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Details of Filing

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Important Information

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Form 33
Rule 16.32

Defence

Federal Court of Australia
District Registry: New South Wales
Division: General

No. NSD 1590/2012

Kathryn Gill and others

Applicants

Ethicon Sàrl and others

Respondents

In answer to the Fifth Further Amended Statement of Claim (**5FASOC**), the First Respondent (**Ethicon Sàrl**), the Second Respondent (**Ethicon, Inc.**) and the Third Respondent (**Johnson & Johnson Medical Pty Ltd**, referred to as **JJM Australia**) (hereinafter referred to collectively as **the Respondents**) state as follows:

Part A - Introduction

(i) Group Members

1. In answer to paragraph 1 of the 5FASOC, the Respondents:

   (a) state that the First Applicant, Mrs Kathryn Gill (**Mrs Gill**) and the Second Applicant, Mrs Diane Dawson (**Mrs Dawson**), do not have an alleged claim in respect of, or arising out of, the same ~~claim~~, similar or related circumstances as those~~at~~ alleged by all ~~Mesh Sub-~~Group Members, and do not have claims that give rise to substantial common issues of law or fact for all Group Members;

   (b) state that the Third Applicant, Mrs Ann Sanders (**Mrs Sanders**), does not have an alleged claim in respect of, or arising out of, the same ~~claim~~, similar or related circumstances as

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those~~at~~ alleged by all ~~Tape Sub-~~Group Members, and does not have claims that give rise to substantial common issues of law or fact for all Group Members;

(c) state that not all Group Members have claims as alleged against the same person or persons as each of the Applicants; and

otherwise do not know and therefore cannot admit the allegations contained in that paragraph.

(ii) The Applicants

2. The Respondents admit paragraphs 2(a) and 2(b) of the 5FASOC but otherwise do not know and therefore cannot admit the allegations contained in paragraph 2(c) of the 5FASOC.

2A. The Respondents admit paragraphs 2A(a) and 2A(b) of the 5FASOC but otherwise do not know and therefore cannot admit the allegations contained in paragraph 2A(c) of the 5FASOC.

2B. The Respondents admit paragraphs 2B(a) and 2B(b) of the 5FASOC but otherwise do not know and therefore cannot admit the allegations contained in paragraph 2B(c) of the 5FASOC.

(iii) The Respondents

3. In answer to paragraph 3 of the 5FASOC, the Respondents:

(a) admit the allegations contained in paragraphs 3(a), 3(b) and 3(f) of the 5FASOC;

(b) state that Ethicon Sàrl was the manufacturer of:

(i) GYNECARE PROLIFT Total, Anterior and Posterior Pelvic Floor Repair Systems, which consisted of pre-cut GYNECARE GYNEMESH PS Nonabsorbable PROLENE Soft Mesh implants and a set of instruments to facilitate mesh implant placement;

(ii) GYNECARE PROLIFT+M Total, Anterior and Posterior Pelvic Floor Repair Systems, which consisted of pre-cut GYNECARE GYNEMESH M Mesh implants and a set of instruments to facilitate mesh implant placement;

(iii) GYNECARE PROSIMA Anterior, Posterior and Combined Pelvic Floor Repair Systems, which consisted of pre-cut GYNECARE GYNEMESH PS Mesh implant(s) and instruments to facilitate mesh implant placement and postoperative support;

(iv) GYNECARE TVT Tension-free Vaginal Tape System, which consists of the GYNECARE TVT Single Use Device, GYNECARE TVT Reusable Introducer and GYNECARE TVT Reusable Rigid Catheter Guide;

(v) GYNECARE TVT ABBREVO Continence System, which consists of the GYNECARE TVT ABBREVO Implant Assembly, GYNECARE TVT ABBREVO Placement Loop, GYNECARE TVT ABBREVO Helical Passers and GYNECARE TVT ABBREVO Atraumatic Winged Guide;

(vi) GYNECARE TVT Obturator System which consists of the GYNECARE TVT Obturator Device, GYNECARE TVT Helical Passers and GYNECARE TVT Atraumatic Winged Guide;

(vii) GYNECARE TVT SECUR System, which consisted of the GYNECARE TVT SECUR System Device and GYNECARE TVT SECUR System Inserters; and

(viii) GYNECARE TVT EXACT Continence System, which consists of the GYNECARE TVT EXACT Continence System Trocar Sheath/ Implant Assembly and the GYNECARE TVT EXACT Continence System Trocar;

(c) state that in the Instructions for Use for each of the devices listed in paragraph 3(b) of the Defence:

(i) Ethicon Sàrl is described as the "legal manufacturer";

(ii) the devices are described as being "manufactured for":

A. "ETHICON Women's Health & Urology" - "A division of ETHICON, INC. a Johnson & Johnson company"; or

B. "GYNECARE WORLDWIDE" - "A division of ETHICON, INC. a Johnson & Johnson company";

(d) state that Ethicon Sàrl supplied the devices listed in paragraph 3(b) of the Defence, including to JJM Australia;

(e) state that Ethicon, Inc. decided to globally discontinue GYNECARE PROLIFT Pelvic Floor Repair System, GYNECARE PROLIFT+M Pelvic Floor Repair System, GYNECARE PROSIMA Pelvic Floor Repair System and GYNECARE TVT SECUR System on or about 5 June 2012. In Australia, the discontinuation process concluded on 15 August 2012;

(f) deny that Ethicon Sàrl was or is in the business in Australia of manufacturing, marketing, promoting or supplying medical devices; and

otherwise deny the allegations contained in that paragraph.

4. In answer to paragraph 4 of the 5FASOC, the Respondents:

(a) admit the allegations contained in paragraphs 4(a), 4(b) and 4(f) of the 5FASOC;

(b) state that Ethicon, Inc. was a manufacturer of GYNECARE GYNEMESH PS Nonabsorbable PROLENE Soft Mesh;

(c) state that Ethicon, Inc. supplied GYNECARE GYNEMESH PS Nonabsorbable PROLENE Soft Mesh, including to JJM Australia;

(d) deny that Ethicon, Inc. was or is in the business in Australia of manufacturing, marketing, promoting or supplying medical devices; and

otherwise deny the allegations contained in that paragraph.

5. In answer to paragraph 5 of the 5FASOC, the Respondents:

(a) admit the allegations contained in paragraphs 5(a), 5(b) and 5(c) of the 5FASOC;

(b) state that JJM Australia was the Australian sponsor, as defined by the *Therapeutic Goods Act* 1989 (Cth) of:

(i) GYNECARE PROLIFT Total, Anterior and Posterior Pelvic Floor Repair Systems;

(ii) GYNECARE PROLIFT+M Total, Anterior and Posterior Pelvic Floor Repair Systems;

(iii) GYNECARE PROSIMA Anterior, Posterior and Combined Pelvic Floor Repair Systems;

(iv) GYNECARE GYNEMESH PS Nonabsorbable PROLENE Soft Mesh;

(v) GYNECARE TVT Tension-free Vaginal Tape System;

(vi) GYNECARE TVT ABBREVO Continence System;

(vii) GYNECARE TVT Obturator System;

(viii) GYNECARE TVT SECUR System; and

(ix) GYNECARE TVT EXACT Continence System;

(c) state that, at all material times, JJM Australia imported and then supplied the devices listed in paragraph 5(b) of the Defence to hospitals in Australia;

(d) state that, at all material times, JJM Australia marketed and promoted the devices listed in paragraph 5(b) of the Defence to surgeons in Australia; and

otherwise deny the allegations contained in that paragraph.

Part B - The Conditions and the Implants

(i) The Conditions

6. In answer to paragraph 6 of the 5FASOC, the Respondents state that pelvic organ prolapse (**POP**):

(a) refers to the bulging or herniation of one or more pelvic organs (uterus, vagina, bowel and bladder) into or out of the vagina;

(b) may occur when pelvic support structures are damaged, weakened or otherwise compromised, as a result of different factors including childbirth injury, multiple vaginal deliveries, previous pelvic surgery, menopause and loss of oestrogen, family history, obesity or repeated heavy lifting;

(c) may arise:

(i) in the front wall of the vagina (anterior compartment) when the bladder or urethra bulges into the vagina (referred to as a cystocoele or cysto-urethrocoele);

(ii) in the back wall of the vagina (posterior compartment) when the lower part of the large bowel (rectum) bulges into the back wall of the vagina (rectocoele) or part of the small intestine bulges into the upper part of the back wall of the vagina (enterocoele);

(iii) when the uterus drops or herniates into the vagina (uterine prolapse);

(iv) following a hysterectomy, when the top part of the vagina may collapse downwards, falling towards or out of the vaginal opening (vaginal vault prolapse); and

(d) gives rise to symptoms that include:

(i) a heavy dragging feeling in the vagina or lower back;

(ii) feeling of a lump in the vagina or outside the vagina;

(iii) urinary symptoms, such as slow urinary stream, a feeling of incomplete bladder emptying, urinary frequency or urgent desire to pass urine and urinary stress incontinence;

(iv) bowel symptoms, such as difficulty moving the bowel or a feeling of not emptying properly or needing to press on the vaginal wall to empty the bowel;

(v) discomfort during sexual intercourse.

6A. In answer to paragraph 6A of the 5FASOC, the Respondents state that stress urinary incontinence (**SUI**):

(a) is the involuntary leakage of urine during activities such as coughing, sneezing, lifting, laughing or exercising;

(b) may occur when pelvic support structures are damaged, weakened or otherwise compromised, as a result of different factors including childbirth injury, multiple vaginal deliveries, previous pelvic surgery, menopause and loss of oestrogen, family history, obesity or repeated heavy lifting;

(c) can adversely affect a woman's life and may limit women's social and personal relationships, as well as limiting physical activity;

and otherwise admit the allegations contained in that paragraph.

