S-151676

No.
Vancouver Registry

In the Supreme Court of British Columbia

Between

DANIELA IANORESCU

PLAINTIFF

and

AMERICAN MEDICAL SYSTEMS, INC., AMERICAN MEDICAL SYSTEMS CANADA INC., AMERICAN MEDICAL SYSTEMS HOLDINGS INC., ENDO PHARMACEUTICALS INC., and ENDO HEALTH SOLUTIONS INC. also known as ENDO PHARMACEUTICALS HOLDINGS, 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

Overview and Parties

1. This action concerns transvaginal mesh implants which are used to treat, *inter alia*, pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). These transvaginal mesh implants are biologically incompatible with human tissue and, accordingly, cause severe complications in their users. The risks of these transvaginal mesh implants outweigh any benefits.

2. The Plaintiff, Daniela Ianorescu, is a resident of North Vancouver, British Columbia. She was implanted with the Monarc Subfascial Hammock, which is a transvaginal mesh product.

3. 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 Pelvic Mesh Products (as defined below) in British Columbia.

4. The transvaginal mesh implants at issue in this claim are those implants which were developed, marketed, manufactured, imported, promoted, licensed, labeled, and/or placed into the stream of commerce by the Defendants or any of them (each a "Pelvic Mesh Product", collectively the "Pelvic Mesh Products"). The Pelvic Mesh Products include, *inter alia*: AMS Triangle Silicone Coated Sling/Mesh; AMS Triangle Silicone Coated Sling/Mesh with Inhibizone; AMS Silicone-Coated Sling and Surgical Mesh; Intemesh Silicone-Coated Surgical Mesh; Intezone Antimicrobial Treated Sling Mesh; Intemesh Silicone-Coated Sling and Surgical Mesh with Inhibizone; Sparc Sling System; Sparc Sling System, IFGS; Monarc Sling System-Polypropylene; Monarc Subfascial Hammock; Monarc + Subfascial Hammock; Monarc C Subfascial Hammock; Straight-In SCP System - II Set; Straight-IN SCP System – II Set Package Contents; Straight-In SCP System-Set Package Contents; Bioarc SP Sling Kit; Bioarc Subfascial

Hammock; Apogee Vault Suspension System; Apogee Vault Suspension System for Biologic Integraft; Apogee Vault Suspension System with Intepro; Perigee System for Biologic Entegraft; Perigee System with Intepro; Apogee System; Apogee System with Intepro; Perigee System with Intepro; Smart Sling System-Sling; Smart Sling System – Reusable Needles; Miniarc 5 Pack; Miniarc Sling System; Miniarc Precise; Miniarc Precise, S; Miniarc Pro Single-Incision Sling System; Elevate Anterior & Apical Prolapse Repair System; Elevate Posterior Prolapse Repair System; Elevate Total Prolapse Repair System; Elevate PC Anterior & Apical Prolapse Repair System; Elevate PC Apical & Posterior Prolapse Repair System; and Retroarc Retropubic Sling System.

5. The Defendant American Medical Systems, Inc. ("AMS") is a Delaware corporation with an address for service c/o The Corporation Trust Company at the Corporation Trust Center, 1209 North Orange Street, Wilmington, Delaware 19801, United States.

6. The Defendant American Medical Systems Canada Inc. ("AMS Canada") is an Ontario corporation with an address for service c/o MacLeod Dixon LLP at #2300 - 79 Wellington Street West, Toronto, Ontario M5K 1H1. AMS Canada is registered extra-provincially in British Columbia. AMS Canada is a subsidiary of AMS.

7. AMS is a wholly owned subsidiary of the Defendant American Medical Systems Holdings Inc. ("AMS Holdings"). AMS Holdings is a Delaware corporation with an address for service c/o The Corporation Trust Company at the Corporation Trust Center, 1209 North Orange Street, Wilmington, Delaware 19801, United States. AMS Holdings is a wholly owned subsidiary of the Defendants Endo Pharmaceuticals, Inc. and Endo Health Solutions Inc.

