S-123826

No.
Vancouver Registry

In the Supreme Court of British Columbia

Between

Beverly Stoughton

Plaintiff

and

Johnson & Johnson, Ethicon SARL, Ethicon, Inc.,
and Johnson & Johnson Inc.

Defendants

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

NOTICE OF CIVIL CLAIM

This action has been started by the plaintiff for the relief set out in Part 2 below.

If you intend to respond to this action, you or your lawyer must

(a) file a response to civil claim in Form 2 in the above-named registry of this court within the time for response to civil claim described below, and
(b) serve a copy of the filed response to civil claim on the plaintiff.

If you intend to make a counterclaim, you or your lawyer must

(a) file a response to civil claim in Form 2 and a counterclaim in Form 3 in the above-named registry of this court within the time for response to civil claim described below, and
(b) serve a copy of the filed response to civil claim and counterclaim on the plaintiff and on any new parties named in the counterclaim.

JUDGMENT MAY BE PRONOUCED AGAINST YOU IF YOU FAIL to file the response to civil claim within the time for response to civil claim described below.

Time for response to civil claim

A response to civil claim must be filed and served on the plaintiff,

(a) if you reside anywhere in Canada, within 21 days after the date on which a copy of the filed notice of civil claim was served on you,
(b) if you reside in the United States of America, within 35 days after the date on which a copy of the filed notice of civil claim was served on you,
(c) if you reside elsewhere, within 49 days after the date on which a copy of the filed notice of civil claim was served on you, or

(d) if the time for response to civil claim has been set by order of the court, within that time.

CLAIM OF THE PLAINTIFF

Part 1: STATEMENT OF FACTS

The Parties

1. The Plaintiff, Beverly Stoughton, is a resident of Chilliwack, British Columbia. She was implanted with the Prolift Anterior Pelvic Floor Repair System which is a transvaginal mesh product.

2. The Plaintiff brings this claim on behalf of herself and on behalf of a class of persons who were implanted with one or more of the TVM Products (as defined below) in British Columbia.

3. The transvaginal mesh products (the "TVM Products") at issue in this claim include:
   a. Prolift Pelvic Floor Repair System (including all components and variations authorized under Licence No. 68486)
   b. Gynecare Prosima Pelvic Floor Repair System, (including all components and variations authorized under Licence No. 75751)
   c. Gynecare Prolift +M Anterior Pelvic Floor Repair System (including all components and variations authorized under Licence 77686)

4. Johnson & Johnson is a New Jersey, U.S.A corporation. It is the worldwide headquarters for the Johnson & Johnson family of companies and is located in New Brunswick, New Jersey, U.S.A. More than 250 operating companies in 57 countries make up the Johnson & Johnson family of companies. The Defendants, Ethicon SARL, Ethicon, Inc., and Johnson & Johnson Inc. are part of the Johnson & Johnson family of companies and they work collectively and collaboratively to co-ordinate their activities.

5. Ethicon SARL is a subsidiary of Johnson & Johnson with head office based in Neuchatel, Switzerland. Ethicon SARL is registered with Health Canada as holding the licences for the TVM Products.

6. Ethicon, Inc. is subsidiary of Johnson & Johnson located in Somerville, New Jersey, U.S.A.

7. Johnson & Johnson Inc., is a federally registered corporation registered in British Columbia as an extraprovincial company with an address for service at Suite 2600, Three Bentall Centre, PO Box 49314, 595 Burrard Street, Vancouver, BC V7X 1L3.

8. Johnson & Johnson, Ethicon SARL, Ethicon, Inc., and Johnson & Johnson Inc. are referred to herein as the "Defendants".

9. At all material times, the Defendants functioned as a joint enterprise under the umbrella of the Defendant Johnson & Johnson for the promotion and sale of the TVM Products in Canada. The Defendants each had an independent responsibility to the Plaintiff and to class members to ensure the safety of the TVM Products. Within this joint enterprise, the Defendants individually and jointly researched, tested, developed, marketed, manufactured, imported, promoted, labeled, monitored adverse reaction reports and placed the TVM Products into the stream of commerce in British Columbia.

The TVM Products

10. The TVM Products are Class III medical devices under the *Food and Drugs Act*, R.S.C. 1985, F-27. The TVM Products may only be sold in Canada with the licence and approval of Health Canada. The Defendants obtained the licences to sell the TVM Products in Canada.