(ii) The Implants

7. In answer to paragraph 7 of the 5FASOC, the Respondents:

(a) admit the allegations contained in paragraph 7(a) of the 5FASOC;

(b) state that the GYNECARE PROLIFT Total Pelvic Floor Repair System:

(i) consisted of:

A. a Total mesh implant constructed from GYNECARE GYNEMESH PS and shaped for performing a total vaginal repair. GYNECARE GYNEMESH PS was mesh constructed of knitted filaments of extruded polypropylene; and

B. a set of instruments to facilitate mesh implant placement, which comprised one GYNECARE PROLIFT Guide, six GYNECARE PROLIFT Cannulas and six GYNECARE PROLIFT Retrieval Devices;

(ii) was indicated for tissue reinforcement and long-lasting stabilisation of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as a mechanical support or bridging material for the fascial defect but was not designed, manufactured or indicated for the treatment of stress urinary incontinence;

(c) state that the GYNECARE PROLIFT Anterior Pelvic Floor Repair System:

(i) consisted of:

A. an Anterior mesh implant constructed from GYNECARE GYNEMESH PS and shaped for repair of anterior vaginal defects. GYNECARE GYNEMESH PS was mesh constructed of knitted filaments of extruded polypropylene; and

B. a set of instruments to facilitate mesh implant placement, which comprised one GYNECARE PROLIFT Guide, four GYNECARE PROLIFT Cannulas and four GYNECARE PROLIFT Retrieval Devices;

(ii) was indicated for tissue reinforcement and long-lasting stabilisation of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as a mechanical support or bridging material for the fascial defect but was not designed, manufactured or indicated for the treatment of stress urinary incontinence;

(d) state that the GYNECARE PROLIFT Posterior Pelvic Floor Repair System:

(i) consisted of:

A. a Posterior mesh implant constructed from GYNECARE GYNEMESH PS and shaped for repair of posterior and apical vaginal vault defects. GYNECARE GYNEMESH PS was mesh constructed of knitted filaments of extruded polypropylene; and

B. a set of instruments to facilitate mesh implant placement, which comprised one GYNECARE PROLIFT Guide, two GYNECARE PROLIFT Cannulas and two GYNECARE PROLIFT Retrieval Devices;

(ii) was indicated for tissue reinforcement and long-lasting stabilisation of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as a mechanical support or bridging material for the fascial defect but was not designed, manufactured or indicated for the treatment of stress urinary incontinence;

(e) state that the GYNECARE PROLIFT+M Total Pelvic Floor Repair System:

(i) consisted of:

A. a Total implant constructed from GYNECARE GYNEMESH M Mesh and shaped for performing a total vaginal repair. GYNECARE GYNEMESH M Mesh was manufactured from approximately equal parts of absorbable poliglecaprone-25 monofilament fiber and non-absorbable polypropylene monofilament fiber; and

B. a set of instruments to facilitate mesh implant placement, which comprised one GYNECARE PROLIFT Guide, six GYNECARE PROLIFT Cannulas and six GYNECARE PROLIFT Retrieval Devices;

(ii) was indicated for tissue reinforcement and long-lasting stabilisation of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as a mechanical support or bridging material for the fascial defect but was not designed, manufactured or indicated for the treatment of stress urinary incontinence;

(f) state that the GYNECARE PROLIFT+M Anterior Pelvic Floor Repair System:

(i) consisted of:

A. an Anterior implant constructed from GYNECARE GYNEMESH M Mesh and shaped for repair of anterior vaginal defects. GYNECARE GYNEMESH M Mesh was manufactured from approximately equal parts of absorbable poliglecaprone-25 monofilament fiber and non-absorbable polypropylene monofilament fiber; and

B. a set of instruments to facilitate mesh implant placement, which comprised one GYNECARE PROLIFT Guide, four GYNECARE PROLIFT Cannulas and four GYNECARE PROLIFT Retrieval Devices;

(ii) was indicated for tissue reinforcement and long-lasting stabilisation of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as a mechanical support or bridging material for the fascial defect but was not designed, manufactured or indicated for the treatment of stress urinary incontinence;

(g) state that the GYNECARE PROLIFT+M Posterior Pelvic Floor Repair System:

(i) consisted of:

A. a Posterior implant constructed from GYNECARE GYNEMESH M Mesh and shaped for repair of posterior and apical vaginal vault defects. GYNECARE GYNEMESH M Mesh was manufactured from approximately equal parts of absorbable poliglecaprone-25 monofilament fiber and non-absorbable polypropylene monofilament fiber; and

B. a set of instruments to facilitate mesh implant placement, which comprised one GYNECARE PROLIFT Guide, two GYNECARE PROLIFT Cannulas and two GYNECARE PROLIFT Retrieval Devices;

(ii) was indicated for tissue reinforcement and long-lasting stabilisation of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as a mechanical support or bridging material for the fascial defect but was not designed, manufactured or indicated for the treatment of stress urinary incontinence;

(h) state that the GYNECARE PROSIMA Combined Pelvic Floor System:

(i) consisted of:

A. two identical mesh implants constructed from GYNECARE GYNEMESH PS, one for anterior vaginal repair and one for posterior vaginal repair. GYNECARE GYNEMESH PS was mesh constructed of knitted filaments of extruded polypropylene; and

B. a set of instruments to facilitate mesh implant placement and postoperative support, which comprised one Vaginal Support Device (**VSD**) - Balloon Assembly, one Anterior Inserter, one Posterior Inserter and one syringe;

(ii) was indicated for tissue reinforcement and long-lasting stabilisation of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as a mechanical support or bridging material for the fascial defect but was not designed, manufactured or indicated for the treatment of stress urinary incontinence;

(i) state that the GYNECARE PROSIMA Anterior Pelvic Floor Repair System:

(i) consisted of:

A. one mesh implant constructed from GYNECARE GYNEMESH PS. GYNECARE GYNEMESH PS was mesh constructed of knitted filaments of extruded polypropylene; and

B. a set of instruments to facilitate mesh implant placement and postoperative support, which comprised one VSD - Balloon Assembly, one Anterior Inserter and one syringe;

(ii) was indicated for tissue reinforcement and long-lasting stabilisation of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as a mechanical support or bridging material for the fascial defect but was not designed, manufactured or indicated for the treatment of stress urinary incontinence;

(j) state that the GYNECARE PROSIMA Posterior Pelvic Floor Repair System:

(i) consisted of:

A. one mesh implant constructed from GYNECARE GYNEMESH PS. GYNECARE GYNEMESH PS was mesh constructed of knitted filaments of extruded polypropylene; and

B. a set of instruments to facilitate mesh implant placement and postoperative support, which comprised one VSD - Balloon Assembly, one Posterior Inserter and one syringe;

(ii) was indicated for tissue reinforcement and long-lasting stabilisation of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as a mechanical support or bridging material for the fascial defect but was not designed, manufactured or indicated for the treatment of stress urinary incontinence;

(k) state that GYNECARE GYNEMESH PS Nonabsorbable PROLENE Soft Mesh:

(i) is constructed of knitted filaments of extruded polypropylene;

(ii) from about May 2003 to October 2013, was indicated for tissue reinforcement and long-lasting stabilisation of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect, but was not designed, manufactured or indicated for the treatment of stress urinary incontinence;

(iii) from about October 2013, is indicated for use as a bridging material for apical vaginal and uterine prolapse where surgical treatment (laparotomy or laparoscopic approach) is warranted, but is not designed, manufactured or indicated for the treatment of stress urinary incontinence;

(l) state that the GYNECARE TVT Tension-free Vaginal Tape System:

(i) consists of:

A. a GYNECARE TVT Device, which is a sterile, single patient use device comprising one piece of undyed or blue PROLENE Polypropylene Mesh (tape) covered by a plastic sheath cut and overlapping in the middle, and held between two stainless steel needles bonded to the mesh and sheath with plastic collars. PROLENE Mesh is constructed of knitted filaments of extruded polypropylene; and

B. a GYNECARE TVT Reusable Introducer and GYNECARE TVT Reusable Rigid Catheter Guide, which are each available separately and intended to facilitate placement of the GYNECARE TVT Device;

(ii) is indicated for use as a pubourethral sling for treatment of stress urinary incontinence, for female urinary incontinence resulting from urethral hypermobility or intrinsic

sphincter deficiency, but is not designed, manufactured or indicated for the treatment of pelvic organ prolapse;

(m) state that the GYNECARE TVT ABBREVO Continence System:

(i) consists of:

A. a GYNECARE TVT ABBREVO Implant Assembly, which is a sterile, single patient use device comprising one piece of blue PROLENE Polypropylene Mesh, covered by clear polyethylene sheaths and held between two Helical Passer Sheaths (white polyethylene tube receptacles). PROLENE Mesh is constructed of knitted monofilaments of extruded polypropylene; and

B. a set of instruments to facilitate mesh implant placement, comprising a GYNECARE TVT ABBREVO Placement Loop, a GYNECARE TVT ABBREVO Helical Passers and a GYNECARE TVT Atraumatic Winged Guide;

(ii) is indicated for use in women as a sub-urethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency, but is not designed, manufactured or indicated for the treatment of pelvic organ prolapse;

(n) state that the GYNECARE TVT Obturator System:

(i) consists of:

A. a GYNECARE TVT Obturator Device, which is a sterile, single patient use device, comprising one piece of undyed or blue PROLENE polypropylene mesh (tape), covered by a plastic sheath overlapping in the middle. Plastic tube receptacles are attached at each end. PROLENE polypropylene mesh is constructed of knitted filaments of extruded polypropylene strands; and

B. a set of instruments to facilitate mesh implant placement, comprising two GYNECARE TVT Helical Passers and a GYNECARE TVT Atraumatic Winged Guide;

(ii) is indicated for use in women as a sub-urethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency,

but is not designed, manufactured or indicated for the treatment of pelvic organ prolapse;

(o) state that the GYNECARE TVT SECUR System:

(i) consisted of:

A. a GYNECARE TVT SECUR System Device, comprising one piece of blue PROLENE polypropylene mesh (tape) with pieces of fleece made from VICRYL (polyglactin 910) and PDS (poly-p-dioxanone) undyed yarn which sandwiched the end sections of the mesh; and

B. a set of instruments to facilitate mesh implant placement, comprising two GYNECARE TVT SECUR System Inserters, a finger pad, a protective cover and a release wire;

(ii) was indicated for use in women as a sub-urethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency, but was not designed, manufactured or indicated for the treatment of pelvic organ prolapse;

(p) state that the GYNECARE TVT EXACT Continence System:

(i) consists of the GYNECARE TVT EXACT Continence System Trocar Sheath/ Implant Assembly and the GYNECARE TVT EXACT Continence System Trocar, where:

A. the GYNECARE TVT EXACT Continence System Trocar Sheath/ Implant Assembly consists of one piece of blue PROLENE polypropylene mesh (Implant) covered by a clear plastic Implant Sheath and held between two white Trocar Sheaths, which are bonded to the Implant and Implant Sheath. PROLENE polypropylene mesh is constructed of knitted filaments of extruded polypropylene strands; and

B. the GYNECARE TVT EXACT Continence System Trocar consists of the stainless steel Trocar Shaft and the plastic Trocar Handle;

(ii) is indicated for use as a pubourethral sling for treatment of female stress urinary incontinence, resulting from urethral hypermobility or intrinsic sphincter deficiency, but is not designed, manufactured or indicated for the treatment of pelvic organ prolapse;

(q) state that before any implant surgery, each Applicant's and each Group Member's treating surgeon would, as a matter of course, have:

(i) consulted with each Applicant and each Group Member and assessed each Applicant's and each Group Member's clinical needs and relevant medical and surgical history;

(ii) synthesised and assessed all relevant information;

(iii) provided each Applicant and each Group Member with information, advice and warnings tailored for each Applicant and each Group Member; and

(iv) determined the most appropriate course or method of treatment, including implantation with one or more of the devices referred to paragraphs 7(b) to 7(p) of the Defence, alternative treatments with or without another implant, alternative surgeries or no surgery, depending on each Applicant's and each Group Member's individual circumstances, the information that each Applicant and each Group Member made available to their treating surgeon, personal preference and the treating surgeon's surgical training and experience;

(r) state that it was reasonable for the Respondents to expect that, prior to implanting one or more of the devices referred to in paragraphs 7(b) to 7(p) of the Defence, each Applicant and Group Members would be informed, by their respective treating surgeon(s), to the degree the surgeon(s) judged appropriate, that such use carried risk, including the risk that the implantation of one or more of the devices may not restore pelvic anatomy, may not alleviate the symptoms associated with their clinical condition, may not improve the patient's quality of life, or may require revision; and

otherwise do not know and cannot admit the allegations contained in that paragraph.

