CITATION: Vester v. Boston Scientific Ltd., 2017 ONSC 1095
COURT FILE NO.: CV-15-527310 CP
DATE: 2017-02-17

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:	)	
	)	
SUSAN VESTER and DARIN VESTER	)	*Daniel E.H. Bach, Jill McCartney* and *Elizabeth deBoer* for the Plaintiffs
Plaintiffs	)	
	)	
– and –	)	
	)	*David Morritt, Sonia L. Bjorkquist,* and *Karin Sachar* for the Defendants
BOSTON SCIENTIFIC LTD. and BOSTON SCIENTIFIC CORPORATION	)	
	)	
Defendants	)	
	)	
	)	**HEARD**: January 30-31, 2017

PERELL J.

REASONS FOR DECISION

A. INTRODUCTION

[1] The Defendants Boston Scientific Ltd. and Boston Scientific Corporation (collectively "Boston Scientific") designed, manufactured, and sold transvaginal mesh medical devices that were implanted into thousands of Canadian women for the treatment of Stress Urinary Incontinence ("SUI") or Pelvic Organ Prolapse ("POP"). The Plaintiff, Susan Vester, who suffered from SUI, had a Lynx transvaginal mesh device implanted, and she suffered painful complications. Mrs. Vester, along with her husband Darin Vester, commenced a proposed class action under the *Class Proceedings Act, 1992*, S.O. 1992, c. 6. They alleged that all the devices are defective and unsafe and that they all can cause immense pain, among other side effects. The Vesters sought to have their action certified as a class action. The certification motion was heard on November 23, 2015, and I released my decision on December 17, 2015. See *Vester v. Boston Scientific Ltd.,* 2015 ONSC 7950.

[2] For the 2015 certification motion, I concluded that: the pleadings disclosed a cause of action for a negligent design claim and a failure to warn claim; there was an identifiable class; and Mrs. Vester and Mr. Vester might qualify as representative plaintiffs. However, the claims of the Class Members did not raise common issues and given the absence of any common issues, a class proceeding was not the preferable procedure. In the result, I adjourned the certification motion to permit Mrs. Vester and Mr. Vester to provide evidence to establish some-basis-in-fact

for common issues for the negligent design claim or for the failure to warn claim; (b) to establish some-basis-in-fact that a class action would be the preferable procedure for the determination of those common issues; and (c) to revise their litigation plan accordingly.

[3] The certification motion now resumes, and for the reasons that follow, I certify the Vesters' action as a class proceeding.

B. FACTUAL BACKGROUND

1. Introduction and the Some-Basis-in-Fact Evidence from the First Certification Motion

[4] To provide the context for this resumed certification motion and to understand my conclusions from the first certification motion hearing - that Mrs. Vester had not satisfied the common issues and preferable procedure criteria for certification - and to understand the significance of the evidence proffered by both sides for the resumption of the certification motion, it is necessary to set out paragraphs 18-24, 34, 35, 38, 40, 42-47, 49-57, 61, 78-82, 116-131, 133-138, 140 and 141 of my 2015 Reasons for Decision, which stated:

> **2. The Parties**
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> 18. The Defendant Boston Scientific Ltd., a Canadian corporation, is a subsidiary of the Defendant Boston Scientific Corporation, a Delaware company. Boston Scientific Ltd. is the sole distributor of Boston Scientific's transvaginal mesh devices in Canada. ...the devices are used to treat SUI and POP, the nature of which is discussed below.
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> 19. On January 4, 2010, Mrs. Vester, who suffers from SUI, the nature of which is discussed below, underwent surgery in which a Boston Scientific "Lynx," a synthetic mesh sling made out of "Advantage" mesh, was transvaginally implanted into her body to support her urethra in an effort to prevent urine leakage. The Lynx was made of Marlex HGX-030-01 polypropylene.
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> 20. Following her surgery, Mrs. Vester began experiencing complications and multiple side effects including pelvic pain, vaginal pain, pain in her buttocks and legs, urinary problems, lower abdominal pain, lower back ache, difficult bowel movements, difficulty walking, difficulty sleeping, difficulty crossing her legs, dyspareunia (pain during sexual intercourse), and emotional stress. She testified that had she been aware of the risks of having a transvaginal mesh device implanted in her, she would not have agreed to have the surgery.
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> 21. Boston Scientific, which was provided with Mrs. Vester's medical records, disputes her assertion that the surgery to cure her SUI was unsuccessful and her assertion that her subsequent complaints are related to the implantation of the Lynx. It points out that Mrs. Vester has a long history of abdominal surgeries, ovarian cysts, and musculoskeletal issues causing hip pain and back pain. She had five abdominal surgeries before her mesh surgery: two C-sections in 1985 and 1997, a Marshall-Marchetti-Krantz sling surgery to treat her SUI in 1998, a hysterectomy in 2001, and a complete abdominoplasty (tummy tuck) in 2005.
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> 22. Darin Vester has been married to Mrs. Vester for approximately 18 years. As a result of his wife's mesh implant and the resulting complications she has suffered, he claims a loss of care, guidance and companionship.
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> **3. The Witnesses for the Certification Motion**
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> 23. Mrs. Vester supported her motion for certification with the following evidence:

- Mrs. Vester swore an affidavit. She was cross-examined.

- Mr. Vester swore an affidavit. He was cross-examined.

- Rachael Pardy, who is a paralegal with Siskinds LLP, Plaintiffs' Counsel, swore affidavits with exhibits including: news releases by the United States' Federal Drug Administration ("FDA") and Health Canada; newspaper articles; medical literature; regulatory filings to the FDA; and transcripts, written submissions and court orders from US proceedings in which Boston Scientific was a defendant.

- Dr. Peter Pommerville, a urologist licenced in the Province of British Columbia with over 30 years of experience, swore an affidavit. He graduated from the University of Ottawa, Faculty of Medicine in 1978 and completed a residency in Urology in 1983 and a fellowship in Urology in 1984. He has been a member of the American Board of Urology since 1992. He is a Fellow of the Royal College of Physicians and Surgeons of Canada and a clinical professor of urology at the University of British Columbia medical school. He was cross-examined.

24. Boston Scientific opposed the motion for certification with the following evidence:

- Dan Krause, the Manager of Regulatory Affairs for Boston Scientific, swore an affidavit. He was cross-examined.

- Dr. Michael L. Douso, an urogynecologist, swore an affidavit. He obtained his Doctor of Medicine degree in 1982 from Hahnemann University, Philadelphia, Pennsylvania. He completed a residency in Obstetrics and Gynecology in 1986 at Sinai Hospital of Baltimore and has been board-certified in Obstetrics and Gynecology since 1989. He is the Chair of the Department of Minimally Invasive Surgery at Capital Regional Medical Center in Tallahassee, Florida. He is a member of the American Association of Gynecological Laparoscopists, the American Urogynecologic Society, the International Urogynecological Association, and the Florida Obstetrical and Gynecological Society. He has extensive experience treating SUI and POP. He was cross-examined.

- Dr. Lonny Green, a urologist, swore an affidavit. He obtained his Doctor of Medicine degree in 1987 and completed the Harvard Program in Urology in 1993. He has treated a wide range of female pelvic floor disorders, with a focus on female SUI. From 1995 to 2005, he established and directed the Virginia Continence Center at Virginia Urology. In 2006, he founded what is now known as the Pelvic Health and Continence Institute at Virginia Women's Center. He has extensive experience implanting the Lynx, Obtryx, and Solyx Mid-urethral Slings, all manufactured by Boston Scientific, and he has performed more than 2,500 mesh surgeries since the early 2000s. Dr. Green reviewed the medical records of Mrs. Vester. He was cross-examined.

- Dr. Stephen F. Badylak, a biomaterials expert, swore an affidavit. After becoming a Doctor of Veterinary Medicine in 1976, he obtained a Ph.D. in Anatomic Pathology in 1981 and a Doctor of Medicine in 1985. He practiced clinical medicine from 1985 to 2001. He is the Deputy Director of the McGowan Institute for Regenerative Medicine and a full Professor in the Departments of Surgery and Bioengineering at the University of Pittsburgh. His research topics include tissue engineering and regenerative medicine, as well as the design of implantable surgical mesh devices, including those made with polypropylene. He was cross-examined.