11. The TVM Products are sold as a commercial "kit" also called a "system" to treat pelvic organ prolapse ("POP"). POP occurs when the muscles supporting a woman's pelvic organs weaken. The pelvic organs can slip out of place (prolapse) causing them to bulge into the vagina and in some cases outside the vagina's opening.

12. The kits are promoted by the Defendants as being a minimally invasive surgical technique to treat POP by placing a broad coverage polypropylene implant without trimming of the vagina or suturing of the mesh to the vagina. The kits allow selective application of anterior, posterior or total vaginal implants.

13. The first of the Defendants' TVM Products was licenced by Health Canada on about May 27, 2005. It was the Prolift Pelvic Floor Repair System. The Defendants' have continued to develop, licence and market further kits for use in POP repair. The TVM Products have been marketed to the medical community and to patients as safe, effective, reliable medical devices that are more effective as compared to the traditional products and procedures for treatment of POP.

14. The Defendants have promoted and sold the TVM Products to the medical community at large through carefully planned marketing campaigns and strategies. These campaign strategies include, but are not limited to, aggressive marketing to health care providers at medical conferences, hospitals, and private offices. Also used are brochures and websites offering exaggerated and misleading expectations as to the safety and utility of the TVM Products.

15. Though risks are included in the Defendants' promotional materials, the benefits are overstated and the risks are minimized. For example in the patient brochures, the Defendants state that the procedure is designed to restore "normal anatomy" and that patients can resume "sexual intimacy" as well as "normal physical activity". These statements are deceptive and misleading; while some patients may resume normal activities, this is not the case for the Plaintiff and many other class members.

16. The patient brochures describe the mesh as "soft" and that "[d]uring the healing process, the body's natural tissues quickly grow into the pores of the mesh, and are strengthened by the presence of the soft mesh." These statements are deceptive and misleading as they make it sound like the mesh easily integrates with the body, which is frequently not the case.

17. In the risk section of the patient brochure, the Defendants' state:

> There is a risk of the mesh material becoming exposed into the vaginal canal. Mesh exposure can be associated with pain during intercourse for the patient and her partner. Exposure may require treatment, such as vaginal medication or removal of the exposed mesh, which may be performed in the office or operating room.

This risk section downplays the seriousness of mesh exposure. It does not explain that once the woman's tissue has grown into the mesh it can be difficult to remove requiring multiple surgeries and may cause permanent damage. Instead, this statement makes it sound like it is easily removed at the doctor's office.

18. In materials for physicians, the Defendants describe the TVM Product Prosima as "your gold standard repair". They state that it "minimizes potential complications", delivers "durable repair" and that it demonstrates "durable results". These are misleading statements as this is a new TVM Product with limited safety evidence available.

19. The Defendants have produced videos about the TVM Product Prosima for potential patients and posted them online. Information in the videos is vague and misleading. The videos mention complications with traditional procedures but do not explain what traditional procedures they are talking about or what types of complications they are talking about. For example, one woman who had the TVM Product implanted 6 weeks earlier said that she had "heard not very good results from some older techniques" and that she "wanted to be sure that that wasn't the path that we were going to take". Another woman said that she would not go ahead with the traditional surgery because of her age and the length of the recovery time but she was willing to have a TVM Product implanted. The material in these videos implies that the procedure using the TVM Products is superior to the traditional procedures but for many women, including the plaintiff and many other class members, it is not.

20. In one of the videos, a woman refers to "the specific statistics" related to the procedure with the TVM Product Prosima and that the statistics "looked like they were high enough" so she "could be confident". There is no mention as to what type of statistics she is referring to. Her statements are misleading as they infer that there is ample safety information regarding the TVM Product which is not accurate.

21. The TVM Products have a high failure, injury and complication rate. They have caused severe and irreversible injuries, conditions, and damage to a significant number of women including the Plaintiff. The Plaintiff alleges that the TVM Products cause an unacceptably high rate of complications which include, but are not limited to, mesh erosion, mesh contraction, fistulas, dyspareunia, perforations in surrounding tissues and organs, infection, blood loss, scar tissue, nerve damage, urinary and fecal incontinence, with the resulting need for one or more corrective surgeries and often leading to permanent damage.