Part C - Importation and Supply of the Implants

(i) Importation and Deemed Manufacturer of the Implants

8. In answer to paragraph 8 of the 5FASOC, the Respondents admit that JJM Australia imported each of the devices described in paragraph 5(b) of the Defence into Australia.

9. In answer to paragraph 9 of the 5FASOC, the Respondents admit that JJM Australia is the deemed manufacturer of the devices listed in paragraph 5(b) of the Defence pursuant to section 74A(4) of the *Trade Practices Act* 1976 (Cth) (**TPA**) and section 7(1)(e) of Schedule 2 of the *Competition and Consumer Act* 2010 (Cth) (**CCA**).

(ii) Supply of the Implants to Group Members

10. In answer to paragraph 10 of the 5FASOC, the Respondents state that JJM Australia imported and supplied each of the devices described in paragraph 5(b) of the Defence to hospitals in Australia and otherwise do not know and therefore cannot admit the allegations contained in that paragraph.

11. In answer to paragraph 11 of the 5FASOC, the Respondents state that JJM Australia imported and supplied each of the devices described in paragraph 5(b) of the Defence to hospitals in Australia and otherwise do not know and therefore cannot admit the allegations contained in that paragraph.

12. In answer to paragraph 12 of the 5FASOC, the Respondents:

    (a) state that before any implant surgery, each Applicant's and each Group Member's treating surgeon would, as a matter of course, have:

        (i) consulted with each Applicant and each Group Member and assessed each Applicant's and each Group Member's clinical needs and relevant medical and surgical history;

        (ii) synthesised and assessed all relevant information;

        (iii) provided each Applicant and each Group Member with information, advice and warnings tailored for each Applicant and each Group Member; and

        (iv) determined the most appropriate course or method of treatment, including implantation with one or more of the devices referred to paragraph 5(b) of the Defence, alternative treatments with or without another implant, alternative surgeries or no surgery, depending on each Applicant's and each Group Member's individual circumstances, the information that each Applicant and each Group Member made available to their treating surgeon, personal preference and the treating surgeon's surgical training and experience;

    (b) state that it was reasonable for the Respondents to expect that, prior to implanting one or more of the devices referred to in paragraph 5(b) of the Defence, each Applicant and Group Members would be informed, by their respective treating surgeon(s), to the degree the surgeons judged appropriate, that such use carried risk, including the risk that the implantation of one or more of the devices may not restore pelvic anatomy, may not alleviate the symptoms associated with their clinical condition, may not improve the patient's quality of life, or may require revision;

(c) state that Mrs Gill received from her treating surgeons including Dr Jay Natalwala and Dr Vincent Chapple, information about pelvic organ prolapse and available treatments, including treatment with and without pelvic mesh and the risks of pelvic reconstructive surgery as contained in Mrs Gill's medical records provided to the Respondents;

(d) state that Mrs Dawson received from her treating surgeon, Dr Jeanette Lim, information about pelvic organ prolapse and available treatments, including treatment with and without pelvic mesh and the risks of pelvic reconstructive surgery as contained in Mrs Dawson's medical records provided to the Respondents; and

otherwise do not know and therefore cannot admit the allegations contained in that paragraph.

13. In answer to paragraph 13 of the 5FASOC, the Respondents state that, individually, the cost of each of the devices described in paragraph 5(b) of the Defence would not have exceeded $40,000.

(iii) Trade and Commerce in Australia

14. In answer to paragraph 14 of the 5FASOC, the Respondents state that the conduct of JJM Australia:

(a) in marketing and promoting the devices listed in 5(b) of the Defence to surgeons in Australia; and

(b) in distributing and supplying the devices listed in 5(b) of the Defence to hospitals in Australia;

was in trade and commerce but otherwise deny the allegations contained in that paragraph.

15. In answer to paragraph 15 of the 5FASOC, the Respondents state that JJM Australia:

(a) made representations to surgeons in the marketing and promotion of the devices listed in 5(b) of the Defence; and

(b) made representations to hospitals in the distribution and supply of the devices listed in 5(b) of the Defence; but

otherwise deny the allegations contained in that paragraph.

16. In answer to paragraph 16 of the 5FASOC, the Respondents state that the conduct of JJM Australia:

(a) in marketing and promoting the devices listed in 5(b) of the Defence to surgeons in Australia; and

(b) in distributing and supplying the devices listed in 5(b) of the Defence to hospitals in Australia;

was in trade and commerce but otherwise deny the allegations contained in that paragraph.

17. In answer to paragraph 17 of the 5FASOC, the Respondents state that the conduct of JJM Australia:

(a) in marketing and promoting the devices listed in 5(b) of the Defence to surgeons in Australia; and

(b) in distributing and supplying the devices listed in 5(b) of the Defence to hospitals in Australia;

was in trade and commerce but otherwise deny the allegations contained in that paragraph.

Part D - The Mesh Implants

(i) Purpose of the Mesh Implants

18. In answer to paragraph 18 of the 5FASOC, the Respondents:

(a) state that:

(i) the GYNECARE PROLIFT Total, Anterior and Posterior Pelvic Floor Repair Systems were designed, manufactured and indicated for tissue reinforcement and long-lasting stabilisation of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as a mechanical support or bridging material for the fascial defect but were not designed, manufactured or indicated for the treatment of stress urinary incontinence;

(ii) the ARTG Registration for GYNECARE PROLIFT (ARTG ID 117686) was cancelled on 21 April 2015;

(iii) the GYNECARE PROLIFT+M Total, Anterior and Posterior Pelvic Floor Repair Systems were designed, manufactured and indicated for tissue reinforcement and long-lasting stabilisation of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as a mechanical support or

bridging material for the fascial defect but were not designed, manufactured or indicated for the treatment of stress urinary incontinence;

(iv) the ARTG Registration for GYNECARE PROLIFT +M (ARTG ID 117686) was cancelled on 21 April 2015;

(v) the GYNECARE PROSIMA Anterior, Posterior and Combined Pelvic Floor Repair Systems were designed, manufactured and indicated for tissue reinforcement and long-lasting stabilisation of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as a mechanical support or bridging material for the fascial defect but were not designed, manufactured or indicated for the treatment of stress urinary incontinence;

(vi) the ARTG Registration for GYNECARE PROSIMA (ARTG ID 117686) was cancelled on 21 April 2015;

(vii) from about May 2003 to October 2013, GYNECARE GYNEMESH PS was designed, manufactured and indicated for tissue reinforcement and long-lasting stabilisation of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect but was not designed, manufactured or indicated for the treatment of stress urinary incontinence;

(viii) from about October 2013, GYNECARE GYNEMESH PS is designed, manufactured and indicated for use as a bridging material for apical vaginal and uterine prolapse where surgical treatment (laparotomy or laparoscopic approach) is warranted;

(b) state that the devices referred to in paragraph 18(a) of the Defence were designed, manufactured and indicated for POP implant surgery but before any implant surgery, each Mesh Sub-Group Member's treating surgeon would, as a matter of course, have:

(i) consulted with each Mesh Sub-Group Member and assessed each Mesh Sub-Group Member's clinical needs and relevant medical and surgical history;

(ii) synthesised and assessed all relevant information;

(iii) provided each Mesh Sub-Group Member with information, advice and warnings tailored for each Mesh Sub-Group Member; and

(iv) determined the most appropriate course or method of treatment, including implantation with one or more of the devices referred to in paragraphs 18(a) of the Defence, alternative treatments with or without another implant, alternative surgeries or no surgery, depending on each Mesh Sub-Group Member's individual circumstances, the information that each Mesh Sub-Group Member made available to their treating surgeon, personal preference and the treating surgeon's surgical training and experience;

(c) state that it was reasonable for the Respondents to expect that, prior to implanting one or more of the devices referred to in paragraph 18(a) of the Defence, Mesh Sub-Group Members would each be informed, by their respective treating surgeon(s), to the degree the surgeons judged appropriate, of the surgical and non-surgical treatment options, that use of one or more of the devices carried risk, including the risk that the implantation of one or more of the devices may not restore pelvic anatomy, may not alleviate the symptoms associated with their clinical condition, may not improve the patient's quality of life, or may require revision; and

otherwise do not know and therefore cannot admit the allegations contained in that paragraph.

19. In answer to paragraph 19 of the 5FASOC, the Respondents repeat paragraph 18 of the Defence and otherwise deny the allegations contained in that paragraph.

20. In answer to paragraph 20 of the 5FASOC, the Respondents repeat paragraph 18 of the Defence and otherwise deny the allegations contained in that paragraph.

21. In answer to paragraph 21 of the 5FASOC, the Respondents repeat paragraphs 12 and 18 of the Defence and otherwise do not know and therefore cannot admit the allegations contained in that paragraph.

22. In answer to paragraph 22 of the 5FASOC, the Respondents repeat paragraph 18 of the Defence and otherwise do not know and therefore cannot admit the allegations contained in that paragraph.