- Henry Ngan, an associate lawyer with Osler Hoskin and Harcourt LLP, Boston Scientific's lawyer of record, swore an affidavit. His affidavit provided information about 13 individual actions brought by women who had been treated with Boston Scientific's transvaginal mesh products.

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5. Stress Urinary Incontinence ("SUI"), Pelvic Organ Prolapse ("POP"), and Transvaginal Mesh Products

(a) Stress Urinary Incontinence ("SUI") and Transvaginal Mesh Products

34. SUI is the involuntary leakage of urine on effort or exertion, such as sneezing or coughing. More scientifically, SUI is the loss of urine from increases in intraabdominal pressure through an intact lower urinary tract caused by urethral hypermobility or intrinsic sphincter deficiency or a combination of both.

35. About 25,000 Canadian women undergo surgical procedures each year for treatment of SUI. Surgical mesh sling devices; i.e. support devices, which are manufactured by several different medical device manufacturers, are implanted in more than 90% of the surgeries.

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(b) Pelvic Organ Prolapse ("POP") and Transvaginal Mesh Products

38. POP is the downward descent of female pelvic organs, including the bladder, the small or large bowel, and uterus or post-hysterectomy vaginal cuff, resulting in protrusion of the vagina, uterus or both. POP occurs because, over time, it is common for pelvic floor muscles to weaken and to lose their ability to offer support with the result that the pelvic organs drop.

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40. About 5,000 Canadian women undergo surgical procedures each year for treatment of POP. Surgical mesh sling devices; i.e. support devices, which are manufactured by several different medical device manufacturers, are implanted in more than 90% of the surgeries. While POP and SUI can occur in the same woman, the potential triggers and risk factors for POP and SUI are different.

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(c) Transvaginal Mesh Devices for the Surgical Treatment of POP and SUI

42. Polypropylene is a non-degradable, non-toxic and non-carcinogenic material that has a more than 60-year history of use for sutures and for hernia repair. Polypropylene medical devices have been used without adverse consequences in hundreds of thousands of surgeries.

43. Surgical mesh; i.e., synthetic mesh products made from polypropylene or other synthetics was initially used to repair abdominal wall hernias. In the 1970s, surgeons began to use surgical mesh products indicated for hernia repair for abdominal repair of POP. In the 1990s, gynecologists began to use surgical mesh for surgical treatment of SUI and the transvaginal repair of POP.

44. Before the introduction of transvaginal mesh, some surgeons adapted the surgical mesh that was used for abdominal hernia repair for the treatment of SUI and POP. The surgeons would cut the surgical mesh to the desired shape for SUI or POP surgeries. Over time, manufacturers responded by developing mesh products specifically designed for SUI and POP treatment. In 1996, the FDA cleared the first surgical mesh product specifically for use in SUI. In 2002, the FDA cleared the first surgical mesh product specifically for use in POP. Surgical mesh kits continue to evolve, adding new insertion tools, tissue fixation anchors, surgical techniques, and absorbable and biologic materials.

45. Type I polypropylene meshes are macroporous and monofilament knitted meshes with a pore size larger than 75 microns, which allows for the healthy migration of cells, as well as deposition of connective tissues that integrate between individual fibers of the mesh. Dr. Badylak opined that

Type I polypropylene meshes such as Advantage Mesh and Polyform Mesh are biocompatible materials that are appropriate for use in pelvic floor repair.

46. All the expert witnesses for the certification motion agreed that mesh slings made of polypropylene had replaced other procedures as the standard treatment for SUI. Dr. Pommerville - who it should be recalled is the Plaintiffs' expert - explained that the standard of care today is to use mesh slings because the operations can be done as an outpatient procedure with no hospital stay, a shorter operating time, and a shorter patient recovery time. Mid-urethral sling operations are designed to result in less post-operative pain, less chance of SUI recurrence, and better quality of life results. Dr. Pommerville explained that biologic slings (unlike synthetic materials) are absorbed over time, resulting in a possible return of the patient's incontinence. Consequently, polypropylene mesh slings became Dr. Pommerville's method of choice for treating SUI in the 1990s, and he continues to use them.

47. It is worth pointing out that the design idea behind transvaginal surgical mesh is that it is a synthetic material that will integrate with human tissue to provide a permanent support structure for human body organs.

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49. As noted above, how the human body responds to polypropylene being implanted is well known to medical scientists. The side effects associated with the transvaginal mesh devices are also well known and include acute or chronic pain, mesh erosion (extrusion or exposure), infection, voiding dysfunction, dyspareunia, organ or blood vessel perforation, neuromuscular damage, bleeding or hemorrhage, as well as recurrence of the issues the mesh was designed to treat.

50. The Plaintiffs' Statement of Claim identified numerous side effects and complications from using transvaginal mesh devices for POP or SUI surgery, including some risks which are common to general surgery. Paragraph 51 of the Statement of Claim sets out a non-exhaustive list of "injuries, conditions, and complications" alleged to arise from Boston Scientific's transvaginal mesh products, including: mesh erosion; mesh contraction; mesh hardening or shrinking; extrusion of the mesh; vaginal erosion; urethral erosion; infection; fistula; inflammation; vaginal scarring; vaginal pain; organ perforation; dyspareunia; blood loss; neuropathic and other acute and chronic nerve damage and pain; pudendal nerve damage; neuromuscular problems; pelvic floor damage; pelvic pain; granuloma formation; urinary and fecal incontinence; prolapse of organs; and psychological damage.

51. It is known that regardless of the size, shape, or implantation method used to place the mesh, a patient receiving synthetic mesh for SUI or POP can experience exposure or extrusion of the mesh. Dr. Pommerville testified that rates of mesh exposure have been recorded at 5%, mesh shrinkage at 18% and chronic pain associated with sexual activity at 14%. Dr. Badylak testified that the published literature reveals rates of mesh shrinkage reported as high as 40%, and "what people refer to as contracture percentages or shrinkage percentages anywhere from 5% up to 40 or 50%."

52. Dr. Douso - who, it should be recalled is one of Boston Scientific's witnesses - stated that "complications associated with surgical mesh can be serious and life threatening." Dr. Douso testified that exposure or erosion are mesh specific complications and that complications from mesh require added surgical intervention which can be "extremely difficult" and "more than one repeat surgery may be required to resolve the issue and in some occasions, the complication may not be satisfactorily resolved."

53. It was Dr. Pommerville's opinion, which is central to whether there is some-basis-in-fact to the Plaintiffs' duty to warn claim, that manufacturers of transvaginal mesh products had not conducted long-term assessments of their products and because of a lack of long-term data, surgeons did not have sufficient knowledge to inform patients about the possible immediate post-

operative surgical complications from the use of transvaginal mesh products, nor did they have the information to inform the patients about the long-term delayed complications. He opined that surgeons were not adequately informed about the risks of transvaginal mesh placement including the frequency of side effects.

54. I will return to this point about the duty to warn below, but it should be noted that Dr. Pommerville's evidence was directed at the medical device industry in general and the brunt of his criticism was about transvaginal mesh products for POP treatment. Before writing his report, he did not read any Boston Scientific Directions For Use ("DFU"), he had never used a Boston Scientific product, and he had not attended any Boston Scientific training sessions.

(d) Boston Scientific's Transvaginal Mesh Products

55. The Boston Scientific product lines at issue include six SUI mesh products and three POP mesh products. The Boston Scientific product lines at issue in this proposed class action are:

- Advantage System, including the Advantage Fit System;
- Obtryx Transobturoator Mid-urethral Sling and Obtryx II;
- Lynx Suprapubic Mid-Urethral Sling System;
- Solyx Single Incision Sling (SIS) System;
- Pinnacle Pelvic Floor Repair Kit, anterior/apical and posterior configuration;
- Uphold Vaginal Support System.

56. Boston Scientific uses a transvaginal mesh known as "Advantage" for the SUI devices and a mesh known as "Polyform" for the POP devices. All of the transvaginal mesh devices at issue in this action are composed of a non-absorbable synthetic polypropylene known as "Type I" polypropylene mesh made out of Marlex HGX-030-01 resin. Marlex's polypropylene is expressly not manufactured for medical use and is manufactured to be used for woven industrial fabric and bags, rope and cordage, woven carpet backing, woven geotextile fabrics, and food packaging applications.