22. In or about October 20, 2008, the United States Federal Drug Agency (FDA) issued a Public Health Notification stating that there were serious complications associated with transvaginal placement of surgical mesh to treat POP and stress urinary incontinence ("SUI"). The FDA also issued a letter to Health Care Practitioners stating that in the three years previous there were over 1,000 reports in the United States from surgical mesh manufacturers of complications relating to mesh used to repair POP and SUI. One of the recommendations made by the FDA was that physicians should obtain specialized training for each mesh placement technique.

23. In or about February 4, 2010, Health Canada issued a Notice to Hospitals directed to the Hospital Chief and Medical Staff titled "Health Canada Issued Important Safety Information on Surgical Mesh for Stress Urinary Incontinence and Pelvic Organ Prolapse." Health Canada issued the notice as it was concerned about Canadian and international reports of various intraoperative and postoperative complications associated with the use of these devices. The reported complications associated with the use of transvaginally placed mesh for the treatment SUI and POP included erosion (vaginal, urethral), pain including dyspareunia, infection as well as perforations and other injuries to adjacent organs including the bowel, bladder and blood vessels. Health Canada made several recommendations one of which was to "be aware of and/or get training on proper case selection, initial implantation procedure and management of complications."

24. In August 2010, a study was published in the Journal of the American College of Obstetricians and Gynecologists about the efficacy of vaginal mesh implants to treat POP. This

study conducted by the Medstart Research Institute in collaboration with the Washington Hospital Centre was comprised of women with POP who were going to have repair surgery using either a TVM Product or traditional surgery. The study stopped early because after three months, there was a high vaginal mesh erosion rate of 15.6% with no difference in the overall objective and subjective cure rates. The study questions whether there is any benefit of using synthetic mesh for POP repairs over traditional surgery.

25. In or about February 2011, the Society of Obstetricians and Gynaecologists of Canada issued a Technical Update entitled, "Transvaginal Mesh Procedures for Pelvic Organ Prolapse" to provide information on Transvaginal Mesh (TVM) procedures. The update reviewed TVM complications and also expressed concern that there have not been long term studies on these products and the TVM procedures need to be more thoroughly evaluated before it is assumed they offer benefits over traditional repairs. The report states that until adequate effectiveness and safety evidence is available, the use of new TVM devices for prolapsed repair should be considered experimental and restricted to use in investigative trials. Additionally, the report states that the mesh complications referenced in the 2008 FDA Notice raised concerns about the adequacy of the training and ability to prevent complications. The TVM systems or kits assume familiarity with pelvic floor anatomy and surgical techniques not typically known to generalist gynecologists who have not specialized in this type of reconstructive surgery.

26. On or about July 13, 2011, the FDA in the United States issued a safety communication update on the Serious Complications Associated with Transvaginal Placement of Surgical Mesh for POP to warn that the complications associated with these products are not rare. The FDA also issued a comprehensive review in or about July 2011 titled, "Urogynecological Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse."

27. On or about January 4, 2012, the FDA in the United States issued an update stating that it is continuing to assess the safety and effectiveness of urogynecologic surgical mesh devices and, among other things, has mandated manufacturers of surgical mesh used in SUI and POP to conduct many post market surveillance studies.

Plaintiff's Injuries

28. The Plaintiff, Ms. Stoughton, underwent surgery on or about June 1, 2010 in Abbotsford, British Columbia to correct her bladder which had prolapsed. She was implanted with the Prolift Anterior Pelvic Floor Repair System.

29. After her surgery, Ms. Stoughton followed her surgeon's advice in the recovery period. She did minimal physical activity and rested to permit the affected area to heal. She was advised that the healing time would be approximately 6-8 weeks. Soon after her surgery, Ms. Stoughton experienced considerable pain in her pelvic and abdominal region.

30. The pain in her pelvic and abdominal region has continued since her surgery. She has discomfort in her groin area and in the right hip flexor and hip. The pain she experiences in her abdominal region is worse when this part of her body is compressed. For example when she is sitting, she has to undo her jeans to relieve pressure on that area. Certain leg movements and any type of bouncing motion such as running also increases the pain. When she pushes on the lower abdominal area it is tender and feels "ropey" and "knotted" and the pain increases. She can also feel a wiry piece inside her vagina that causes pain to her partner preventing them from having intercourse.