(ii) Mesh Risks and Mesh Complications

23. In answer to paragraph 23 of the 5FASOC, the Respondents:

(a) repeat paragraph 18 of the Defence;

(b) state that non-absorbable polypropylene mesh, which formed a component of each of the devices described in paragraphs 5(b)(i) to 5(b)(iv) of the Defence, was designed to allow for an inflammatory response that is necessary for tissue ingrowth;

(c) state that all surgical procedures present risks; and

otherwise deny the allegations contained in that paragraph.

23A. In answer to paragraph 23A of the 5FASOC, the Respondents:

(a) repeat paragraph 18 of the Defence;

(b) state that each of the devices described in paragraphs 5(b)(i) to 5(b)(iv) of the Defence were designed, manufactured and indicated as a mechanical support or bridging material for tissue reinforcement and long-lasting stabilisation of fascial structures of the pelvic floor in vaginal wall prolapse;

(c) state that all surgical procedures present risks; and

otherwise deny the allegations contained in that paragraph.

23B. In answer to paragraph 23B of the 5FASOC, the Respondents:

(a) repeat paragraph 18 of the Defence;

(b) state that reconstructive surgery for the treatment of POP may be undertaken, depending upon the specific patient's history, preference and the surgeon's judgment, with or without the use of mesh implants;

(c) state that all surgical procedures present risks; and

otherwise deny the allegations contained in that paragraph.

23BA. The Respondents deny the allegations contained in paragraph 23BA of the 5FASOC.

23C. In answer to paragraph 23C of the 5FASOC, the Respondents:

(a) repeat paragraph 18 of the Defence;

(b) state that they made available information, including warnings, to surgeons;

(c) deny that:

(i) the information and those warnings were not sufficient; and

(ii) the matters pleaded in paragraph 23C(d) of the 5FASOC ought to have been the subject of any information or warning to the Mesh Sub-Group Members, their Treating Hospitals and/or Treating Doctors; and

(d) state that there is no reason to believe that any warning containing the information as set out in paragraph 23C(d) of the 5FASOC would have made any material difference to the matters outlined in sub-paragraphs 18(b) and (c) of the Defence;

otherwise deny the allegations contained in that paragraph.

Mrs Gill's Mesh Implant

23D. In answer to paragraph 23D of the 5FASOC, the Respondents:

(a) state that on or about 22 February 2004, Mrs Gill was admitted to Glengarry Private Hospital for post-partum bleeding, at which time she reported that, over the last few days, she had noticed a bulge at the introitus, and that a GP had diagnosed her with a cystocoele;

(b) state that on or about 1 February 2005, Mrs Gill was referred by Dr Dianne Prior to Dr Jay Natalwala for urgency and a cystocoele;

(c) state that on or about 7 February 2005, Mrs Gill attended a consultation with Dr Natalwala, during which:

(i) Dr Natalwala recorded that Mrs Gill reported prolapse symptoms including:

A. a vaginal lump;

B. urinary frequency, urinary urgency and severe urge incontinence;

(ii) on examination of Mrs Gill, Dr Natalwala found that Mrs Gill had a grade II - III cysto-urethrocoele and a grade II - III rectocoele;

(iii) Dr Natalwala provided Mrs Gill with information about her clinical condition and the possible treatment options, including surgical intervention;

(iv) Dr Natalwala referred Mrs Gill to Fiona O'Connell for pelvic floor physiotherapy;

(d) state that on or about 10 March 2005, Mrs Gill attended a consultation with Dr Natalwala, during which Dr Natalwala:

(i) provided Mrs Gill with information about her clinical condition;

(ii) recommended that Mrs Gill not have a mesh repair but instead recommended a vaginal repair with a possible paravaginal repair and culdoplasty;

(iii) discussed with Mrs Gill the surgery he recommended;

(e) state that on or about 23 October 2006, Mrs Gill attended a consultation with Dr Vince Chapple, during which:

(i) Dr Chapple recorded that Mrs Gill reported prolapse symptoms, most of which dated back to her last confinement two and a half years earlier, including urge incontinence and defecatory difficulty;

(ii) on examination of Mrs Gill, Dr Chapple reported that he observed:

A. a large cysto-urethrocoele;

B. a grade III uterine prolapse;

C. a moderate rectocoele;

D. a normal anteverted uterus with no pelvic masses or tenderness;

(iii) Dr Chapple recommended that Mrs Gill have surgical treatment to address her prolapse symptoms;

(iv) Dr Chapple provided Mrs Gill with information about treatment options, including the use of prosthetic devices to augment repairs and the possibility of a vaginal hysterectomy with anterior posterior vaginal repair, with or without a mesh prosthesis, using abdominal sacro-hysteropexy; and

otherwise do not know and cannot admit the allegations contained in that paragraph.

PARTICULARS

1) Total Care Progress Report, dated 22 February 2004
[GIL.MESH.00001121]

2) Referral letter from Dr Dianne Prior to Dr Jay Natalwala dated 1 February 2005 **[GIL.MESH.00000160]**

3) Letter from Dr Jay Natalwala to Dr Dianne Prior dated 7 February 2005 **[GIL.MESH.00000159]**

4) Letter from Dr Jay Natalwala to Dr Dianne Prior dated 10 March 2005 **[GIL.MESH.00000157]**

5) Letter from Dr Vince Chapple to Dr Sobha Eranki dated 24 October 2006 **[GIL.MESH.00000144]**

23E. In answer to paragraph 23E of the 5FASOC, the Respondents:

(a) repeat paragraph 23D of the Defence;

(b) state further that:

(i) on or about 30 November 2006, Mrs Gill attended a consultation with Dr Chapple in which he provided Mrs Gill with information about surgical treatment for her condition, including with a GYNECARE PROLIFT device;

(ii) on or about 6 December 2006, Mrs Gill attended a consultation with Dr Chapple during which they discussed the pros and cons of a GYNECARE PROLIFT device and abdominal sacrohysteropexy and vaginal hysterectomy, anterior and posterior repair, and Mrs Gill elected to have a GYNECARE PROLIFT device; and

otherwise do not know and cannot admit the allegations contained in that paragraph.

PARTICULARS

1) Letter from Dr Vince Chapple to Dr Sobha Eranki dated 30 November 2006 **[GIL.MESH.00000143]**

2) Consultation Record, Dr Vince Chapple, dated 6 December 2006 **[GIL.MESH.00000106] at [00000108]**

23F. In answer to paragraph 23F of the 5FASOC, the Respondents repeat paragraphs 23C, 23D and 23E of the Defence and otherwise deny the allegations contained in that paragraph.

23G. In answer to paragraph 23G of the 5FASOC, the Respondents state that, on or about 12 January 2007, Dr Chapple performed surgery on Mrs Gill at Joondalup Health Campus to insert a GYNECARE PROLIFT Total device, to perform a cystoscopy and to insert a Mirena for contraception and cycle control.

PARTICULARS

1) Joondalup Health Campus Operation Record dated 12 January 2007 **[GIL.MESH.00000117]**

23H. In answer to paragraph 23H of the 5FASOC, the Respondents repeat paragraphs 18, 23D and 23E of the Defence and otherwise do not know and cannot admit the allegations contained in that paragraph.

23I. In answer to paragraph 23I of the 5FASOC, the Respondents:

(a) state that Mrs Gill was admitted to hospital (on or about 20 February 2007 to Joondalup Emergency Department and on or about 22 February 2007 to Glengarry Hospital) and treated for an infection following her surgery on 12 January 2007;

(b) state that Mrs Gill consulted Dr Chapple including on or about 30 January 2007, 22 February 2007, 26 March 2007 and 11 June 2007, during which consultations:

(i) Mrs Gill reported her condition to Dr Chapple;

(ii) Dr Chapple examined Mrs Gill and recorded his findings;

(c) state that Mrs Gill consulted Dr Jessica Yin including on or about 14 June 2007, during which consultation:

(i) Mrs Gill reported her condition to Dr Yin;

(ii) Dr Yin examined Mrs Gill and recorded her findings;

(d) state that, during surgery performed by Dr Yin on or about 10 September 2007, Dr Yin reported that Mrs Gill had a mesh erosion 2 cm x 1 cm which was excised;

(e) state that some or all of the conditions described in paragraph 23I of the 5FASOC may occur as the result of different factors including childbirth injury, multiple vaginal deliveries and family history, as described in paragraphs 6 and 6A of the Defence, which Mrs Gill had; and

otherwise do not know and cannot admit the allegations contained in that paragraph.

PARTICULARS

1) Emergency Department Triage/ Nursing Assessment, Joondalup Health Campus, dated 20 February 2007 **[GIL.MESH.00000438]**

2) Total Care Progress Notes, Glengarry Hospital, dated 22 February 2007 **[GIL.MESH.00001008]**

3) Consultation Record, Dr Vince Chapple, dated 30 January 2007 **[GIL.MESH.00000106] at [00000108]**

4) Letter from Dr Vince Chapple to Dr Sobha Eranki dated 22 February 2007 **[GIL.MESH.00000142]**

5) Letter from Dr Vince Chapple to Dr Sobha Eranki dated 26 March 2007 **[GIL.MESH.00000141]**

6) Letter from Dr Vince Chapple to Dr Sobha Eranki dated 11 June 2007 **[GIL.MESH.00000140]**

7) Letter from Dr Jessica Yin to Dr Sobha Eranki dated 14 June 2007 **[GIL.MESH.00000150]**

8) Operation Report, Dr Jessica Yin, addressed to Dr Stephen Hellmuth, dated 10 September 2007 **[GIL.MESH.00000152]**

23J. In answer to paragraph 23J of the 5FASOC, the Respondents state that Dr Yin performed surgery on Mrs Gill on or about 10 September 2007 at Hollywood Private Hospital, including a cystoscopy and excision of a mesh erosion on the anterior vaginal wall, with examination under anaesthesia, and otherwise do not know and cannot admit the allegations contained in that paragraph.

PARTICULARS

1) Operation Report, Dr Jessica Yin, addressed to Dr Stephen Hellmuth, dated 10 September 2007 **[GIL.MESH.00000152]**

23K. In answer to paragraph 23K of the 5FASOC, the Respondents:

(a) state that Mrs Gill consulted Dr Yin on or about 17 October 2007 and 14 May 2008, during which consultations:

(i) Mrs Gill reported her condition to Dr Yin;

(ii) Dr Yin examined Mrs Gill and recorded her findings;

(b) state that Mrs Gill consulted Dr Robyn Leake on or about 21 May 2008, during which consultation:

(i) Mrs Gill reported her condition to Dr Leake;

(ii) Dr Leake examined Mrs Gill and recorded her findings;

(c) state that, during surgery performed by Dr Yin and Dr Leake on or about 20 June 2008, Dr Yin and Dr Leake reported that they removed the anterior right arm half way to the obturator fossa, including an exposed area, and also removed the posterior left arm of the mesh implant;

(d) state that some or all of the conditions described in paragraph 23K of the 5FASOC may occur as the result of different factors including childbirth injury, multiple vaginal deliveries and family history, as described in paragraphs 6 and 6A of the Defence, which Mrs Gill had; and

otherwise do not know and cannot admit the allegations contained in that paragraph.