57. Although the Boston Scientific products that are the subject of this proposed class action all use the same Type I polypropylene mesh, their development, design, methods of and reasons for use, and potential complications differ in type, severity, and frequency. The products have different dimensions, function, features, configurations, method of fixation, and routes of application. The mesh used for the POP products has a different fiber diameter and pore size than the mesh used for the SUI products. The devices have different DFU.

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61. Boston Scientific has sold over 35,000 transvaginal mesh devices in Canada. Less than 1% of the devices are used to treat POP; the balance of the devices are used to treat SUI.

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7. The Proposed Class Action

78. On August 28, 2012, Mrs. Vester and Mr. Vester commenced a proposed class action.

79. The Statement of Claim alleges, among other things, that Boston Scientific's transvaginal mesh devices were negligently designed, marketed, sold, and instructed for use and that the Class Members suffered injuries and complications and have been forced to undergo intensive medical treatment, including, but not limited to, operations to locate and remove the mesh,

operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine and the vagina, and operations to remove portions of the female genitalia.

80. Further, the Claim alleges that Boston Scientific knew or ought to have known of the serious health related complications associated with their transvaginal mesh. It is alleged Boston Scientific was in breach of its duty to warn.

81. In the Plaintiffs' Statement of Claim, they do not identify any manufacturing defect in Boston Scientific's transvaginal mesh products, and the Plaintiffs' negligence claim appears to be a design negligence claim to the effect that Boston Scientific designed their medical device to be safer and more effective than the traditional methods for the treatment of POP and SUI but this was not the case and the design failed to be an improvement and had adverse medical consequences. What in particular was wrong with the design or designs is not specified. ....

82. The Plaintiffs also advance a failure to warn negligence claim. The Plaintiffs allege that the risks associated with the transvaginal mesh devices were not known to, and could not have been known by, the Class Members, and the Class Members' injuries would not have occurred but for Boston Scientific's negligence in failing to ensure that the transvaginal mesh devices were safe for use, or, in the alternative, for failing to provide an adequate warning of the risks associated with their use. The Plaintiffs plead that as a result of Boston Scientific's negligence, the Class Members have suffered and continue to suffer injury.

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6. Common Issues Analysis and Discussion

(a) The Design Negligence Claim

116. In the case at bar, given the absence of identifying a design defect in using Type I polypropylene mesh for a transvaginal mesh device, the fact that there were adverse consequences from the use of Advantage Mesh and Polyform Mesh does not provide some-basis-in-fact for concluding that there is a common issue with respect to the standard of care with respect to the design, development, testing, manufacture, licensing, assembly, labelling, marketing, instruction for use, distribution and/or sale of Boston Scientific's transvaginal mesh products. If the use of Type I polypropylene mesh is the design defect, the Plaintiffs have presented no evidence explaining why Type I polypropylene mesh is inappropriate for the treatment of SUI or POP. The Plaintiffs have not proposed any alternative or better material for use in transvaginal mesh products and the alternative of going back to the pre-existing treatments is not suggested save perhaps for the treatment of POP.

117. The Plaintiffs criticize Boston Scientific's argument that commonality of a negligent design claim is refuted by the differences in design, dimension, function, features, method of fixation, and route of application of Boston Scientific's nine products, all of which utilize Type I polypropylene mesh. The Plaintiffs submit that Boston Scientific's argument is deficient because it has not provided evidence that these differences are "clinically significant;" i.e. that the differences matter to patient outcomes and, therefore, Boston Scientific cannot show that the purported distinctions matter in the certification context. Apart from the fact that there was evidence that differences in design and dimension would be clinically significant and apart from the fact that it is self-evident that differences in design and method of fixation etc. would be clinically significant, and given their own expert's evidence that he uses and would continue to use polypropylene mesh products, the Plaintiffs' counterargument hoists them on their own petard for failing to show what it is that is clinically deficient about Type I polypropylene mesh in each of Boston Scientific's transvaginal mesh products.

118. The Plaintiffs criticize Boston Scientific's arguments about the want of commonality for the design negligence claim as an improper diversion of the certification motion into the merits of the

Plaintiffs' case rather than addressing on the certification motion that there is some-basis-in-fact for common issues, which is a different matter from a preliminary merits review. I disagree with this criticism. Unless the Plaintiffs in the immediate case can show some-basis-in-fact for submitting that just the use of Type I polypropylene mesh in a transvaginal medical device is a design defect for all transvaginal medical devices, which they have not done and which their own expert disavows to be the case, it is necessary to at least identify what might be proven at a common issues trial to be the design defect in using this mesh. A common issues trial about design negligence cannot function and was not meant to function as an inquiry or investigation as to whether there is some common design negligence leading to misadventures from the use of the product. Rather it is meant to be an adjudication of whether a common design defect is proven. To require some-basis-in-fact for the identification of that common design defect at the certification motion is not a diversion into the merits.

119. The Plaintiffs, however, emphasize or focus on the common feature of Type I polypropylene mesh in all of Boston Scientific's devices. However, a common feature in a multiproduct products liability case does not establish a common issue and is rather just a coincidence, unless the common feature relates to an identified common defect in manufacture or design, and in the case at bar, none of the Plaintiffs' proposed common issues identifies what is the defect that makes the use of Type I polypropylene mesh negligent.

120. Indeed, the common issues do not even mention polypropylene or identify its use as a design defect. Moreover, the evidence on the certification motion establishes that using Type I polypropylene mesh is part of the standard treatment for POP and SUI; i.e., to use polypropylene is not a patent defect in manufacture or design. There is no basis-in-fact that the use of polypropylene makes a transvaginal mesh product defective or that its use in the design of SUI and POP products is negligent. Dr. Badylak gave unchallenged evidence that Polyform Mesh and Advantage Mesh are biocompatible and safe for use in the body. Drs. Douso and Green state that the polypropylene products at issue are safe and effective for the treatment of SUI and POP. In his practice, Dr. Pommerville – the Plaintiffs' expert - uses polypropylene mesh SUI products.

121. The absence of the identification of the defect in using Type I polypropylene mesh, which is just part of the design of nine differently designed products, presents insurmountable problems for the Plaintiffs' proposed negligent design class action. By way of analogy, recalling that mesh slings are support structures, if a class of persons were injured by the collapse of a concrete bridge, a support structure that they all used, it would not be good enough for certification of a class action to just prove that the representative plaintiff was on the concrete bridge that collapsed and then to just argue that there must have been something wrong with the concrete used for the concrete bridge that collapsed.

122. In *O'Brien v. Bard*, 2015 ONSC 2470, there were 18 different transvaginal mesh devices and no common defect was identified, and for that reason I refused to certify the class action. The case at bar is similar. In *O'Brien v. Bard*, the case was said to be "all about the mesh," but there was, in fact, different types of mesh material and different types of polypropylene, and the case thus wanted for a common issue; however, the case at bar, which is "all about the one kind of mesh" also suffers from a want of commonality that is not solved by the coincidence that one kind of polypropylene is used in all of Boston Scientific's products.

123. Granted that the immediate case is about the one kind of mesh, but what's defective in design in using that mesh is never explained. It may be true that there is a design defect about the use of Type I polypropylene mesh in each of Boston Scientific's transvaginal mesh products, but, if there is a defect or defects, it or they have not been identified. At this juncture, the prospects are that there are no design defects or up to nine different design defects. If there were nine different design defects, then it would likely follow that the proposed class action should be disassembled into nine distinct class actions because a determination about one design defect would not advance the case for Class Members implanted with the other transvaginal mesh devices. With distinct design defects, a nuanced answer about one defect is not likely helpful in determining whether there was a breach of a duty of care about a different design defect.

124. The Plaintiffs' design defect case is not assisted by their argument that commonality has been established because of Boston Scientific's application in the United States to obtain approval for the distribution of its products which linked all the products to the ProteGen as a common predecessor. Apart from the fact that in a contested certification motion, the court is obliged to screen the questions for genuine and not admitted or confessed commonality, else the common issues trial will be an unproductive shamble, once again, a common feature must be connected in a meaningful and productive way to the plaintiff's claims, and in the immediate case, there is no basis-in-fact for that connection.