31. Before the surgery, Ms. Stoughton never experienced any pain in this area of her body. She was a very active person teaching aquafit and participating in many sports including hiking and skiing. She is trying to get back to her usual physical activities but in doing so, the pain in her pelvic area increases. She has also been constipated since her surgery and often feels urinary urgency which are two things she never experienced prior to her surgery.

32. Ms. Stoughton has seen several specialists since her surgery including three obstetrician/ gynecologists and a pelvic floor physiotherapist. She has been advised by one of her specialists who conducted a manual exam that the mesh that was implanted has eroded through her vaginal wall in three places. She has also been advised that she needs to have surgery or surgeries to remove the mesh that has eroded. She is scheduled to have surgery in June 2012. She has been told that the surgery may not be successful in alleviating the pain and that it also carries its own set of risks. Her tissue has grown into the mesh used in the TVM Product making it difficult to

remove without damaging the tissue in that area. She has been told that the TVM Product may have caused permanent damage to her.

33. Ms. Stoughton has made many trips to the doctor which has had a significant impact on her life. She has spent time travelling to appointments and paying fees for prescriptions such as pain relief medication and a prescription of Vagifem to estrogenize the vagina to bury the exposed mesh. To date, nothing has been successful.

34. Ms. Stoughton's employment has been impacted as a result of the damage caused by the TVM Product. She has not been able to actively search for a job due to the pain she has experienced, the lengthy recovery period after the initial surgery and the fact that she now has to undergo another surgery. She has incurred and will continue to incur, loss of employment income and out of pocket expenses.

35. Prior to being implanted with the TVM Product, Ms. Stoughton received inadequate warnings about the risks associated with it. If Ms. Stoughton had been aware of the risks she would never have agreed to being implanted with the TVM Product.

Part 2: RELIEF SOUGHT

36. The Plaintiff claims, on her own behalf and on behalf of a class of similarly situated persons:

(a) an order certifying this action as a class proceeding and appointing her as representative plaintiff under the *Class Proceedings Act*;
(b) general damages and special damages;
(c) punitive damages;
(d) declaratory and injunctive relief as well as statutory damages under the *Business Practices and Consumer Protection Act*;
(e) recovery of health care costs incurred by the Ministry of Health Services on their behalf pursuant to the *Health Care Cost Recovery Act*, S.B.C. 2008, c. 27;
(f) pre-judgment interest;
(g) costs; and
(h) such further and other relief this Honourable court may deem just.

Part 3: LEGAL BASIS

Defendants' Negligence

37. As the manufacturers, marketers, developers, suppliers, distributors, promoters and/or importers of the TVM Products, the Defendants were in such a close and proximate relationship to the Plaintiff and other class members to owe them a duty of care. They caused the TVM Products to be introduced into the stream of commerce in British Columbia, and they knew that any defects in the TVM Products would cause foreseeable injury to the Plaintiff and class members.

38. The Defendants owed a duty to the Plaintiff and class members to exercise reasonable care when researching, designing, testing, manufacturing, marketing, labeling, promoting, distributing, importing and selling the TVM Products. The Defendants breached the standard of care expected in the circumstances.

39. The Defendants had a duty to the Plaintiff and class members to disclose and warn of the defective nature of the TVM Products because they were in a superior position to know the safety and efficacy of the TVM Products.

40. The Defendants jointly and severally owed a duty of care to the Plaintiff and class members to ensure that the TVM Products were safe for the intended use. Particulars of the Defendants' negligence include:

a) manufacturing and/or marketing a device which they knew or ought to have known, had an unreasonably high risk of complications in patients;
b) failing to test the TVM Products properly and thoroughly before releasing the TVM Products to the market;
c) failing to adequately disclose the serious complications associated with the TVM Products;
d) failing to conduct an adequate and timely analysis of adverse event reports;

e) failing to instruct their employees to accurately and candidly disclose consumer complaints and complications associated with the TVM Products to Health Canada in a timely manner, or at all;

f) failing to warn consumers, their health providers, and Health Canada of the increased complications presented by the TVM Products;

g) failing to recall the TVM Products;

h) failing to provide effective, complete and clear training and information to physicians;

i) marketing the TVM Products which were unsafe, not fit for the intended purpose, and not of merchantable quality;

j) marketing the TVM Products in such a way to give the Plaintiff and class members no reason to suspect that the TVM Products had potentially harmful complications associated with them;

k) failing to design and implement an appropriate post marketing surveillance system to monitor and quickly identify the complications associated with the TVM Products;

l) designing, manufacturing and /or marketing a product which was not reasonably safe and effective in comparison to already available alternative products and surgical techniques;

m) failing to design and establish a safe, effective procedure for removal of the TVM Products in the event of failure, injury or complications;

n) placing the TVM Products on the market when they knew or ought to have known that the potential complications of these TVM Products outweighed any potential benefits;and

o) such further and other particulars of negligence that is within the knowledge of the Defendants.