PARTICULARS

1) Letter from Dr Jessica Yin to Dr Sobha Eranki dated 17 October 2007 **[GIL.MESH.00000148]**

2) Letter from Dr Jessica Yin to Dr Sobha Eranki dated 14 May 2008 **[GIL.MESH.00000019]**

3) Consultation Record, Dr Robyn Leake, dated 21 May 2008 **[GIL.MESH.00000086]**

4) Operation Sheet, Hollywood Private Hospital, dated 20 June 2008 **[GIL.MESH.00000274] at [00000275]**

23L. In answer to paragraph 23L of the 5FASOC, the Respondents state that, on or about 20 June 2008, Dr Yin performed surgery with Dr Robyn Leake on Mrs Gill at Hollywood Private Hospital, including removal of the anterior right arm half way to the obturator fossa and posterior left arm of the mesh implant, and otherwise do not know and cannot admit the allegations contained in that paragraph.

PARTICULARS

1) Operation Sheet, Hollywood Private Hospital, dated 20 June 2008 **[GIL.MESH.00000274] at [00000275]**

23M. In answer to paragraph 23M of the 5FASOC, the Respondents:

(a) state that Mrs Gill consulted Dr Yin on or about 1 July 2008 and 23 July 2008, during which consultations:

(i) Mrs Gill reported her condition to Dr Yin;

(ii) Dr Yin examined Mrs Gill and recorded her findings;

(b) state that Mrs Gill consulted Dr Leake on or about 27 June 2008, 25 August 2008, 9 September 2008 and 25 July 2011, during which consultations:

(i) Mrs Gill reported her condition to Dr Leake;

(ii) Dr Leake examined Mrs Gill and recorded her findings;

(c) state that Mrs Gill consulted Dr Caroline Dowling on or about 5 June 2013, during which consultation:

(i) Mrs Gill reported her condition to Dr Dowling;

(ii) Dr Dowling examined Mrs Gill and recorded her findings;

(d) state that, on or about 16 July 2013, Dr Dowling explained to Mrs Gill the nature of her clinical condition and her planned treatment course of cystoscopy, change to Mirena, examination under anaesthesia and trim mesh, if exposed, including the associated risks of mesh exposure recurrence, rare injury to underlying structure and urinary tract infection;

(e) state that, during surgery performed by Dr Caroline Dowling on or about 8 August 2013, Dr Dowling reported that she removed a 2 cm mesh exposure lying vertically to midline just distal to the cervix in the anterior vaginal wall;

(f) state that some or all of the conditions described in paragraph 23K of the 5FASOC may occur as the result of different factors including childbirth injury, multiple vaginal deliveries and family history, as described in paragraphs 6 and 6A of the Defence, which Mrs Gill had; and

otherwise do not know and cannot admit the allegations contained in that paragraph.

PARTICULARS

1) Letter from Dr Robyn Leake to Dr Jessica Yin dated 27 June 2008 **[GIL.MESH.00000101]**

2) Consultation Record, Dr Jessica Yin, Hollywood Private Hospital, dated 1 July 2008 **[GIL.MESH.00000309] at [00000309]**

3) Letter from Dr Jessica Yin to Dr Robyn Leake dated 23 July 2008 **[GIL.MESH.00000023]**

4) Letter from Dr Robyn Leake to Dr Jessica Yin dated 25 August 2008 **[GIL.MESH.00000100]**

5) Letter from Dr Robyn Leake to Dr Stephen Hellmuth dated 9 September 2008 **[GIL.MESH.00000099]**

6) Consultation Record, Dr Robyn Leake, dated 25 July 2011 **[GIL.MESH.00000078]**

7) Letter from Dr Caroline Dowling to Dr Genevieve Seabrook dated 5 June 2013 **[GIL.MESH.00000002]**

8) Informed Consent to Treatment Form, dated 16 July 2013 **[GIL.MESH.00000467]**

9) Operation Record, St Vincent's Private Hospital, Melbourne, dated 8 August 2013 **[GIL.MESH.00000685]**

23N. In answer to paragraph 23N of the 5FASOC, the Respondents state that, on or about 8 August 2013, Dr Caroline Dowling performed surgery on Mrs Gill at St Vincent's Private Hospital, Melbourne, including removal of anterior vaginal mesh distal to cervix in midline, excision of midline exclusion cyst, anterior vaginal repair (with 2/0 PDS and 2/0 Vicryl), cystoscopy and insertion of a Mirena, and otherwise do not know and cannot admit the allegations contained in that paragraph.

PARTICULARS

1) Operation Record, St Vincent's Private Hospital, Melbourne, dated 8 August 2013 **[GIL.MESH.00000685]**

2) Surgical Record, St Vincent's Private Hospital, Melbourne, dated 8 August 2013 **[GIL.MESH.00000521]**

3) Letter from Dr Caroline Dowling to Dr Genevieve Seabrook dated 8 August 2013 **[GIL.MESH.00000006]**

23O. In answer to paragraph 23O of the 5FASOC, the Respondents:

(a) state that Mrs Gill consulted Dr Caroline Dowling on or about 12 November 2013, during which consultation:

(i) Mrs Gill reported her condition to Dr Dowling;

(ii) Dr Dowling examined Mrs Gill and recorded her findings;

(b) state that Mrs Gill consulted Dr Tim Jeffery on or about 14 August 2014, during which consultation:

(i) Mrs Gill reported her condition to Dr Jeffery;

(ii) Dr Jeffery examined Mrs Gill and recorded his findings;

(c) state that Mrs Gill consulted Dr Nicolas Tsokos on or about 28 October 2014, during which consultation:

(i) Mrs Gill reported her condition to Dr Tsokos;

(ii) Dr Tsokos examined Mrs Gill and recorded his findings;

(d) state that some or all of the conditions described in paragraph 23K of the 5FASOC may occur as the result of different factors including childbirth injury, multiple vaginal deliveries and family history, as described in paragraphs 6 and 6A of the Defence, which Mrs Gill had; and

otherwise do not know and cannot admit the allegations contained in that paragraph.

PARTICULARS

1) Letter from Dr Caroline Dowling to Dr Genevieve Seabrook dated 12 November 2013 **[GIL.MESH.00000009]**

2) Letter from Dr Tim Jeffery to Dr Jessica Yin dated 14 August 2014 **[GIL.MESH.00000729]**

3) Letter from Dr Nicolas Tsokos to Dr Tim Jeffery dated 28 October 2014 **[GIL.MESH.00000727]**

23P. The Respondents do not know and otherwise cannot admit the allegations contained in paragraph 23P of the 5FASOC.

Mrs Dawson's Mesh Implant

23Q. In answer to paragraph 23Q of the 5FASOC, the Respondents:

(a) state that prior to 8 May 2009, Mrs Dawson underwent pelvic surgery, including pelvic reconstructive surgery, including:

(i) in or about 2001, Mrs Dawson underwent surgery performed by Dr Judith Fleming, including a vaginal hysterectomy and anterior and posterior prolapse repair, to treat prolapse and incontinence;

(ii) in or about 2004, Mrs Dawson underwent surgery performed by Dr Russell Dalton at St John of God Hospital;

(b) state that on or about 28 January 2009, Mrs Dawson consulted with Dr Jeanette Lim, during which Dr Lim recorded her clinical diagnosis that Mrs Sanders was suffering from:

(i) moderate prolapse;

(ii) mild urge incontinence;

(iii) superficial dyspareunia;

(c) state that Dr Lim reported Mrs Dawson's condition on 8 May 2009 surgery as a grade 1 cystocoele and rectocoele (moderate size) and good vault support; and

otherwise do not know and cannot admit the allegations contained in that paragraph.

PARTICULARS

1) Outpatient Progress Report, Mercy Hospital for Women, notes dated 26 November 2013 **[DAW.MESH.00000051] at [00000052]**

2) Letter from Dr Stephen Tobin to Dr Mark Churcher dated 11 August 2009 **[DAW.MESH.00000658]**

3) Referral letter from Dr Jeanette Lim to Dr Marcus Carey dated 17 February 2010 **[DAW.MESH.00000129]**

4) Operation Notes, Dr Russell Dalton dated 26 April 2004 **[DAW.MESH.00000518]**

5) Operation Record, Dr Russell Dalton dated 26 April 2004 **[DAW.MESH.00000519]**

6) Urogynaecological Unit History notes dated 28 January 2009 **[DAW.MESH.00000022]**

7) Operation Record, Dr Jeanette Lim, dated 8 May 2009 **[DAW.MESH.00000319] at [00000322]**

23R. In answer to paragraph 23R of the 5FASOC, the Respondents state that on or about 20 February 2009, Mrs Dawson attended a consultation with Dr Lim, during which:

(a) Dr Lim recommended surgery including anterior and posterior repair with mesh and splint, and a cystoscopy;

(b) Dr Lim recorded that Mrs Dawson declined to have a mid-urethral sling implanted at the time of the prolapse surgery;

(c) Dr Lim explained to Mrs Dawson the risks of surgery including anterior and posterior repair with mesh and splint, and a cystoscopy, including erosion, recurrence, visceral injury, de novo stress urinary incontinence and dyspareunia; and

otherwise do not know and cannot admit the allegations contained in that paragraph.

PARTICULARS

1) Patient Care Notes, St John of God Hospital dated 20 February 2009 **[DAW.MESH.00000014]**

2) Acknowledgment of Consent for Treatment dated 26 February 2009 **[DAW.MESH.00000418]**

23S. In answer to paragraph 23S of the 5FASOC, the Respondents repeat paragraph 23C, 23Q and 23R of the Defence and otherwise deny the allegations contained in that paragraph.

23T. In answer to paragraph 23T of the 5FASOC, the Respondents state that, on or about 8 May 2009, Dr Lim performed surgery on Mrs Dawson at St John of God Hospital, which included an anterior and posterior vaginal repair with GYNECARE GYNEMESH PS (10 cm x 15 cm) (with product code GPSLL02) and a vaginal support device or small splint, as well as a cystoscopy, and otherwise do not know and cannot admit the allegations contained in that paragraph.