8. The Defendant Endo Pharmaceuticals Inc. ("Endo Pharmaceuticals") is a Delaware corporation with an address for service c/o The Corporation Trust Company at Corporation Trust Center, 1209 North Orange Street, Wilmington, Delaware 19801, United States.

9. The Defendant Endo Health Solutions Inc. ("Endo Health Solutions") is a Delaware corporation and is the parent company of AMS, AMS Canada, AMS Holdings and Endo

Pharmaceuticals. Prior to May 23, 2012, Endo Health Solutions did business as Endo Pharmaceuticals Holdings, Inc. Endo Health Solutions has an address for service c/o The Corporation Trust Company at the Corporation Trust Center, 1209 North Orange Street, Wilmington, Delaware 19801, United States. Endo Health Solutions has its principal executive offices at 1400 Atwater Drive, Malvern, Pennsylvania 19355, United States. In 2013, Endo Health Solutions generated revenues of US$2.6 billion. Its AMS portfolio accounted for 19% of Endo Health Solutions' total revenues in 2013.

10. At all material times, the Defendants functioned as a joint enterprise for the promotion and sale of the Pelvic Mesh Products within Canada for their mutual benefit and profit. The Defendants individually and jointly researched, tested, developed, marketed, manufactured, imported, promoted, licensed, labeled, monitored adverse reactions to, and placed into the stream of commerce the Pelvic Mesh Products for sale in Canada.

11. Each Defendant had an independent responsibility to ensure the safety of the Pelvic Mesh Products and the adequacy of the warnings.

Pelvic Mesh Products

12. The Pelvic Mesh Products are Class III medical devices under the *Food and Drugs Act*, R.S.C. 1985, F-27. The Pelvic Mesh Products may only be sold in Canada with the license and approval of Health Canada. At all material times, the Defendants obtained licenses to sell the Pelvic Mesh Products in Canada.

13. The Pelvic Mesh Products are sold as a commercial "kit" or "system" to treat, *inter alia*, POP and SUI. 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. SUI occurs when weakened pelvic muscles and tissue result in the bladder and urethra relaxing from their normal positions such that sudden abdominal pressure may cause the accidental loss of urine.

14. The first of the Defendants' Pelvic Mesh Products, the AMS Triangle Silicone Coated Sling/Mesh, was licensed by Health Canada on or about December 7, 2000. The Defendants continue to develop, license and market transvaginal mesh kits and systems in Canada.

Defendants' Marketing Materials

15. The Defendants have promoted and sold the Pelvic Mesh Products through carefully planned marketing campaigns and strategies. These campaign strategies have included, but have not been 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 Pelvic Mesh Products. The Pelvic Mesh Products have been marketed to the medical community and public as safe, effective and reliable medical devices that are more effective than traditional products and procedures for the treatment of POP and SUI.

16. The risks associated with the Pelvic Mesh Products, which risks were known to the Defendants at all material times, have not been adequately communicated to patients or physicians.

17. For example, on the "Patients" section of AMS' website, the Defendants state that POP can be treated with a "minimally invasive solution". The Defendants state that the Pelvic Mesh Products are "designed to minimize tissue trauma and pain compared to more invasive procedures". With respect to SUI, the Defendants state that it can be treated with a "minimally invasive procedure" that "[u]sually takes less than 30 minutes", and that their slings "have been used to treat stress urinary incontinence in more than 1 million women". These statements are deceptive and misleading; they minimize the significance of being implanted with a Pelvic Mesh Product and the risks inherent in doing so.

18. The risks associated with the implantation of the Pelvic Mesh Products are framed generally on the "Patients" webpage for the treatment of POP as "known risks of *surgical procedures* for the treatment of pelvic organ prolapse". On the "Patients" webpage for the treatment of SUI, the Defendants state: "*As with most surgical procedures*, potential adverse reactions may occur". On the "Professionals" component of the website, the Defendants

repeatedly use the phrase: "*As with any surgical procedure*, inherent risks are present". [emphasis added] These statements imply that the stated risks are associated with the surgical component of the procedures and are therefore analogous to the risks inherent in all surgeries, including traditional surgical procedures for the treatment of POP and SUI. This inference is deceptive, as many of the stated complications only arise when the Defendants' Pelvic Mesh Products are implanted.

