be taken under limited circumstances, for short term use in the treatment of severe symptoms of menopause and only where such symptoms were non-responsive to other treatments;

(n) failing to accurately, candidly, promptly and truthfully disclose consumer complaints and serious side effects regarding Premarin and Premplus to Health Canada in a timely manner or at all;

(o) failing to initiate timely review, evaluation and investigation of the side effects of Premarin and Premplus following complaints of injury or death or hazard to health;

(p) failing to act promptly, or at all, to conduct a proper long term assessment of the safety of Premarin and Premplus;

(q) failing to adequately assess and investigate complaints regarding Premarin and Premplus upon receipt;

(r) failing to conform with the applicable disclosure requirements pursuant to the *Food and Drug Act*, R.S.C. 1985, c. F-27;

(s) hiring incompetent personnel and appointing incompetent officers and directors;

(t) failing to instruct their servants, agents and officers to act responsibly;

(u) encouraging their employees to increase sales volumes of Premarin and Premplus while neglecting to inform consumers, retailers, hospitals, physicians and pharmacists of the limited efficacy and of the side effects of these drugs;

(v) instructing their sales force to market Premarin and Premplus in such a manner as to undermine the effectiveness of the drugs' product monographs by over-playing the benefits of the drugs and down-playing the risks as described in the product monographs;

(w) failing to withdraw Premarin and Premplus from the marketplace or to otherwise take reasonable steps to restrict the sale of Premarin and Premplus, to ensure that the if these drugs were to be taken at all, then they would only be taken for short term use in very limited cases.

Trade Practices Act* and *Business Practices and Consumer Protection Act

16. The Defendants' solicitations, offers, advertisements, promotions, sales and supply of Premarin and Premplus for personal use by the Plaintiff and by class members were "consumer transactions" within the meaning of the *Trade Practices Act*, R.S.B.C. 1996, c. 457, ("TPA") and its successor statute, the *Business Practices and Consumer Protection Act*, S.B.C. 2004, c. 2 ("BPCPA"). With respect to those transactions, the Plaintiff and class members who purchased Premarin or Premplus in British Columbia for personal use are "consumers" and the Defendants are "suppliers" within the meaning of these Acts.

17. The Defendants' conduct in their solicitations, offers, advertisements, promotions, sales and supply of Premarin and Premplus, as particularized above, had the capability, tendency or effect of deceiving or misleading consumers regarding the efficacy and safety of Premarin and Premplus. The Defendants' conduct in their solicitations, offers, advertisements, promotions, sales and supply of Premarin and Premplus were deceptive acts and practices contrary to s.3 of the TPA and s.4 of the BPCPA. The Defendants' deceptive acts and practices included the Defendants' failure to properly disclose all material facts regarding the efficacy and safety of Premarin and Premplus, or lack thereof.

18. As a result of the Defendants' deceptive acts and practices, the Plaintiff and class members have suffered loss and damages. The Plaintiff seeks damages and statutory compensation pursuant to the TPA and the BPCPA on her own behalf and on behalf of class members who purchased Premarin or Premplus in British Columbia for their personal use.

19. It is not necessary for the Plaintiff and class members to establish reliance on the Defendants' deceptive acts or practices in order to establish breach of the TPA and BPCPA and a remedy for that breach.

20. In the alternative, if reliance is required to establish statutory breach and/or remedy, such reliance may be assumed or inferred on the facts of this case.

21. In the further alternative, there was actual reliance by the Plaintiff and class members on the Defendants' deceptive acts and practices.

Damages

22. As a result of the Defendants' negligence and the Defendants' deceptive acts and practices, the Plaintiff and class members have suffered and will continue to suffer loss and damage. Such loss and damage was foreseeable by the Defendants.

23. Particulars of the loss and damage suffered by the Plaintiff and class members which were caused or materially contributed to by the aforementioned acts of the Defendants include:

(a) pain, suffering, loss of quality and enjoyment of life, and loss of life expectancy;

(b) damages for past and future loss of income;

(c) damages for loss of earning capacity and future loss of opportunity;

(d) damages for past and future cost of care; and

(e) special damages and expenses including medical expenses.

Punitive Damages

24. The Defendants promoted Premarin and Premplus for long-term use in post-menopausal women. The Defendants knew, however, that there was almost no credible evidence that such use was of benefit to women's health. They knew, as well, that long-term use of Premarin and Premplus carried serious health risks. The Defendants knew that, for the vast majority of women, the serious risks of using Premarin and Premplus outweighed the limited benefits.

25. The Defendants were reckless to the consequences to public health flowing from their conduct. The Defendants deliberately chose to value their own profits over public safety.

26. The Defendants' conduct was highly reprehensible and departed to a marked degree from ordinary standards of decent behaviour. The Defendants' wanton and reckless disregard for public safety is deserving of punishment and condemnation by means of an award of punitive damages.

27. The Plaintiff and class members are particularly vulnerable to the harm flowing from the Defendants' wrongful conduct. The Plaintiffs and class members had no practical way to independently investigate the efficacy and safety of Premarin and Premplus. The Plaintiff and class members were dependant on the Defendants to fully and fairly disclose the efficacy and safety, or lack thereof, of Premarin and Premplus to the Plaintiff and other class members and their physicians. The Defendants recklessly and shamefully failed to do so in order to maximize profits from the sale of these dangerous drugs.

28. This case raises issues of general deterrence. A punitive damage award in this case is necessary to express society's condemnation of conduct such as the Defendants', to advance public safety and to achieve the goal of both specific and general deterrence.

Relief Sought

29. The Plaintiff claims, on her own behalf, and on behalf of a class of similarly situated persons resident in British Columbia and elsewhere in Canada:

(a) an order certifying this action as a class proceeding;
(b) general damages;
(c) special damages;
(d) punitive damages;
(e) damages and statutory compensation available under the TPA and BPCPA;
(f) pre-judgment interest;
(g) costs; and
(h) such further and other relief as this Honourable Court may deem just.

Dated: May 20, 2005

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