PARTICULARS

1) Operation Record, St John of God Hospital, dated 8 May 2009 **[DAW.MESH.00000319] at [00000322]**

2) Operation Record, St John of God Hospital, dated 8 May 2009 **[DAW.MESH.00000445] at [00000446]**

3) Letter from Dr Jeanette Lim to Dr Mark Churcher dated 8 May 2009 **[DAW.MESH.00000006]**

23U. In answer to paragraph 23U of the 5FASOC, the Respondents repeat paragraphs 18, 23Q and 23R of the Defence, and otherwise do not know and cannot admit the allegations contained in that paragraph.

23V. In answer to paragraph 23V of the 5FASOC, the Respondents:

(a) state that Mrs Dawson consulted Dr Lim including on or about 3 June 2009, 29 July 2009, 9 September 2009 and 8 October 2009, during which consultations:

(i) Mrs Dawson reported her condition to Dr Lim;

(ii) Dr Lim examined Mrs Dawson and recorded her findings; and

(b) state that during Mrs Dawson's consultation with Dr Lim on or about 8 October 2009:

(i) Dr Lim recommended surgery for excision of mesh erosion and cystoscopy, sigmoidoscopy and examination under anaesthesia;

(ii) Dr Lim explained the risks associated with those procedures;

(c) state that Mrs Dawson consulted Dr John Nelson, Orthopaedic Surgeon, including on or about 2 July 2009 and 30 July 2009, during which consultations:

(i) Mrs Dawson reported her condition to Dr Nelson; and

(ii) Dr Nelson examined Mrs Dawson and recorded his findings;

(d) state that Mrs Dawson consulted Dr Stephen Tobin, General Surgeon, including on or about 11 August 2009, during which consultation:

(i) Mrs Dawson reported her condition to Dr Tobin; and

(ii) Dr Tobin examined Mrs Dawson and recorded his findings;

(e) state that Mrs Dawson reported that she experienced some of the conditions described in paragraph 23V of the 5FASOC before implantation of her GYNECARE GYNEMESH PS implant, including a dragging prolapse sensation, pain and dyspareunia;

(f) state that some or all of the conditions described in paragraph 23V of the 5FASOC may occur as the result of different factors including childbirth injury, multiple vaginal deliveries, previous pelvic surgery and menopause, as described in paragraphs 6 and 6A of the Defence, which Mrs Dawson had; and

otherwise do not know and cannot admit the allegations contained in that paragraph.

PARTICULARS

1) Letter from Dr Jeanette Lim to Dr Mark Churcher dated 3 June 2009 **[DAW.MESH.00000005]**

2) Letter from Dr John Nelson to Dr Mark Churcher dated 2 July 2009 **[DAW.MESH.00000400]**

3) Letter from Dr Jeanette Lim to Dr Mark Churcher dated 23 July 2009 **[DAW.MESH.00000319] at [00000323] to [00000325]**

4) Letter from Dr John Nelson to Dr Mark Churcher dated 30 July 2009 **[DAW.MESH.00000399]**

5) Letter from Dr Stephen Tobin to Dr Mark Churcher dated 11 August 2009 **[DAW.MESH.00000658]**

6) Letter from Dr Jeanette Lim to Dr Mark Churcher dated 9 September 2009 **[DAW.MESH.00000008]**

7) Letter from Dr Jeanette Lim to Dr Mark Churcher dated 8 October 2009 **[DAW.MESH.00000007]**

8) Consent Form dated 8 October 2009 **[DAW.MESH.00000363]**

23W. In answer to paragraph 23W of the 5FASOC, the Respondents:

(a) state that, on or about 14 October 2009, Dr Lim performed surgery on Mrs Dawson at St John of God Hospital, which included excision of a small anterior vaginal mesh erosion and cystoscopy;

(b) state further that, on or about 14 October 2009, during the surgery performed on Mrs Dawson by Dr Lim, Dr Tobin performed an examination under anaesthesia and sigmoidoscopy on Mrs Dawson at St John of God Hospital; and

otherwise do not know and cannot admit the allegations contained in that paragraph.

PARTICULARS

1) Operation Notes, Dr Lim, dated 14 October 2009 **[DAW.MESH.00000126]**

2) Operation Notes, Dr Tobin, dated 14 October 2009
[DAW.MESH.00000380]

3) Operation Record, Drs Lim and Tobin, dated 14 October 2009
[DAW.MESH.00000382]

23X. In answer to paragraph 23X of the 5FASOC, the Respondents:

(a) state that Mrs Dawson consulted Dr Lim including on or about 2 December 2009, during which consultation:

(i) Mrs Dawson reported her condition to Dr Lim;

(ii) Dr Lim examined Mrs Dawson and recorded her findings;

(b) state that Mrs Dawson consulted Dr James Swan including on or about 27 June 2012, 30 August 2012 and 14 March 2013, during which consultations:

(i) Mrs Dawson reported her condition to Dr Swan;

(ii) Dr Swan examined Mrs Dawson and recorded her findings;

(c) state that Mrs Dawson consulted Professor Peter Dwyer including on or about 2 September 2013 during which consultation:

(i) Mrs Dawson reported her condition to Professor Dwyer;

(ii) Professor Dwyer examined Mrs Dawson and recorded his findings;

(d) state that Mrs Dawson consulted Dr Amber Kennedy including on or about 26 November 2013 during which consultation:

(i) Mrs Dawson reported her condition to Dr Kennedy;

(ii) Dr Kennedy examined Mrs Dawson and recorded her findings;

(e) state that Mrs Dawson consulted Dr Yik Lim including on or about 21 January 2014 during which consultation:

(i) Mrs Dawson reported her condition to Dr Lim;

(ii) Dr Lim examined Mrs Dawson and recorded his findings;

(f) state that Mrs Dawson experienced some or all of the conditions described in paragraph 23X of the 5FASOC before implantation of her GYNECARE GYNEMESH PS implant, including stress urinary incontinence, dyspareunia, pain and incomplete defecation;

(g) state that some or all of the conditions described in paragraph 23X of the 5FASOC may occur as the result of different factors including childbirth injury, multiple vaginal deliveries, previous pelvic surgery and menopause, as described in paragraphs 6 and 6A of the Defence, which Mrs Dawson had; and

otherwise do not know and cannot admit the allegations contained in that paragraph.

PARTICULARS

1) Letter from Dr Jeanette Lim to Dr Mark Churcher dated 2 December 2009 **[DAW.MESH.00000003]**

2) Letter from Dr James Swan to Dr Mark Churcher dated 3 July 2012 **[DAW.MESH.00000316]**

3) Letter from Dr James Swan to Dr Mark Churcher dated 4 September 2012 **[DAW.MESH.00000314]**

4) Referral letter from Dr Swan to Dr Prof Dwyer dated14 March 2013 **[DAW.MESH.00000306]**; **[DAW.MESH.00000116]**

5) Letter from Professor Peter Dwyer to Dr James Swan dated 3 September 2013 **[DAW.MESH.00000141]**

6) Letter from Dr Amber Kennedy to Dr James Swan dated 26 November 2013 **[DAW.MESH.00000113]**

7) Outpatient Progress Report, Mercy Melbourne Hospital for Women, dated 14 January 2014 **[DAW.MESH.00000055]**

23Y. In answer to paragraph 23Y of the 5FASOC, the Respondents state that, on or about 31 January 2014, Professor Peter Dwyer performed surgery on Mrs Dawson at Mercy Melbourne Hospital for Women, which included excision of the mesh arm on the left and a small (less than 5mm) mesh at the vault, as well as a cystoscopy, and otherwise do not know and cannot admit the allegations contained in that paragraph.

PARTICULARS

1) Operation Report, Professor Peter Dwyer, Mercy Melbourne Hospital for Women **[DAW.MESH.00000248]**

23Z. In answer to paragraph 23Z of the 5FASOC, the Respondents:

(a) state that Mrs Dawson consulted Professor Dwyer including on or about 13 March 2014, during which consultation:

(i) Mrs Dawson reported her condition to Professor Dwyer;

(ii) Professor Dwyer examined Mrs Dawson and recorded her findings;

(b) state that Mrs Dawson consulted Dr Lin Li Ow including on or about 29 May 2014 and 27 November 2014 (with Dr Lore Schierlitz), during which consultations:

(i) Mrs Dawson reported her condition to Dr Ow;

(ii) Dr Ow examined Mrs Dawson and recorded her findings;

(c) state that Mrs Dawson consulted Dr Schierlitz including on or about 19 March 2015, during which consultation:

(i) Mrs Dawson reported her condition to Dr Schierlitz;

(ii) Dr Schierlitz examined Mrs Dawson and recorded her findings;

(iii) Dr Schierlitz provided information and advice to Mrs Dawson about her treatment options and the likely possibility that removal of the mesh may not improve her pain, as well as risks of treatment including infection, bleeding, recurrence, damage to bladder and rectum or voiding difficulty;

(iv) Mrs Dawson elected to have further surgery to remove the mesh;

(d) state that Mrs Dawson experienced some or all of the conditions described in paragraph 23Z of the 5FASOC before implantation of her GYNECARE GYNEMESH PS implant, including dyspareunia and pain;

(e) state that some of the conditions described in paragraph 23Z of the 5FASOC may occur as the result of different factors including childbirth injury, multiple vaginal deliveries, previous

pelvic surgery and menopause as described in paragraphs 6 and 6A of the Defence, which Mrs Dawson had; and

otherwise do not know and cannot admit the allegations contained in that paragraph.

PARTICULARS

1) Letter from Professor Peter Dwyer to Dr James Swan dated 14 April 2014 **[DAW.MESH.00000100]**

2) Letter from Dr Lin Li Ow to Dr James Swan dated 16 July 2014 **[DAW.MESH.00000099]**

3) Letter from Dr Lin Li Ow to Dr James Swan dated 14 January 2015 **[DAW.MESH.00000097]**

4) Letter from Dr Lore Schierlitz to Dr Mark Churcher dated 29 May 2015 **[DAW.MESH.00000084]**

5) Outpatient Progress Report notes, Mercy Melbourne Hospital for Women **[DAW.MESH.00000043]**

23AA. In answer to paragraph 23AA of the 5FASOC, the Respondents state that, on or about 15 May 2015, Dr Schierlitz performed surgery on Mrs Dawson at Mercy Melbourne Hospital for Women, which included excision of mesh from the anterior vaginal wall, vault and left vaginal wall, as well as a cystoscopy, and otherwise do not know and cannot admit the allegations contained in that paragraph.