19. The Defendants note, with respect to the use of the Pelvic Mesh Products to treat POP, that the patient "will need to refrain from sexual intercourse, heavy lifting, and rigorous exercise for six to eight weeks" to allow her body "time to heal". This statement is deceptive and misleading. First, this statement implies that mild to moderate exercise can occur after surgery without the necessity of waiting six to eight weeks. Further, while some patients may be able to resume normal activities, such as work and sexual intercourse, this is not the case for many class members who, after having a Pelvic Mesh Product inserted to treat POP, have been unable to resume normal activities.

20. With respect to the recovery period for the use of the Pelvic Mesh Products to treat SUI, the Defendants state: "Some general guidelines include no heavy lifting, exercise or intercourse for a minimum of four weeks. You can return to other normal daily activities at your physician's discretion, often in one to two weeks". This statement is deceptive and misleading. While some patients may be able to resume normal daily activities in one to two weeks, and heavy lifting, exercise and sexual intercourse in four weeks, this is not the case for the Plaintiff and many other class members who, after having a Pelvic Mesh Product inserted to treat SUI, have been unable to resume normal activities.

21. In order to view more detailed information on the risks associated with the Pelvic Mesh Products for the treatment of POP and SUI, the patient is required to click a link entitled "view important safety information". On this webpage, the Defendants note various risks such as vaginal extrusion, erosion through the desired location or other surrounding tissue, migration of the device from the desired location, contracture, fistula formation and/or inflammation and note that "these responses may require removal or revision" of the implant or sling. This section downplays the risk of mesh exposure/erosion/contraction, and implies that the implant or sling

can be easily removed. In reality, the woman's tissue often grows into the mesh; accordingly, it can be difficult or impossible to remove all of the mesh. The Defendants fail to note that removal of the mesh may require multiple surgeries and may cause permanent damage.

22. On the "Professionals" section of the AMS website, the Defendants state, with respect to the risks associated with the use of the Pelvic Mesh Products to treat SUI: "Although *rare*, some of the most severe risks with sling procedures include infection, erosion, and vessel or urethra perforation. Some of the more common risks include urinary tract infections, urge symptoms, and urinary retention". Likewise, with respect to the risks associated with the use of the Pelvic Mesh Products to treat POP, the Defendants state: "Although *rare*, some of the most severe risks associated with prolapse procedures include bleeding (hematoma), perforation of vessels, nerves, bladder, urethra, or bowel; erosion of the implant through neighboring tissue, and infection. Some of the most common risks include; [sic] vaginal extrusion, De Novo/worsening incontinence, dyspareunia, and pain". [emphasis added]

23. The Defendants' description of the "most severe risks" as "rare" is deceptive and inaccurate. As early as 2006, the medical literature noted the high erosion rate seen with transvaginal mesh material, and cautioned that the long term erosion rates associated with synthetic mesh were unknown.

24. The Defendants' warnings with respect to the Pelvic Mesh Products have been and remain inadequate. The Defendants have failed to warn of the frequency, seriousness and predictability of the complications caused by the Pelvic Mesh Products. The Defendants have also failed to advise that, while implantation of the Pelvic Mesh Products exposes patients to significant risks, the success rate of the Pelvic Mesh Products is no better than that of traditional procedures for POP and SUI repair.

Complications with Pelvic Mesh Products

25. The Pelvic Mesh 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 Pelvic Mesh 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 and urinary and fecal incontinence. These complications often result in the need for one or more corrective surgeries, and often leading to permanent damage.