125. The case at bar is not a case like *Ragoonanan v. Imperial Tobacco Canada Ltd., supra*, where the design defect was designing a cigarette that was not fire safe. In *Ragoonanan*, it was alleged that the defendant's cigarettes could have been designed with reductions in circumference, paper porosity and tobacco-packing density or with alternative nicotine-delivery devices to produce a self-extinguishing cigarette. Nor is the case at bar like *Rentway v. Laidlaw, supra*, where a truck was designed with the headlights on a single electrical circuit when separate circuits would make for a safer vehicle or like *Nicholson v. John Deere Ltd., supra*, where a lawnmower was designed dangerously because the gas tank was close to the battery. In those cases, the designer made design choices that were not justified based on a risk to safety analysis.

126. The evidence on this certification motion - including the evidence of the Plaintiffs' expert, Dr. Pommerville, is that using Type I polypropylene mesh is the standard treatment of SUI. No defect in the polypropylene was identified. Since no design defect in any of the products was identified, it follows that no common defect across the nine products was identified.

(b) The Failure to Warn Claim

127. I turn now to the Plaintiffs' failure to warn claim. Since Boston Scientific's products do come with warnings, to be more precise, the Plaintiffs' duty to warn claim is an allegation that the warnings were inadequate. In my opinion, once again, there is a problem of commonality.

128. The want of commonality in the allegations of failure to warn can be quickly illustrated by the example of Health Canada's notices which historically have differentiated the use of surgical mesh for the treatment of SUI from its use for the treatment of POP suggesting that the risks to be warned about are different.

129. Historically, and speaking it comparative terms, it seems that using mesh to treat POP is more risky than using mesh to treat SUI, which, in turn, suggests that the duty to warn may be more urgent for three of Boston Scientific's nine products, which, in turn, suggests a want of commonality in the duties to warn for each and every of the nine products.

130. The want of commonality about the failure to warn is also demonstrated by the diversity and large number of "injuries, conditions, and complications" alleged to arise from Boston Scientific's transvaginal mesh products for which there is said to be a failure to warn. The problem here is not that the number of adverse consequences is large; rather, the problem is that the diversity of the injuries, conditions, and complications belies commonality.

131. The case at bar is not like *Parker v. Pfizer Canada Inc.*, 2012 ONSC 3681, where I certified a products liability failure to warn action against the manufacturer of a smoking cessation drug of a long list of neuropsychiatric adverse events including suicidal and homicidal ideation. The long list of neuropsychiatric adverse events did not eradicate a common complaint about a failure to warn. The case at bar is not like *Boulanger v. Johnson & Johnson Corp.*, [2007] O.J. No. 179 (S.C.J.), where Justice E.M. Macdonald certified the common issue whether the drug Prepulsid can cause or materially contribute to cardiac arrhythmia, including ventricular tachycardia, cardiac arrest, prolonged QT, torsades de pointes, ventricular fibrillation, sudden death and other heart disease, all of which were adverse cardiac events. Rather, the case at bar is similar to *Merck Frosst Canada Ltd. v. Wuttunee, supra*, which was not certified because the diversity of the alleged adverse consequence from using the drug Vioxx meant that the question of whether the drug

increased the risk of two different and unrelated types of physical injury, that is, gastro-intestinal injuries and cardiovascular injuries, did not present a common issue. ....

....

133. I also observe that the problem in the immediate case for the Plaintiffs is that at the present time they have not shown some-basis-in-fact for a common issue but it is indeterminate whether there is some-basis-in-fact for a common issue about a design defect or a negligent failure to warn. At the moment, given the number and diversity of the adverse consequences for which there is an alleged but un-particularized inadequacy of warnings, there is no commonality in the proposed common issues about a failure to warn.

134. There is also an evidentiary problem with respect to the alleged commonality of the inadequacy of Boston Scientific's warnings found in its DFU. As noted above, Dr. Pommerville's evidence was directed at the medical device industry. Before writing his report, he did not read any Boston Scientific DFU and he has never used a Boston Scientific product, nor attended any Boston Scientific training sessions. Thus, Dr. Pommerville did not provide useful evidence as to whether Boston Scientific's DFU were inadequate.

(c) Conclusion on the Commonality Criterion

135. The Plaintiffs failed to show some-basis-in-fact for a design defect or inadequate warning across the nine Boston Scientific products at issue, which are used to treat two entirely different conditions with different treatment indications within each condition. The nine products differ in design, dimension, function, features, method of fixation, route of application and other characteristics. The DFU for the products are also different. I conclude that the Plaintiffs have failed to show some-basis-in-fact for any of the proposed common issues.

136. My attention has been focused on the design negligence claim and the duty to warn claim, but I add that there was no basis-in-fact for concluding that there is a common issue about how Boston Scientific developed, tested, manufactured, licensed, assembled, labelled, marketed or distributed its nine products in Canada.

137. This brings the discussion to s. 5(4) of the *Class Proceedings Act, 1992*, which provides that the court may adjourn the motion for certification to permit the parties to amend their materials or pleadings or to permit further evidence.

138. In my opinion, the case at bar is an appropriate case for an adjournment to permit the Plaintiffs to specify what precisely is wrong with the Type I polypropylene mesh in each of Boston Scientific's nine products and to specify what is the failure to warn for each of the nine products.

7. Preferable Procedure Criterion

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140. As I stated in *O'Brien v. Bard, supra* at para. 221, it is axiomatic that if there is no basis-in-fact for common issues, then there is no basis-in-fact for a class action satisfying the preferable procedure criterion.

141. Given my conclusions about the absence of common issues and my decision to adjourn the certification motion, no purpose would be served by an analysis and discussion of the preferable procedure criterion. On the present record, with an absence of common issues, this criterion has not been satisfied.

2. The New Evidence

[5] After the adjournment of the 2015 certification hearing, the Vesters served the following additional expert reports: (a) the report of Dr. Scott Guelcher, Ph.D., a chemical engineer, who was cross-examined; (b) the report of Dr. Vladimir Iakovlev, M.D, an anatomical pathologist, who was cross-examined; and (c) the report of Dr. Cheryl Blume, Ph.D.; the President of Pharmaceutical Development Group, Inc., who was cross-examined.

[6] Boston Scientific responded with the following additional reports or evidence: (a) the report of Dr. Stephen Badylak, an anatomic pathologist, who had been a witness at the original hearing and who was cross-examined for the first hearing but not the second hearing; (b) the evidence of Dan Krause, Manager of Regulatory Affairs for Boston Scientific, a witness at the original hearing and who was cross-examined for the first hearing but not the second hearing; and (c) the report of Dr. Michael Douso, an urogynaecologist, who had been a witness at the first hearing and who was cross-examined for the first hearing but not the second hearing.

3. Preliminary Evidentiary Issues

[7] In my 2015 Decision, I concluded that the Marlex Material Safety Data Sheet (MSDS) was not admissible for the truth of its contents. For the second hearing, Dr. Guelcher referred to the MSDS in his report, and Boston Scientific took issue with his comments and reliance on the document. My views about the MSDS have not changed, and it is not admissible for the truth of its contents. In any event, I do not rely on the MSDS in coming to my decision and so nothing turns on it, whatever relevance it ultimately may have later in this proceeding.

[8] Boston Scientific also challenges the admissibility of other documents that are footnoted in Dr. Guelcher's report as inadmissible hearsay. Once again, nothing turns on these documents because I do not rely on them in coming to my decision that the Vesters' action should be certified.

4. Dr. Guelcher's Opinion and the Challenge to it from Dr. Badylak and Dr. Douso

[9] Dr. Guelcher is an Associate Professor in the Department of Chemical and Biomolecular Engineering at Vanderbilt University with a BA, MA, and Ph.D. in chemical engineering. He completed training as a post-doctoral research associate in biomedical engineering. His areas of research include biomaterials design and development, drug and gene delivery, tissue engineering, and *in vitro* models for cancer metastasis.

[10] Dr. Guelcher observed that all of Boston Scientific's transvaginal products are designed to be permanent implants and that all of the products use mesh that contains polypropylene made out of resin HGX-030-01. He noted that additives to the resin included the antioxidants Irganox 3114 and Irgafos 168 and that these additives and the acid scavenger DHT-4A were blended into the polypropylene to modify its properties.