PARTICULARS

1) Operation Report and Post-Operative Orders Checklist, Dr Lore Schierlitz, Mercy Melbourne Hospital for Women, dated 15 May 2015 **[DAW.MESH.00000090]**

23AB. In answer to paragraph 23AB of the 5FASOC, the Respondents:

(a) state that Mrs Dawson consulted Dr Schierlitz including on or about 28 May 2015, 9 July 2015 and 3 September 2015, during which consultations:

(i) Mrs Dawson reported her condition to Dr Schierlitz;

(ii) Dr Schierlitz examined Mrs Dawson and recorded her findings;

(b) state that, during her consultation with Dr Schierlitz on 3 September 2015:

(i) Dr Schierlitz provided information and advice to Mrs Dawson about surgery to remove mesh from the posterior vaginal wall, possible removal of granulation tissue and possible cystoscopy, including risks of surgery including infection, bleeding, damage to rectum, prolapse recurrence after mesh removal, possible persistence of pain, dyspareunia or possible further mesh exposure later;

(ii) Mrs Dawson elected to have further surgery to remove the mesh;

(c) state that Mrs Dawson experienced some or all of the conditions described in paragraph 23AB of the 5FASOC before her implantation of her GYNECARE GYNEMESH PS implant, including dyspareunia;

(d) state that some of the conditions described in paragraph 23AB of the 5FASOC may occur as the result of different factors including childbirth injury, multiple vaginal deliveries, previous pelvic surgery and menopause as described in paragraphs 6 and 6A of the Defence, which Mrs Dawson had; and

otherwise do not know and cannot admit the allegations contained in that paragraph.

PARTICULARS

1) Letter from Dr Lore Schierlitz to Dr James Swan dated 2 September 2015 **[DAW.MESH.00000082]**

2) Letter from Dr Lore Schierlitz to Dr Mark Churcher dated 22 October 2015 **[DAW.MESH.00000077]**

3) Outpatient Progress Report notes, Mercy Melbourne Hospital for Women **[DAW.MESH.00000043]**

4) Patient Consent to Operative Treatment dated 3 September 2015 (and signed 30 October 2015 in respect of anaesthesia), Mercy Melbourne Hospital for Women **[DAW.MESH.00000148]**

23AC. In answer to paragraph 23AC of the 5FASOC, the Respondents state that, on or about 30 October 2015, Dr Schierlitz performed surgery on Mrs Dawson at Mercy Melbourne Hospital for

Women, which included excision of mesh from the posterior and anterior vaginal wall, and otherwise do not know and cannot admit the allegations contained in that paragraph.

PARTICULARS

1) Operation Report and Post-Operative Orders Checklist, Dr Lore Schierlitz, Mercy Melbourne Hospital for Women, dated 30 October 2015 **[DAW.MESH.00000163]**

23AD. In answer to paragraph 23AD of the 5FASOC, the Respondents:

(a) state that Mrs Dawson consulted Dr Churcher including on or about 29 December 2015 during which consultation Mrs Dawson reported her condition to Dr Churcher;

(b) state that Mrs Dawson experienced some or all of the conditions described in paragraph 23AD of the 5FASOC before her implantation of her GYNECARE GYNEMESH PS implant, including pain and dyspareunia;

(c) state that some of the conditions described in paragraph 23AB of the 5FASOC may occur as the result of different factors including childbirth injury, multiple vaginal deliveries, previous pelvic surgery and menopause as described in paragraphs 6 and 6A of the Defence, which Mrs Dawson had; and

otherwise do not know and cannot admit the allegations contained in that paragraph.

PARTICULARS

1) UFS Medical Progress Notes of Dr Mark Churcher, dated 29 December 2015 **[DAW.MESH.00000582] at [00000583]**

23AE. The Respondents do not know and therefore cannot admit the allegations contained in paragraph 23AE of the 5FASOC.

(v) Claims under the Trade Practices Act and the Competition and Consumer Act

24. In answer to paragraph 24 of the 5FASOC, the Respondents admit that the devices referred to in paragraphs 5(b)(i) to 5(b)(iv) of the Defence are goods for the purposes of section 4 of the TPA and section 2 of Schedule 2 of the CCA and otherwise admit paragraph 24 of the 5FASOC.

25. The Respondents admit the allegations contained in paragraph 25 of the 5FASOC.

26. In answer to paragraph 26 of the 5FASOC, the Respondents repeat paragraphs 7, 18 to 23C of the Defence and otherwise deny the allegations contained in that paragraph.

27. In answer to paragraph 27 of the 5FASOC, the Respondents:

    (a) repeat paragraphs 7, 18 to 23C of the Defence;

    (b) state that each Mesh Sub-Group Member did not rely, or it was unreasonable for any Mesh Sub-Group Member to rely, on the skill or judgment of any of the Respondents in acquiring one or more of the devices listed in paragraphs 5(b)(i) to 5(b)(iv) of the Defence; and

    otherwise deny the allegations contained in that paragraph.

28. In answer to paragraph 28 of the 5FASOC, the Respondents:

    (a) repeat paragraphs 7, 18 to 23C of the Defence;

    (b) state that each Mesh Sub-Group Member did not rely, or it was unreasonable for any Mesh Sub-Group Member to rely, on the skill or judgment of any of the Respondents in acquiring one or more of the devices listed in paragraphs 5(b)(i) to 5(b)(iv) of the Defence; and

    otherwise deny the allegations contained in that paragraph.

29. The Respondents deny the allegations contained in paragraph 29 of the 5FASOC.

30. In answer to paragraph 30 of the 5FASOC, the Respondents:

    (a) deny the allegations contained in that paragraph;

    (b) repeat paragraphs 3 and 4 of the Defence and state that neither Ethicon Sàrl nor Ethicon, Inc. carried on business in Australia and are not subject to the consumer protection provisions of the TPA or Schedule 2 of the CCA relied upon by each of the Mesh Sub-Group Members; and

    (c) state that neither Ethicon Sàrl nor Ethicon, Inc. are liable to compensate any Mesh Sub-Group Member pursuant to the provisions of the TPA or Schedule 2 of the CCA.

(vi) Claims in Negligence

31. In answer to paragraph 31 of the 5FASOC, the Respondents:

(a) state that:

(i) the Commonwealth Government has established a legislative scheme for the registration of medical devices which is embodied in the *Therapeutic Goods Act* 1989 (Cth) and the delegated legislation made under that Act;

(ii) under that legislative scheme, medical devices are included on the Australian Register of Therapeutic Goods (**ARTG**) in accordance with a risk-based assessment;

(iii) each of the devices described in paragraphs 5(b)(i) to 5(b)(iv) of the Defence was, at all material times:

A. included on the ARTG as a class IIb medical device;

B. available only on recommendation of a permitted surgeon;

C. marketed to surgeons;

(iv) as manufacturers of the devices described in paragraphs 3(b) and 4(b) of the Defence, Ethicon Sàrl and Ethicon, Inc. made available to JJM Australia information about each of those devices for provision to surgeons;

(v) before any implant surgery, each Mesh Sub-Group Member's treating surgeon would, as a matter of course, have:

A. consulted with each Mesh Sub-Group Member and assessed each Mesh Sub-Group Member's clinical needs and relevant medical and surgical history;

B. synthesised and assessed all relevant information;

C. provided each Mesh Sub-Group Member with information, advice and warnings tailored for each Mesh Sub-Group Member; and

D. determined the most appropriate course or method of treatment, including implantation with one or more of the devices referred to paragraphs 5(b)(i) to 5(b)(iv) of the Defence, alternative treatments with or without another implant, alternative surgeries or no surgery, depending on each Mesh Sub-Group

Member's individual circumstances, the information that each Mesh Sub-Group Member made available to their treating surgeon, personal preference and the treating surgeon's surgical training and experience;

(vi) it was reasonable for the Respondents to expect that, prior to implanting one or more of the devices referred to in paragraphs 5(b)(i) to 5(b)(iv) of the Defence, each of the Mesh Sub-Group Members would be informed, by their respective treating surgeon(s), to the degree the surgeons judged appropriate, that such use carried risk, including the risk that the implantation of one or more of the devices may not restore pelvic anatomy, may not alleviate the symptoms associated with their clinical condition, may not improve the patient's quality of life, or may require revision;

(b) state that, as a consequences of the matters pleaded in paragraph 31(a) of the Defence:

(i) neither Ethicon Sàrl nor Ethicon, Inc. owed any Mesh Sub-Group Member the duty of care as alleged in paragraph 31 of the 5FASOC; or

(ii) in the alternative, satisfied any applicable standard of care; and

otherwise deny the allegations contained in that paragraph.

31A. In answer to paragraph 31A of the 5FASOC, the Respondents repeat paragraphs 18, 19, 20, 22 and 23BA of the Defence, and otherwise deny the allegations contained in that paragraph.

32. In answer to paragraph 32 of the 5FASOC, the Respondents repeat paragraphs 18, 19, 20, 22, 23 and 23A of the Defence, and otherwise deny the allegations contained in that paragraph.

32A. The Respondents deny the allegations contained in paragraph 32A of the 5FASOC.

32B. In answer to paragraph 32B of the 5FASOC, the Respondents:

(a) repeat paragraph 32 of the Defence;

(b) state that post-market surveillance was carried out in relation to the devices referred to in paragraphs 5(b)(i) to 5(b)(iv) of the Defence;

(c) deny that such post-market surveillance was not adequate; and

otherwise deny the allegations contained in that paragraph.

32C. In answer to paragraph 32C of the 5FASOC, the Respondents repeat paragraphs 18, 23, 23A, 23B, 23C and 32 of the Defence, and otherwise deny the allegations contained in that paragraph.

32D. Not used.

33. The Respondents deny the allegations contained in paragraph 33 of the 5FASOC.

34. In answer to paragraph 34 of the 5FASOC, the Respondents:

(a) state that the common law does not relevantly operate to impose obligations that are more onerous or extensive than those imposed on the Respondents by sections 74B, 74D, 75AC and 75AD of the TPA and sections 9, 54, 55, 138, 271 and 272 of Schedule 2 of the CCA;

(b) deny that the Respondents were negligent; and

(c) do not know and therefore cannot admit that any Mesh Sub-Group Member suffered loss or damage.