26. In or about August of 2008, the Society of Obstetricians and Gynecologists of Canada (the "SOGC") issued a Technical Update titled "Midurethral Minimally Invasive Sling Procedures for Stress Urinary Incontinence". In this update, they outlined some of the complications associated with the procedure such as groin abscesses and vaginal erosion. The SOGC also noted that "[d]espite the suggested simplicity of pre-packaged surgical kits for midurethral procedures, specific training is recommended prior to performing any of these surgical procedures."

27. On or about October 20, 2008, the United States Food and Drug Administration (the "FDA") issued a Public Health Notification stating that there were serious complications associated with transvaginal placement of surgical mesh to treat POP and 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 that "led to a significant decrease in patient quality of life due to discomfort and pain". One of the recommendations made by the FDA was that physicians should obtain specialized training for each mesh placement technique.

28. On 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." In the notice, Health Canada noted its concern 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 of SUI and POP included erosion (vaginal and urethral), pain including dyspareunia, infection, and 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."

29. Between 2007 and 2009, surgeons at three university hospitals in the United States conducted a double-blind randomized controlled trial to compare outcomes between traditional surgery for POP and surgery using mesh. In August of 2010, a study titled "Vaginal Mesh for Prolapse: A Randomized Controlled Trial" 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 was comprised of women with POP who were going to have repair surgery using either a transvaginal mesh product or traditional surgery. The researchers ended the study early because of an "unacceptably high rate" (15.6%) of vaginal mesh erosion. The authors concluded that there was "no statistically significant differences in subjective or objective cure rates" between traditional procedures and mesh procedures. The authors questioned the value of using synthetic mesh for POP repairs over traditional surgery.

30. In or about February of 2011, the SOGC issued a Technical Update titled "Transvaginal Mesh Procedures for Pelvic Organ Prolapse" to provide information on transvaginal mesh procedures. In the update, the SOGC reviewed complications resulting from transvaginal mesh procedures, and expressed concern regarding the lack of long term studies done on transvaginal mesh products. The SOGC concluded that transvaginal mesh procedures needed to be more thoroughly evaluated before it could be assumed that they offered benefits over traditional repairs. The SOGC stated that until adequate effectiveness and safety evidence was available, the use of new transvaginal mesh devices for POP should be considered experimental and restricted to use in investigative trials.

31. 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 "serious complications associated with surgical mesh for transvaginal repair of POP are *not rare*". [emphasis in original] The FDA also issued a comprehensive review in or about July of 2011 titled "Urogynecological Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse." In the 2011 update, the

FDA reported various complications associated with transvaginal mesh for the treatment of POP, including recurrent prolapse, neuromuscular problems, vaginal scarring and shrinkage, severe pelvic pain, painful sexual intercourse, inability to engage in sexual intercourse, and emotional problems. The FDA noted that many patients who experience complications with surgical mesh for transvaginal repair require additional surgeries or hospitalization. The FDA further noted that erosions (the most commonly reported complication) could be debilitating and may remain unresolved, even after multiple surgeries.

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

Plaintiff's Injuries

33. The Plaintiff, Ms. Ianorescu, underwent surgery on or about June 3, 2010 to treat SUI. She was implanted with a Monarc Subfascial Hammock.

34. After her surgery, Ms. Ianorescu 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.

35. Soon after her surgery, Ms. Ianorescu experienced considerable pain in her pelvic region, which was worse on her right side. The pain was persistent. It was burning in nature and at times stabbing. The pain was aggravated by activity and, at times, was so severe that it radiated down her right leg. As a consequence of the pain, Ms. Ianorescu went to the hospital emergency on more than one occasion.

36. Despite her surgery, Ms. Ianorescu continued to experience SUI. She also experienced sensations of urinary urgency, the sensation of incomplete bowel emptying, and occasional anal incontinence.

37. Ms. Ianorescu saw several specialists. She was advised to undergo laser therapy, trigger point injections and pelvic physiotherapy sessions to treat her pelvic pain. Ms. Ianorescu tried all of these treatments, but none improved or decreased the chronic pain that she was experiencing in her pelvic region.