[11] He opined that like all polypropylene that is implanted, HGX-030-01 elicits a response in the implantee, the person undergoing the surgery. The human body responds when any foreign object is implanted and Dr. Guelcher explained that in the case of implanted HGX-030-01

polypropylene, the body's response would cause embrittlement of the polypropylene and its degradation, which in turn could lead to adverse events such as erosion, scarring, inflammation, and pain. It was Dr. Guelcher's opinion that after implantation in the body, Boston Scientific's polypropylene mesh reacts with reactive oxygen species that are secreted by inflammatory cells, causing it to oxidize and degrade and the reaction does not stop until all of the implanted mesh is removed from the body.

[12] Dr. Guelcher deposed that upon implantation of the HGX-030-01 polypropylene, the human body recognizes the mesh as a foreign body and responds with an inflammatory response known as the foreign body reaction. The body secretes reactive oxygen species (ROS), acids, and enzymes to which the surface of the mesh is exposed. He said that the chemical composition of the mesh and biomaterial will determine the mesh's susceptibility to oxidative degradation. He stated that the degradation is caused by an oxidative attack and a break at the tertiary hydrogen bond of the molecular chain which degrading reaction continues until no more polypropylene can be broken down.

[13] Dr. Guelcher said that in 2015, he, along with Dr. Iakovlev, did a study by microscopy in which they examined explanted polypropylene pelvic meshes. They examined 163 samples, and they found the presence of inflammatory cells and oxidation staining near the surface of the polypropylene fibers. He said that his examination revealed microcracks and cracked fibers in the degraded polypropylene.

[14] Dr. Guelcher said that the scientific literature confirmed that polypropylene mesh changes after implantation, causing adverse events like pain, scarring and inflammation. He said that the studies linked complaints of chronic pain and sclerosis to the foreign body reaction to implanted mesh and the consequent degradation and microcracking near the surface of polypropylene fibers.

[15] Dr. Guelcher said that polypropylene can be stabilized against oxidation by adding antioxidants to the molten polymer to act as scavengers that will react with oxidative species and delay oxidation, degradation, and embrittlement. Dr. Guelcher said that the antioxidants in the HGX-030-01 polypropylene were designed to protect the mesh during processing and storage, and it was his opinion that they were not sufficient to protect the polypropylene from degradation and changes after it was implanted. Thus, it was his opinion that the presence of antioxidants in the HGX-030-01 polypropylene did not protect the mesh against degradation and that Boston Scientific ought to have tested the stability of its meshes in an oxidative environment representative of the foreign body reaction in the human body.

[16] Dr. Guelcher opined that HGX-030-01 was a poor material and design choice for the uses of all of Boston Scientific's transvaginal products.

[17] Dr. Badylak's competing evidence confirmed the science of the body's reaction to implanted foreign objects but he indicated that the type, size, location, or method of implantation of the polypropylene implant would not change the deterioration of the HGX-030-01 polypropylene because the foreign body reaction per unit of mesh surface is the same regardless of the size or configuration of the mesh.

[18] Dr. Badylak stated, however, that there was no evidence that cracking of the polypropylene occurs and he said that even if cracking were assumed to occur, it would be clinically insignificant. It was Dr. Badylak's opinion that the degradation reported by Dr. Guelcher was in the order of microns (1,000th of a millimeter) and would not occur inside the body where the temperatures were below that necessary to cause a reaction.

[19] Dr. Douso also disputed that polypropylene degrades, and he stated that he had never removed mesh due to a problem with the material and that he had never seen evidence that the mesh has deformed or degraded after he had implanted it.

[20] Dr. Douso repeated his view that the medical profession supported the use of mesh products for the treatment of POP and SUI, and he referred to the June 2016 Position Statement from the American Urogynecologic Society ("AUGS") and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction ("SUFU"), which Statement was also supported by the American College of Obstetricians and Gynecologists, the Association of Gynecological Laparoscopists, the National Association for Continence; the Society of Gynecologic Surgeons, and the Women's Health Foundation.

5. Dr. Iakovlev's Opinion and the Challenge to It

[21] Dr. Iakovlev is an Anatomical Pathologist and Director of Cytopathology at the Department of Laboratory Medicine at St. Michael's Hospital in Toronto, with an appointment at the Department of Laboratory Medicine and Pathobiology at the University of Toronto. His practice involves diagnostic examination of specimens surgically removed from human patients. Dr. Iakovlev has been analyzing mesh implants since 2012, commencing with hernia mesh implants, and since that time, he has reviewed over 300 samples of explanted mesh, including over 200 transvaginal mesh specimens. Dr. Guelcher and Dr. Iakovlev have collaborated on *in vivo* polypropylene degradation research, including a 2015 study that examined 164 explanted pelvic meshes by microscopy.

[22] Based on his own experience as a pathologist and his own research in collaboration with others, and based on a review of the scientific literature, Dr. Iakovlev said that when a foreign body or material is placed in the human body, it immediately becomes coated with human proteins followed by the appearance of inflammatory cells and inflammatory mediators. He said that the cells secrete an array of substances including reactive oxygen metabolites. The inflammation supplies mediators that cause tissue hypersensitivity to pain.

[23] Dr. Iakovlev said that the polypropylene mesh integrates with the body tissue. He said that the integration begins with blood clots and a complex process of scarring that yields to the development of fibrous tissue and a composite mesh-scar structure in the body as the fibrous tissue fills the spaces within the mesh and also surrounds the mesh. The scar tissue is living tissue with veins (vasculature), nerves (innervation) and immune response. The scar tissue is subject to regular mechanisms of pain and the mesh-scar structure can directly cause pain to adjacent organs and nerves. He said that the inflammation caused by the implanting of foreign material continues until the foreign object s surgically removed.

[24] Dr. Iakovlev opined that in the case of polypropylene mesh, the inflammation degrades the mesh and, among other things, produces scarring, and tissue sensitization to pain in the patient. He said that the degraded material showed cracking indicating brittleness and stiffening of the mesh. Dr. Iakovlev said that the polypropylene will degrade *in vivo* if not adequately protected by antioxidants and that the main feature of the degradation is cracking of the polypropylene surface which causes the mesh to lose tensile strength, to become brittle, to shrink and to deform in shape. He said that the reaction to the mesh is observable microscopically and continues until the mesh is removed.

[25] Dr. Iakovlev said that degradation of the mesh had clinical significance including damage to the tissue, nerve damage, vascular damage, muscular damage, and damage to neighbouring organs and associated pain. Dr. Iakovlev opined that the mesh can move from its intended position (deformation) and it can migrate through the tissue and into adjacent organs. He said that the mesh can be constricted by the contraction of surrounding tissue and the contraction of the mesh can lead to tissue and organ damage. He said that there was a higher risk of pain from transvaginal mesh because the female genital area has much higher nerve density compared to the midline anterior abdominal wall and groin. He said that the pathological changes were a cause of chronic pain, a cause of dyspareunia (pain during intercourse), urinary symptoms, and rectal dysfunction.

[26] Dr. Iakovlev stated that the removal of the mesh cannot restore the pre-existent tissue state and it may not be possible to remove the mesh in its entirety. Dr. Iakovlev said that if the chemical and physical properties change while in the body, the material should not be used for permanent applications and for anatomical sites from which the devices cannot be safely removed and that there should be planned exit strategies for complete and safe device removal and with minimal residual tissue damage.

[27] Dr. Badylak challenged Dr. Iakovlev's opinion. Dr. Badylak disputed that Dr. Iakovlev's evidence proved that there had been any degradation of the polypropylene mesh, and he said that the mesh samples observed by Drs. Guelcher and Iakovlev are inherently different upon removal; i.e., their extraction changes them and, therefore, conclusions cannot reliably be drawn regarding the *in situ* state of the mesh.

[28] Dr. Badylak contended that Dr. Iakovlev, as a pathologist, was not qualified to opine what might be the cause of pain. Dr. Badylak said: "Put simply, there is no way to see pain on a slide."

[29] Dr. Douso also challenged Dr. Iakovlev's opinion. Dr. Douso said that the biggest weakness in the reports of Drs. Guelcher and Iakovlev is that microscopically small reactions on the surface of mesh would not make a difference to a patient. His opinion was that the degradation, if any, was not clinically significant.