41. The Defendants' common law duties are informed by the *Medical Devices Regulations*, SOR/92/82. Pursuant to s.1 of those regulations, each of the Defendants is a "manufacturer". They designed and assembled the TVM Products, attached their trade name to it, labeled them and assigned them a purpose.

42. The regulations impose continuous obligations on the Defendants, commencing at licencing and continuing thereafter. They require the Defendants to ensure the safety of the TVM Products before selling them, and to continuously monitor the safety of the TVM Products,

monitoring any complaints from doctors, hospitals and patients, keeping up with any new developments in the scientific literature, conducting further testing as necessary, and promptly taking corrective action, including issuing a warning or recall, if new information becomes available which alters the TVM Products' risk profile.

43. Pursuant to s.9(2) of the *Medical Devices Regulations,* the Defendants were required to maintain objective evidence to establish the safety of the devices. The Defendants breached this section. They failed to adequately obtain such information about the TVM Products before licensing and they failed to promptly update such information thereafter.

44. Pursuant to s. 10 of the *Medical Devices Regulations*, the Defendants were required to identify the risks of the device to eliminate or reduce those risks if possible, and to provide safety information with the device concerning those risks which remained. The Defendants breached this section. They failed to eliminate the complications caused by the the TVM Products and failed to warn about the complications.

45. Pursuant to s. 11 of the *Medical Devices Regulations*, the Defendants were required to assess the risks of the TVM Products against the benefits, and not to sell a products whose risks outweigh the benefits. The Defendants breached this section. The risks of the TVM Products outweighed the benefits.

46. Pursuant to s. 12 of the *Medical Devices Regulations*, the Defendants were required to ensure that the TVM Products were effective for the uses for which they were represented. The Defendants breached this section. The TVM Products were not effective and caused complications.

Business Practices and Consumer Protection Act

47. The Defendants' solicitations, offers, advertisements, promotions, sales and supply of the TVM Products for personal use by the Plaintiff and by class members were "consumer transactions" within the meaning of 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

were implanted with the TVM Products are "consumers" and the Defendants are "suppliers" within the meaning of the BPCPA.

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

49. As a result of the Defendants' deceptive acts and practices, the Plaintiff and class members have suffered loss and damages. The Plaintiff seeks injunctive relief and declaratory relief and damages and statutory compensation pursuant to ss.171 and 172 of the BPCPA on her own behalf and on behalf of class members implanted with the TVM Products in British Columbia. Such relief includes the disgorgement of the profits or revenues received by the defendants from the sale of the TVM Products in British Columbia.

50. The declaratory and injunctive relief sought by the Plaintiff in this case includes an order under s.172 of the BPCPA that the Defendants advertise any judgment against them and that they properly inform consumers and their physicians of the risk of complications associated with the TVM Products which includes sending a "Dear Doctor Letter" to alert physicians to this problem.

51. 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 BPCPA and a remedy for that breach. 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. In the further alternative, there was actual reliance by the Plaintiff and class members on the Defendants' deceptive acts and practices.

Causation and Damages

52. As a result of the Defendants' negligence and the Defendants' breach of the BPCPA the Plaintiff and class members have suffered and will continue to suffer loss and damage. Such loss and damage was foreseeable by the defendants. 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) personal injury;
(b) special damages for medical expenses and out of pocket expenses;
(c) loss of both past and prospective income; and
(d) cost of future care.

53. The conduct of the Defendants warrants a claim for punitive damages. They have conducted themselves in a high-handed, wanton and reckless manner, and without regard to public safety. Particularly egregious is the Defendants' lack of warnings regarding the frequency of serious complications associated with the TVM Products. The Defendants have continued to market the TVM Product in Canada as safe and effective when they knew or should have known of the risks associated with its use.

54. 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.