38. Before she had the Defendants' Pelvic Mesh Product implanted, Ms. Ianorescu never experienced this type of pain in her pelvic region. She was an active person employed as a special education assistant. Ms. Ianorescu was taking her teacher's training course and was excited at the prospect of becoming a teacher.

39. The implantation of the Pelvic Mesh Product has had a significant impact on Ms. Ianorescu's life. As a consequence of the pain that Ms. Ianorescu experienced as a result of the Pelvic Mesh Product, she had to take time off work to travel to numerous doctors' appointments. Ms. Ianorescu was ultimately forced to quit her teacher's training course and go on long term disability.

40. The complications with the Pelvic Mesh Product make intercourse painful for Ms. Ianorescu and have affected her relationship with her husband, both emotionally and sexually.

41. Ms. Ianorescu has experienced pain and suffering as a result of the failure of the Defendants' Pelvic Mesh Product. She has incurred and will continue to incur loss of employment income and out of pocket expenses.

42. Prior to being implanted with the Defendants' Pelvic Mesh Product, Ms. Ianorescu received inadequate warnings about the risks associated with it. If she had been aware of the risks, she would never have agreed to be implanted with the Pelvic Mesh Product.

43. In or about March of 2013, Ms. Ianorescu was referred to the Cross Roads Clinic for Bladder Health, Female Incontinence and Prolapse located in Vancouver, British Columbia (the "Clinic"). At the Clinic, she was advised by a specialist that the Pelvic Mesh Product implanted in her had contracted and was the cause of the severe and chronic pain in her pelvic region. The specialist recommended mesh excision.

44. Accordingly, on or about July 5, 2013, Ms. Ianorescu underwent surgery to permanently remove the Pelvic Mesh Product. Due to the migration and location of the mesh, the surgeon was only able to remove a portion of the mesh.

Part 2: RELIEF SOUGHT

45. 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*, S.B.C. 2004, c. 2;

(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

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

47. 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 Pelvic Mesh Products. The Defendants breached the standard of care expected in the circumstances.

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

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

a) manufacturing and/or marketing devices which they knew or ought to have known, had an unreasonably high risk of complications in patients;
b) failing to test the Pelvic Mesh Products properly and thoroughly before releasing the Pelvic Mesh Products to the market;
c) failing to conduct adequate tests and clinical trials initially and on an ongoing basis to determine whether the design of the Pelvic Mesh Product was defective, thereby increasing the risks of injury and harm associated with the use of the Pelvic Mesh Products;
d) failing to adequately disclose the serious complications associated with the Pelvic Mesh Products;
e) failing to conduct an adequate and timely analysis of adverse event reports;
f) failing to instruct their employees to accurately and candidly disclose consumer complaints and complications associated with the Pelvic Mesh Products to Health Canada in a timely manner, or at all;
g) failing to warn consumers, their health providers, and Health Canada of the complications presented by the Pelvic Mesh Products;
h) failing to provide proper long term investigations of the effects and risks of the continued use of the Pelvic Mesh Product;
i) failing to recall the Pelvic Mesh Products;
j) failing to provide effective, complete and clear training and information to physicians;
k) marketing the Pelvic Mesh Products which were unsafe, not fit for their intended purpose, and not of merchantable quality;

l) marketing the Pelvic Mesh Products in such a way to give the Plaintiff and class members no reason to suspect that the Pelvic Mesh Products had potentially harmful complications;

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

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

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

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

q) such further and other particulars of negligence that are within the knowledge of the Defendants.

Regulatory Duties

50. The Plaintiff pleads and relies upon the following statute and regulations which were breached by the Defendants:

a) *Food and Drugs Act*, R.S.C. 1985, c. F-27, s.20(1); and

b) *The Medical Devices Regulations*, SOR/98-282, ss.9-13, 59-61.1 and 64-65.1.

51. The Defendants' common law duties are informed by the *Medical Devices Regulations*. Pursuant to s.1 of those regulations, each Defendant is a "manufacturer". Each Defendant sold the Pelvic Mesh Products. Each Defendant designed, manufactured, assembled, processed, labelled, packaged and/or modified the Pelvic Mesh Products, attached their trade name to them, and assigned them a purpose.