6. Mr. Krause's Evidence

[30] As explained below, Dr. Blume opined that Boston Scientific's DFU did not comply with Canadian regulatory requirements. In response to Dr. Blume's affidavit and evidence, discussed below, Mr. Krause, Boston Scientific's Manager of Regulatory Affairs, responded with an affidavit in which he disagreed with Dr. Blume and in which he deposed about regulatory events since the 2015 certification hearing.

[31] In his affidavit, Mr. Krause deposed that in 2016, Boston Scientific stopped manufacturing its Uphold and Pinnacle POP medical devices and it had applied to Health Canada for approval for Uphold Lite for POP.

[32] Mr. Krause deposed that in March 2016, before receiving a request to do so, Boston Scientific updated its DFU for its SUI products. Using the DFU for the Obtryx™ System – Halo as an illustration, the pertinent parts of the DFU before and after the revisions made by Boston Scientific are set out below:

Before	After
GENERAL WARNING .... PROCEDURAL WARNING	GENERAL WARNING ...
	• Mesh is considered a permanent implant. Removal of mesh or correction of mesh related complications may involve multiple surgeries. • Complete removal of mesh may not be possible and additional surgeries may not always fully correct the complications.
POST PROCEDURAL WARNING • If subsequent infection occurs, the entire mesh may have to be removed or revised, follow appropriate medical intervention practices.	POST PROCEDURAL WARNING • If subsequent infection occurs, follow appropriate medical intervention practices. ....
POTENTIAL COMPLICATIONS The following complications have been reported due to suburethral sling placement, but are not limited to: .... The occurrence of these responses may require removal of the entire mesh.	ADVERSE EVENTS The following adverse events have been reported due to suburethral sling placement, but are not limited to: .... The occurrence of these events may require surgical intervention and possible removal of the entire mesh. ....
	The occurrence of these events may require surgical intervention. In some instances the response to these events may persist as a permanent condition after the intervention.

[33] It seems that Boston Scientific's update was prescient, because in August 2016 Health Canada requested a change to the DFU, and in September 2016, Boston Scientific advised that the updated DFU already incorporated Health Canada's suggestions.

[34] Mr. Krause said that Boston Scientific had complied with the Canadian regulations as evidenced by the fact that the pelvic mesh devices had remained in the market since approved by Health Canada.

7. Dr. Blume's Evidence and the Challenge to It

(a) The Motion to Disqualify Dr. Blume as an Expert Witness

[35] The Vesters retained Dr. Blume to provide an opinion about the currency and completeness of the DFU in Boston Scientific's pelvic mesh products for SUI and POP.

[36] Dr. Blume is the President of Pharmaceutical Development Group, a consulting firm specializing in pharmaceuticals, medical devices, and related healthcare products, whose efforts include pre-approval and post-launch development, registration, regulatory and safety-related oversight responsibilities. She has a doctorate in medical pharmacology and over 30 years of regulatory and industrial experience mainly with non-prescription, prescription and biologic drug products, but she has also provided consulting services with respect to medical devices. Her education and faculty experience is mainly in pharmacology, specifically medicine and drugs. She spends approximately half her time giving evidence in litigation, usually for plaintiffs. Dr. Blume has been involved in mesh-related litigation and was an expert witness in pelvic mesh litigation against Ethicon and against Boston Scientific in the United States.

[37] However, Boston Scientific brought a preliminary motion to have Dr. Blume's evidence excluded from the resumed certification motion. It submitted that she did not have the requisite experience or impartiality to meet the minimum threshold for admissibility of expert evidence in Ontario. Dr. Blume is not a medical doctor, and Boston Scientific submitted that she does not have the qualifications to opine on treatment options for POP and SUI, or on complications, or on risks or risk tolerances or on whether treatments are elective or non-elective. Boston Scientific submitted that her medical scientific knowledge is with respect to pharmaceuticals and not medical devices. Boston Scientific submitted that notwithstanding having spent 224.25 billable hours at US$600/hour, Dr. Blume delivered an unimpressive 20-paragraph affidavit alleging breaches of Canadian regulatory standards.

[38] Boston Scientific submitted that in her affidavit and in her cross-examination, Dr. Blume revealed herself to be an advocate and partisan spokesperson for the Vesters. Boston Scientific submitted that Dr. Blume was self-justifying, ignorant, or ill-informed of fundamental information, and unfairly critical of industry evidence without investigation or justification.

[39] Relying on *Martin v. Astrazeneca Pharmaceuticals PLC*, 2012 ONSC 274, Boston Scientific submitted that Dr. Blume's evidence should not be admitted because: (1) she is not qualified to opine on the Canadian regulation of medical devices nor a medical doctor trained in the treatment of pelvic floor disorders; (2) she is partisan and non-objective; and (3) her affidavit does not comply with the *Rules of Civil Procedure* because contrary to rule 53.03(2.1)(6)(iii),

she did not list every document that she had relied on in arriving at her opinion.

[40] It does appear that Dr. Blume had a less than stellar day when she was cross-examined on her affidavit. From the cross-examination, it emerged that she had little personal experience with the regulatory process in Canada and few dealings with Health Canada and she had only modest knowledge of the Canadian regulator's published guidelines for DFU. She was unable to meaningfully discuss the Canadian *Medical Devices Regulations* (SOR/98-282). During Dr. Blume's cross-examination, she acknowledged the possibility of mesh removal and backed off the categorical statements in her affidavit. She was vague and bald in her criticisms of Boston Scientific's DFU. Although her opinion depended in part on medical knowledge about the treatment of POP or SUI, she was both unfamiliar and dismissive of the June 2016 Position Statement of AUGS and SUFU.

[41] Although as I shall explain below, I did not find Dr. Blume's evidence particularly helpful or necessary on the issue of whether there was some-basis-in-fact for a common issue about the duty to warn, in my opinion, she was qualified to give her evidence, and Boston Scientific's motion to have her disqualified as an expert witness should be dismissed.

[42] I begin my explanation of why I am admitting Dr. Blume's evidence by noting that for the purposes of the certification motion in this particular case, evidence about whether Boston Scientific's DFU complied with the regulatory requirements of Health Canada is, in and of itself, not a major issue, as is evidenced by the fact that compliance or non-compliance was not a major issue at the first certification motion hearing. The issue in this particular class action is not whether Boston Scientific complied with the Canadian *Medical Devices Regulations* (SOR/98-282); rather, the issue is whether Boston Scientific's DFU provided an adequate warning regardless of compliance or non-compliance with those regulations. What was expressed in the DFU, which are indeed regulated documents, is relevant to that issue, but compliance or non-compliance with the Canadian regulations begs the question of whether the warnings were adequate for the patients implanted with Boston Scientific's transvaginal medical devices made of polypropylene.

[43] The problem that emerged at the first hearing was that the Vesters had not identified in what way the warnings in the DFU were inadequate. Dr. Blume was the expert witness retained to redress this problem, and she was retained to point out what was inadequate in the DFU. Dr. Blume had the professional qualifications and sufficient scientific knowledge without being a physician to provide this evidence. Her scientific knowledge about how the body responds to pharmaceuticals and how that should be reported in DFU, was more than adequate to also opine about how the body responds to polypropylene and how that should be reported in DFU.

[44] I discussed at considerable length the recent developments in the law about the disqualification of expert witnesses on the grounds of partisanship and the absence of objectivity in *Wise v. Abbott Laboratories, Limited*, 2016 ONSC 7275, and I will not repeat that discussion here. For present purposes, I will simply say that I applied the law described in *Wise v. Abbott Laboratories, Limited* and for the purposes of the certification motion, Dr. Blume was qualified to provide the evidence that she provided and in my opinion, in all the circumstances, she did not cross the line of demonstrating non-objectivity or bias about what could be said to be inadequate about the information contained in the DFU.

[45] It is true that Dr. Blume's affidavit does not comply with the *Rules of Civil Procedure*

because, contrary to rule 53.03(2.1)(6)(iii), she did not list every document that she had relied on in arriving at her opinion. However, a proper list was eventually provided and Boston Scientific was not prejudiced by the non-compliance.

[46] As I suggested during the argument of the motion, in the context of products liability duty to warn class actions, how much evidence, if any, is required to identify whether there is some-basis-in-fact for a breach of the duty to warn will vary from case to case. I can add here that in the immediate case, the outcome would be the same even if I refused to admit Dr. Blume's evidence in its entirety. For Boston Scientific, ironically, there was some-basis-in-fact for the duty to warn allegations against it based on the evidence of Mr. Krause, which was proffered to refute Dr. Blume.