Health Care Cost Recovery

55. The Plaintiff and class members have a claim for the recovery of health care costs incurred on their behalf by the British Columbia Ministry of Health Services and by other provincial and territorial governments. The Plaintiff pleads the *Health Care Cost Recovery Act,* S.B.C. 2008, c. 27.

Jurisdiction

56. The Plaintiff relies on ss. 3, 7 and 10 of the *Court Jurisdiction and Proceedings Transfer Act*, S.B.C. 2003, c.28 and pleads that there is a real and substantial connection between the subject matter of this action and the Province of British Columbia for the following reasons:

(a) the Defendants promoted and sold the TVM Products in British Columbia;

(b) the Plaintiff resides in British Columbia; and

(c) the Plaintiff's damages were sustained in British Columbia.

ENDORSEMENT ON ORIGINATING PLEADING OR PETITION FOR SERVICE OUTSIDE BRITISH COLUMBIA

The Plaintiff claims the right to serve this pleading on the Defendants outside British Columbia on the grounds that:

(a) this action concerns a tort committed in British Columbia pursuant to section 10(g) of the *Court Jurisdiction and Proceeding Transfer Act*, S.B.C. 2003, c.28;

(b) this action concerns a business carried on in British Columbia, pursuant to section 10(h) of the *Court Jurisdiction and Proceeding Transfer Act*, S.B.C. 2003, c.28

Plaintiff's address for service:
Suite 400, 1385 West 8th Avenue
Vancouver, BC V6H 3V9
Fax number address for service: (604)874-7171

Place of trial: Vancouver

The address of the registry is: 800 Smithe Street
Vancouver, BC V6Z 2E1

Date: May 28, 2012

"David A. Klein"
Signature of David A. Klein
[ ]plaintiff [x] lawyer for the plaintiff

Rule 7-1 (1) of the Supreme Court Civil Rules states:

> (1) Unless all parties of record consent or the court otherwise orders, each party of record to an action must, within 35 days after the end of the pleading period,
>
> (a) prepare a list of documents in Form 22 that lists
>
> (i) all documents that are or have been in the party's possession or control and that could, if available, be used by any party at trial to prove or disprove a material fact, and
>
> (ii) all other documents to which the party intends to refer at trial, and
>
> (b) serve the list on all parties of record.

Appendix

[The following information is provided for data collection purposes only and is of no legal effect.]

Part 1: CONCISE SUMMARY OF NATURE OF CLAIM:

This action is a proposed class proceeding concerning transvaginal mesh products that have been implanted into the Plaintiff and class members. The Plaintiff and other class members suffered personal injuries and damages after being implanted with the TVM Products. The Defendants researched, designed, tested, manufactured, marketed, labeled, promoted, distributed, imported and sold the TVM Products. They breached duties to the Plaintiff and class members by failing to adequately test the TVM Products, by failing to adequately monitor and investigate complications associated with the TVM Products and by failing to issue timely warnings. The Defendants also breached statutory obligations under the *Business Practices and Consumer Protection Act.*

Part 2: THIS CLAIM ARISES FROM THE FOLLOWING:

[Check one box below for the case type that best describes this case.]

A personal injury arising out of:

[ ] a motor vehicle accident

[ ] medical malpractice

[ ] another cause

A dispute concerning:

[ ] contaminated sites

[ ] construction defects

[ ] real property (real estate)

[ ] personal property

[ ] the provision of goods or services or other general commercial matters

[ ] investment losses

[ ] the lending of money

[ ] an employment relationship

[ ] a will or other issues concerning the probate of an estate

[ ] a matter not listed here

Part 3: THIS CLAIM INVOLVES:

[Check all boxes below that apply to this case]

[x] a class action

[ ] maritime law

[ ] aboriginal law

[ ] constitutional law

[ ] conflict of laws

[ ] none of the above

[ ] do not know

Part 4:

Business Practices and Consumer Protection Act, S.B.C. 2004, c. 2

Class Proceedings Act, R.S.B.C. 1996, c. 50

Court Order Interest Act, R.S.B.C. 1996, c. 79

Court Jurisdiction and Proceeding Transfer Act, S.B.C. 2003, c. 28

Food and Drugs Act, R.S.C. 1985, F-27

Health Care Cost Recovery Act, S.B.C. 2008, c. 27

Medical Devices Regulations, SOR/92/82