52. The regulations impose continuous obligations on the Defendants, commencing at licensing and continuing thereafter. They require the Defendants to ensure the safety of the Pelvic Mesh Products before selling them, and to continuously monitor the safety of the Pelvic Mesh 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 Pelvic Mesh Products' risk profile.

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

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

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

56. Pursuant to s. 12 of the *Medical Devices Regulations*, the Defendants were required to ensure that the Pelvic Mesh Products were effective for the purposes and uses for which they were manufactured, sold or represented. The Defendants breached this section. The Pelvic Mesh Products were not effective and caused complications in their users.

Business Practices and Consumer Protection Act

57. The Defendants' solicitations, offers, advertisements, promotions, sales and supply of the Pelvic Mesh 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 ("*Consumer Protection Act*"). With respect to those consumer transactions, the

Plaintiff and class members who were implanted with the Pelvic Mesh Products are "consumers" and the Defendants are "suppliers" within the meaning of the *Consumer Protection Act.*

58. The Defendants' conduct in their solicitations, offers, advertisements, promotions, sales and supply of the Pelvic Mesh Products, as particularized above, had the capability, tendency or effect of deceiving or misleading consumers regarding the safety and efficacy of the Pelvic Mesh Products. The Defendants' conduct in its solicitations, offers, advertisements, promotions, sales and supply of the Pelvic Mesh Products constituted deceptive acts and practices within the meaning of s.4 of the *Consumer Protection Act* and contrary to s. 5 of the *Consumer Protection Act.*

59. The Defendants' deceptive acts and practices included the failure to properly disclose all material facts regarding the safety and efficacy of the Pelvic Mesh Products. The Defendants represented that the Pelvic Mesh Products were of a particular standard and quality when they were not. Further, the Defendants represented that the Pelvic Mesh Products had benefits and characteristics that they did not have.

60. 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, declaratory relief, damages and statutory compensation pursuant to ss.171 and 172 of the *Consumer Protection Act* on her own behalf and on behalf of class members implanted with the Pelvic Mesh Products in British Columbia.

61. The declaratory and injunctive relief sought by the Plaintiff in this case includes an order under s.172 of the *Consumer Protection Act* 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 Pelvic Mesh Products, which includes sending a "Dear Doctor Letter" to alert physicians to the problems and risks associated with the Pelvic Mesh Products.

62. 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 *Consumer Protection Act* and a remedy for that breach. In the alternative, if reliance is required to establish a 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

63. As a result of the Defendants' negligence and the Defendants' breach of the *Consumer Protection Act*, 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.

64. 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 Pelvic Mesh Products. The Defendants have continued to market the Pelvic Mesh Products in Canada as safe and effective when they knew or should have known of the risks associated with the use of the Pelvic Mesh Products.

65. 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.

Discoverability

66. The Plaintiff could not reasonably have known that her injury, loss or damage was caused by or contributed to by the Defendants' negligence, nor could she have known the nature of the Defendants' negligence until, at the very earliest, March of 2013 when she attended the Clinic and was advised by a specialist that the Pelvic Mesh Product implanted in her had contracted and was the cause of the chronic pain in her pelvic region.

Health Care Cost Recovery

67. 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

68. 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 Pelvic Mesh 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; and

(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: February 27, 2015

David A. Klein,
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

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 other class members. The Plaintiff and other class members suffered personal injuries and damages after being implanted with the Pelvic Mesh Products. The Defendants researched, designed, tested, manufactured, marketed, labeled, promoted, distributed, imported and sold the Pelvic Mesh Products. They breached duties to the Plaintiff and class members by failing to adequately test the Pelvic Mesh Products, by failing to adequately monitor and investigate complications associated with the Pelvic Mesh 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:

A personal injury arising out of:

[ ] a motor vehicle accident

[ ] medical malpractice

[x] 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:

[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/98-282