(b) The Challenge to Dr. Blume's Evidence

[47] In Dr. Blume's opinion, the DFU did not provide all data and information necessary for a meaningful benefit-risk analysis relative to the other available treatments for SUI or POP. She said that the DFU contained misleading and obsolete information. She said that given that SUI is a non-life-threatening medical concern that generally does not progress to more serious health consequences and given that it can be addressed with non-surgical and surgical (non-mesh) approaches, it is imperative that physicians and patients be aware of all negative health consequences associated with the pelvic mesh products. Dr. Blume opined that the warning included in Boston Scientific's DFU did not provide the information necessary for a meaningful benefit-risk analysis because it failed to inform healthcare professionals and their patients about the magnitude and severity of reported medical events and the inability to remove the entire mesh. She said that the DFU failed to communicate the consequences of the mesh's permanence and the consequences of mesh removal efforts.

[48] Dr. Blume said that the information in the DFU that certain tissue responses may require the removal of the entire mesh was misleading because reports demonstrated that complete mesh removal is not possible even with successive surgeries and that the mesh would remain imbedded. She said that the DFU failed to adequately communicate the escalating risks associated with mesh products, including the serious and life-threatening risks of additional surgeries, hospitalizations, and post-surgery convalescence requirements. In her opinion, the DFU did not comply with regulatory standards expected of medical product manufacturers.

[49] As noted above, Mr. Krause disputed Dr. Blume's report.

[50] And in his report, Dr. Douso stated that there was nothing inadequate, inaccurate, or misleading in Boston Scientific's DFU and that any surgeon would know that removal is one of many options in the arsenal of responses to a problem with a medical device, but also that he or she may or may not be able to retrieve the entire device, depending on anatomical location and other factors.

C. THE REVISED COMMON ISSUES

1. The Proposed Common Issues

[51] Mrs. Vester and Mr. Vester propose the following common issues:

> 1. Is HGX-030-01 unfit for use in the female pelvis such that it can cause complications including erosion, extrusion, mesh contraction, hardening and/or shrinking, scarring, pain including dyspareunia, organ perforation, pelvic floor damage, incontinence and psychological damage?
>
> 2. If the answer to (1) is "yes", is use of HGX-030-01 in the defendants' transvaginal mesh products a design defect?
>
> 3. If the answer to (2) is "yes," did the defendants breach the standard of care with respect to the design, development and/or testing of their transvaginal mesh products? If so, when and how?
>
> 4. Did the DFU for the defendants' transvaginal mesh products fail to disclose that the polypropylene used by the defendants will degrade causing complications; that the permanence of the transvaginal mesh products (*sic*); [that] removal, if possible at all, could require multiple surgeries; and/or that removal, if possible at all, may not correct complications, such that adverse events may persist as a permanent condition? If so, did that constitute a failure to warn?
>
> 5. If the answer to one or more of (1)-(4) is "yes," what was the defendants' knowledge with respect to the safety and permanence of transvaginal mesh and when was that knowledge acquired?
>
> 6. Can the past and/or future healthcare costs of the provincial health insurers be determined on an aggregate basis? If so, what is the appropriate amount? [withdrawn]
>
> 7. Should the defendants, or any of them, pay exemplary or punitive damages?

D. ANALYSIS AND DISCUSSION

1. Some-Basis-in-Fact for Common Issues in the Design Negligence Claim and Duty to Warn Claim

[52] As foreshadowed in the introduction to these Reasons for Decision, I am satisfied that the Vesters' action should be certified as a class action. The new evidence redresses the problem from the first certification motion hearing, which was that they had not shown a common issue for their design negligence claim or for the failure to warn claim.

[53] In my opinion, unlike the situation at the first certification motion, the Vesters have identified the manufacturing defect in Boston Scientific's transvaginal mesh products. What in particular is wrong with the design is now specified. Although Boston Scientific does not agree, there is some-basis-in-fact that the polypropylene mesh in each of Boston Scientific's transvaginal devices has a clinically significant deficiency. Although Boston Scientific does not agree, there is some-basis-in-fact that the use of HGX-030-01 polypropylene makes a transvaginal mesh product defective and that the use of HGX-030-01 polypropylene in the design of Boston Scientific's SUI and POP products is negligent.

[54] As for the failure to warn claim, the inadequacy in the DFU has been identified and there

is some-basis-in-fact for duty to warn common issues.

2. The Recast Common Issues

[55] Notwithstanding Boston Scientific's arguments to the contrary, the Vesters have met the test to certify the following somewhat recast common issues.

[56] From the original set of questions, question 6 was withdrawn. I am recasting the original set of questions for the purposes of clarity, precision, consistency, and congruence with the some basis-in-fact test for a common issue as follows:

> *Design Negligence*
>
> 1. Does the embrittlement and degradation of HGX-030-01 make it unfit for use in the female pelvis for the treatment of POP or SUI?
>
> 2. If the answer to (1) is "yes," then is use of HGX-030-01 in the defendants' transvaginal mesh products a design defect?
>
> 3. If the answer to (2) is "yes," then did the defendants breach the standard of care with respect to the design, development and/or testing of their transvaginal mesh products?
>
> 4. Does the embrittlement and degradation of HGX-030-01 after it is implanted in the female pelvis for the treatment of POP and SUI cause complications including erosion, extrusion, mesh contraction, hardening and/or shrinking, scarring, pain including dyspareunia, organ perforation, pelvic floor damage, incontinence, and psychological damage?
>
> *Duty to Warn*
>
> 5. Did the defendants' failure to disclose in their DFU that HGX-030-01 degrades constitute a breach of their duty to warn?
>
> 6. If the answer to (5) is "yes," when did the breach of duty occur?
>
> 7. Did the defendants' failure to disclose in their DFU that the degradation of HGX-030-01 causes complications including erosion, extrusion, mesh contraction, hardening and/or shrinking, scarring, pain including dyspareunia, organ perforation, pelvic floor damage, incontinence, and psychological damage constitute a breach of their duty to warn?
>
> 8. If the answer to (7) is "yes," when did the breach of duty occur?
>
> 9. Did the defendants' failure to disclose in their DFU that the removal of their transvaginal mesh to remediate complications might not be possible and if possible could require multiple surgeries constitute a breach of the duty to warn?
>
> 10. If the answer to (9) is "yes," when did the breach of duty occur?
>
> 11. If the answer(s) of any of questions (3), (5), (7), or (9) is "yes" would the defendants' breach of duty justify an award of exemplary or punitive damages?

3. Boston Scientific's Argument that the Common Issues and Preferable Procedure Criterion Have Not Been Satisfied

(a) Boston Scientific's Submissions

[57] Boston Scientific submits that the Vesters have identified a common feature of the transvaginal mesh products but, nevertheless, failed to establish that the common feature is connected in a meaningful way to the Class Members' claims and, therefore, there is no-basis-in-fact for the connection.

[58] Boston Scientific submits that there is no-basis-in-fact for a connection to the Vesters' claims beyond the fact that polypropylene changes after it is implanted, but the alleged changes occur at microscopic levels and have no clinical significance and do not connect to the complications that arise from the treatments. Boston Scientific submits that there is no evidence that a superficial surface crack, which requires a scanning electron microscope at magnification 1000 to see, would affect clinical performance or cause adverse effects. Boston Scientific says that there is evidence of commonality but no evidence that a claim actually exists.

[59] Boston Scientific submits that the Vesters have failed to demonstrate a methodology to prove that degradation causes or is associated with the alleged complications and in the absence of a demonstrated methodology the common issues criterion cannot be satisfied. Boston Scientific submits that the Vesters at this stage of the proceedings must provide some-basis-in-fact that the alleged degradation has the potential or capacity to cause the alleged harm by showing evidence of a methodology that will enable them to prove causation on a class-wide basis, which Boston Scientific submits the Vesters have not done because they have not proposed any methodology that would enable them to prove that any degradation occurs *in vivo* and that the degradation is associated with the disparate alleged complications.

[60] Boston Scientific submits that the effects of the alleged degradation cannot be assessed in common across the products or in relation to an extensive list of complications. Further, it submits that the Vesters' evidence does not provide a basis-in-fact to support their allegation that use of polypropylene is a patent defect. Boston Scientific submits that the Vesters have not provided an evidentiary basis-in-fact for any reasonable alternative design, which it submits is essential for a negligent design case. It submits that it is left uninformed about what it should have done differently in designing the product.

[61] With respect to the Vesters' duty to warn claim, Boston Scientific submits that Dr. Blume is not qualified to advance the opinions expressed and that her evidence is not admissible or credible. Boston Scientific submits that a company does not have a duty to explain a theory or the science behind a complication and, in any event, its DFU were adequate and there is no-basis-in-fact for the alleged failure to warn in respect of mesh permanence and the impossibility or difficulty of its removal that could not be assessed in common across the various products.

[62] Boston Scientific submits that resolution of the proposed common issues would not materially advance the claims of the Class Members and that a class proceeding is not the preferable procedure because a proliferation of significant individual issues remains and in the alternative, the issues in relation to SUI and POP differ such that they cannot be tried together.

(b) Analysis and Discussion

[63] Section 5(5) of the *Class Proceedings Act, 1992* provides that an order certifying a class proceeding is not a determination of the merits of the proceeding. All of Boston Scientific's arguments against certification are in their essence merits arguments, which may or may not ultimately succeed, but they are not arguments that refute that the Vesters have met the low some-basis-in-fact standard for the common issues and preferable procedure criteria. Boston Scientific did not submit that its merits-based arguments were so strong and so uncontestable that it had shown that there was no-basis-in-fact for the common issues.

[64] Unlike the first certification hearing, the Vesters and their witnesses have identified a discrete defect common to all of Boston Scientific's medical devices, and the witnesses have demonstrated some-basis-in-fact that the defect exists and that there is a plausible medical theory about how the choice of the material for the Boston Scientific medical devices may have been a negligent design decision that led to the persons implanted with the device suffering harm.

[65] It is a merits-based argument to submit, as Boston Scientific does, that there was no evidence that the degradation in the polypropylene has no clinical significance. Drs. Guelcher and Iakovlev testified that the polypropylene degraded and that the degradation had clinical significance, and they provided a theory of how the degradation could cause harm. The truth of this evidence may ultimately be refuted, but it has not been refuted yet simply by Drs. Badylak's and Douso's skepticism.

[66] Boston Scientific's argument about the alleged absence of a methodology and about the absence of design alternatives as obstacles to certifying the common issues are just more disguised merits-based arguments. The available methodology – at the some-basis-in-fact level – was demonstrated by the certification motion itself. The evidence on the certification motion also demonstrated Boston Scientific had choices and made decisions about the suitability of the material it used for its medical devices. The evidence on the certification motion demonstrated that steps could be taken to modify the polypropylene with additives. Both sides already know what they need to do to prove or disprove the certified common issues, and the case at bar does not present any insurmountable methodological challenges.

[67] The case at bar is not a case like *Charlton v. Abbott Laboratories Ltd.*, 2015 BCCA 26, rev'g 2013 BCSC 1712 or *Batten v. Boehringer Ingelheim (Canada) Ltd.*, 2017 ONSC 53 that wanted for a methodology. It is a case like *Miller v. Merck Frosst Canada Ltd.*, 2013 BCSC 544, affd. 2015 BCCA 353, where Justice Savage stated at paras. 48-50:

> 48.Unsurprisingly, the type of evidence required to overcome the common issue methodology hurdle will be different in every factual scenario. In *Microsoft*, the economic context demanded expert testimony about the applicability of multiple regression analyses; in this case, there is other evidence available to suggest that there is a way the plaintiff can establish general causation at trial as I have noted.
>
> 49. It is not necessary at this stage that there be specified a "gold standard" randomized, double blind, clinical trial involving thousands of men over a lengthy period establishing persistent sexual dysfunction. Dr. Wright did not suggest a specific scientific test – but he did

not have to, nor does the adoption of the Bradford-Hill criteria (which I will discuss below) require one. In my view, to suggest otherwise is to impute an overly narrow definition of the term "methodology" as used by the Supreme Court in *Microsoft*. That proposition is reinforced by consideration of what evidence is available at the certification stage of the litigation.

50. In *Microsoft*, the Supreme Court of Canada rejected Microsoft's submissions that "the 'credible or plausible methodology' standard adopted by [the chambers judge] was too permissive and allowed for a claim to be founded on insufficient evidence", partially because the Canadian class action regime does not have rigorous pre-certification discovery:

> 119. To hold the methodology to the robust or rigorous standard suggested by Microsoft, for instance to require the plaintiff to demonstrate actual harm, would be inappropriate at the certification stage. In Canada, unlike the U.S., pre-certification discovery does not occur as a matter of right. ...

[68] It is true that the degradation in the polypropylene is microscopic, but it is not necessarily true that because the degradation is microscopic that it cannot have a profound adverse effect on a woman's body. It is true that pain cannot be viewed on a slide, but neither can death be viewed on a slide, and just as a pathologist can opine on the cause of death by looking at a slide of microscopic tissue revealing cancer, Dr. Iakovlev could and did provide some-basis-in-fact for why the microscopic degradation of the polypropylene was a clinically significant cause of pain. Drs. Iakovlev's and Guelcher's opinion may ultimately be shown to be wrong, but that is a merits-based determination.

[69] Boston Scientific's arguments based on an alleged multiplicity of differences between the products, patients, and the complications, do not negate the commonality of the proposed common issues. The arguments and conflate lack of commonality with the normal circumstance that there may ultimately be a nuanced answer to the common issues that provides different answers having regard to those differences in the individual circumstances of the Class Members and having regard to the fact that in a personal injury action, specific causation always remains an individual issue.

[70] In the immediate case, if the court determines that the microscopic degradation of the polypropylene does not occur in the body or that if it occurs, it has no clinical significance, then there will be a common answer to all of the Class Members' claims.

[71] In the immediate case, if the court determines absolutely or in a nuanced way that: the microscopic degradation of the polypropylene does occur in the body; the degradation has clinical significance; and, Boston Scientific, by choosing HGX-030-01 polypropylene in designing its medical devices for implanting in women's bodies did not meet the standard of care, then there will be a common answer to the common question.

[72] In either event of the outcome of the common issues, there are productive common issues that justify certifying the Vesters' action as a class proceeding.

[73] As noted above, independent of Dr. Blume's report, there is some-basis-in-fact for common issues about a duty to warn now that the alleged dangers associated with the

possibility or not of removing a medical device designed to be permanent have been identified. As was the case in *Miller v. Merck Frosst Canada Ltd.*, *supra*, the complaints of persistent side effects and the resulting change in the warnings provide circumstantial evidence in support of certification.

[74] Section 5(4) of the *Class Proceedings Act, 1992* provides that the court may adjourn the motion for certification to permit the parties to amend their materials or pleadings or to permit further evidence. I adjourned the certification motion because it was my opinion that given that the Vesters had satisfied three of the five certification criteria, and given that there was evidence of real suffering by Class Members but an absence of any common issues, the Vesters should be given an opportunity to define common issues and to demonstrate that there was some-basis-in-fact for them. The Vesters did not abandon their proposed class action, and they have returned with productive common issues. They have brought this class action within the realm of other medical products liability actions that are suitable for a class action. A class action is the preferable procedure, and deficiencies in the Vesters' litigation plan, if any, can be resolved by proper case management as the action proceeds.

E. CONCLUSION

[75] For the above reasons, I certify the Vesters' action as a class proceeding.

[76] If the parties cannot agree about the matter of costs, they may make submissions in writing beginning with the Vesters' within 20 days of the release of these Reasons for Decision followed by Boston Scientific's submissions within a further 20 days.

Perell, J.

Released: February 17 2017

CITATION: Vester v. Boston Scientific Ltd., 2017 ONSC 1095
COURT FILE NO.: CV-15-527310 CP
DATE: 2017-02-17

ONTARIO
SUPERIOR COURT OF JUSTICE

BETWEEN:

SUSAN VESTER and DARIN VESTER

Plaintiffs

– and –

BOSTON SCIENTIFIC LTD. and BOSTON SCIENTIFIC CORPORATION

Defendants

REASONS FOR DECISION

PERELL J.

Released: February 17, 2017