35. In answer to paragraph 35 of the 5FASOC, the Respondents:

(a) state that:

(i) the Commonwealth Government has established a legislative scheme for the registration of medical devices which is embodied in the *Therapeutic Goods Act* 1989 (Cth) and the delegated legislation made under that Act;

(ii) under that legislative scheme, medical devices are included on the ARTG in accordance with a risk-based assessment;

(iii) each of the devices described in paragraphs 5(b)(i) to 5(b)(iv) of the Defence was, at all material times:

A. included on the ARTG as a class IIb medical device;

B. available only on recommendation of a permitted surgeon;

C. marketed to surgeons;

(iv) before any implant surgery, each Mesh Sub-Group Member's treating surgeon would, as a matter of course, have:

A. consulted with each Mesh Sub-Group Member and assessed each Group Member's clinical needs and relevant medical history;

B. synthesised and assessed all relevant information;

C. provided each Mesh Sub-Group Member with information, advice and warnings tailored for each Mesh Sub-Group Member; and

D. determined the most appropriate course or method of treatment, including implantation with one or more of the devices referred to paragraphs 5(b)(i) to 5(b)(iv) of the Defence, alternative treatments with or without another implant, alternative surgeries or no surgery, depending on each of the Mesh Sub-Group Member's individual circumstances, the information that each Mesh Sub-Group Member made available to their treating surgeon, personal preference and the treating surgeon's surgical training and experience;

(v) it was reasonable for the Respondents to expect that, prior to using one or more of the devices referred to paragraphs 5(b)(i) to 5(b)(iv),, each of the Mesh Sub-Group Members would be informed, by their respective treating surgeon(s), to the degree the surgeons judged appropriate, that such use of the Implants carried risk, including the risk that the implantation of one or more of the devices referred to in paragraphs 5(b)(i) to 5(b)(iv) of the Defence may not restore pelvic anatomy, may not alleviate the symptoms associated with their clinical condition, may not improve the patient's quality of life, or may require revision;

(b) state that, as a consequences of the matters pleaded in paragraph 35(a) of the Defence:

(i) JJM Australia did not owe any Mesh Sub-Group Member the duty of care as alleged in paragraph 35 of the 5FASOC; or

(ii) in the alternative, satisfied any applicable standard of care; and

otherwise deny the allegations contained in that paragraph.

35A. In answer to paragraph 35A of the 5FASOC, the Respondents repeat paragraphs 18, 19, 20 and 22 of the Defence, and otherwise deny the allegations contained in that paragraph.

36. In answer to paragraph 36 of the 5FASOC, the Respondents repeat paragraphs 18, 19, 20, 22, 23 and 23A of the Defence, and otherwise deny the allegations contained in that paragraph.

36A. The Respondents deny the allegations contained in paragraph 36A of the 5FASOC.

36B. In answer to paragraph 36B of the 5FASOC, the Respondents:

(a) repeat paragraph 32B of the Defence;

(b) state that JJM did conduct post-market surveillance in relation to the devices referred to in paragraphs 5(b)(i) to 5(b)(iv) of the Defence;

(c) deny that such post-market surveillance was not adequate; and

otherwise deny the allegations contained in that paragraph.

36C. In answer to paragraph 36B of the 5FASOC, the Respondents repeat paragraphs 18, 23, 23A, 23B, 23C and 36 of the Defence, and otherwise deny the allegations contained in that paragraph.

36D. In answer to paragraph 36D of the 5FASOC, the Respondents repeat paragraph 32D of the Defence.

37. The Respondents deny the allegations contained in paragraph 37 of the 5FASOC.

38. In answer to paragraph 38 of the 5FASOC, the Respondents:

(a) state that the common law does not relevantly operate to impose obligations that are more onerous or extensive than those imposed on the Respondents by sections 74B, 74D, 75AC and 75AD of the TPA and sections 9, 54, 55, 138, 271 and 272 of Schedule 2 of the CCA;

(b) deny that the Respondents were negligent; and

(c) do not know and therefore cannot admit that any Mesh Sub-Group Member suffered loss or damage.

39. The Respondents deny that they were negligent and that they are thereby liable for loss or damage, if any, suffered by any Mesh Sub-Group Member.

(vii) Misleading Conduct Claims under the TPA and the Australian Consumer Law

39A. In answer to paragraph 39A of the 5FASOC, the Respondents repeat paragraphs 5, 15, 16, 17, 18, 19, 20, 23, 23A, 23B, 23BA, 23C, 31A, 32, 32A, 35A, 36 and 36C of the Defence.

39B. The Respondents deny the allegations contained in paragraph 39B of the 5FASOC.

39C. The Respondents deny the allegations contained in paragraph 39C of the 5FASOC.

39D. In answer to paragraph 39D of the 5FASOC, the Respondents:

(a) state that pursuant to section 82(1AAA) of the TPA and sections 137C and 137E of the CCA the Mesh Sub-Group Members may not recover the amount of any loss or damage from personal injury;

(b) repeat paragraphs 3 and 4 of the Defence;

(c) state that neither Ethicon Sàrl nor Ethicon, Inc. carried on business in Australia and are not subject to Part V of the TPA or Schedule 2 of the CCA relied upon by each of the Mesh Sub-Group Members;

(d) state that neither Ethicon Sàrl nor Ethicon, Inc. are liable to compensate any Mesh Sub-Group Member pursuant to the provisions of the TPA or Schedule 2 of the CCA; and

otherwise deny the allegations contained in that paragraph.

Part E - The Tape Implants

(i) Tape Purpose

40. In answer to paragraph 40 of the 5FASOC, the Respondents:

(a) state that:

(i) the GYNECARE TVT Tension-free Vaginal Tape System is designed, manufactured and indicated for use as a pubourethral sling for treatment of stress urinary incontinence, for female urinary incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency but is not designed, manufactured or indicated for the treatment of pelvic organ prolapse;

(ii) the GYNECARE TVT ABBREVO Continence System is designed, manufactured and indicated for use in women as a sub-urethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency but is not designed, manufactured or indicated for the treatment of pelvic organ prolapse;

(iii) the GYNECARE TVT Obturator System is designed, manufactured and indicated for use in women as a sub-urethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency but is not designed, manufactured or indicated for the treatment of pelvic organ prolapse;

(iv) the GYNECARE TVT SECUR System was designed, manufactured and indicated for use in women as a sub-urethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency but was not designed, manufactured or indicated for the treatment of pelvic organ prolapse;

(v) GYNECARE TVT EXACT Continence System is designed, manufactured and indicated for use as a pubourethral sling for treatment of female stress urinary incontinence, resulting from urethral hypermobility or intrinsic sphincter deficiency, but is not designed, manufactured or indicated for the treatment of pelvic organ prolapse;

(b) state that the devices referred to in paragraphs 5(b)(v) to 5(b)(ix) of the Defence were designed, manufactured and indicated for implant surgery to treat stress urinary incontinence, but before any implant surgery, each Tape Sub-Group Member's treating surgeon would, as a matter of course, have:

(i) consulted with each Tape Sub-Group Member and assessed each Tape Sub-Group Member's clinical needs and relevant medical and surgical history;

(ii) synthesised and assessed all relevant information;

(iii) provided each Tape Sub-Group Member with information, advice and warnings tailored for each Tape Sub-Group Member; and

(iv) determined the most appropriate course or method of treatment, including implantation with one or more of the devices referred to in paragraphs 5(b)(v) to 5(b)(ix) of the Defence, alternative treatments with or without another implant, alternative surgeries or no surgery, depending on each Tape Sub-Group Member's individual circumstances, the information that each Tape Sub-Group Member made available to their treating surgeon, personal preference and the treating surgeon's surgical training and experience;

(c) state that it was reasonable for the Respondents to expect that, prior to implanting one or more of the devices referred to in paragraphs 5(b)(v) to 5(b)(ix) of the Defence, Tape Sub-

Group Members would each be informed, by their respective treating surgeon(s), to the degree the surgeons judged appropriate, of the surgical and non-surgical treatment options, that use of one or more of the devices carried risk, including the risk that the implantation of one or more of the devices may not alleviate the patient's stress urinary incontinence, may not improve the patient's quality of life, or may require revision; and

otherwise do not know and therefore cannot admit the allegations contained in that paragraph.

41. In answer to paragraph 41 of the 5FASOC, the Respondents repeat paragraph 40 of the Defence and otherwise deny the allegations contained in that paragraph.

42. In answer to paragraph 42 of the 5FASOC, the Respondents repeat paragraph 40 of the Defence and otherwise deny the allegations contained in that paragraph.

43. In answer to paragraph 43 of the 5FASOC, the Respondents repeat paragraphs 12 and 40 of the Defence and otherwise do not know and cannot admit the allegations contained in that paragraph.

44. In answer to paragraph 44 of the 5FASOC, the Respondents repeat paragraph 40 of the Defence and otherwise do not know and cannot admit the allegations contained in that paragraph.

45. In answer to paragraph 45 of the 5FASOC, the Respondents:

(a) repeat paragraph 40 of the Defence;

(b) state that non-absorbable polypropylene mesh, which formed a component of each of the devices described in paragraphs 5(b)(v) to 5(b)(ix) of the Defence, was designed to allow for an inflammatory response that is necessary for tissue ingrowth;

(c) state that all surgical procedures present risks; and

otherwise deny the allegations contained in that paragraph.

(ii) Tape Risks and Tape Complications

46. In answer to paragraph 46 of the 5FASOC, the Respondents:

(a) repeat paragraph 40 of the Defence;

(b) state that each of the devices described in paragraphs 5(b)(v) to 5(b)(ix) of the Defence were designed, manufactured and indicated for use in women as a pubo-urethral or sub-urethral

sling for the treatment of stress urinary incontinence resulting from urethral hypermobility or intrinsic sphincter deficiency;

(c) state that all surgical procedures present risks; and

otherwise deny the allegations contained in that paragraph.

47. In answer to paragraph 47 of the 5FASOC, the Respondents:

(a) repeat paragraph 40 of the Defence;

(b) state that reconstructive surgery for the treatment of SUI may be undertaken, depending upon the specific patient's history, preference and the surgeon's judgment, with or without the use of tape implants;

(c) state that all surgical procedures present risks; and

otherwise deny the allegations contained in that paragraph.

47A. The Respondents deny the allegations contained in paragraph 47A of the 5FASOC.

48. In answer to paragraph 48 of the 5FASOC, the Respondents:

(a) repeat paragraph 40 of the Defence;

(b) state that they made available information, including warnings, to surgeons;

(c) deny that:

(i) the information and those warnings were not sufficient; and

(ii) the matters pleaded in paragraph 48(d) of the 5FASOC ought to have been the subject of any information or warning to the Tape Sub-Group Members, their Treating Hospitals and/or Treating Doctors; and

(d) state that there is no reason to believe that any warning containing the information as set out in paragraph 48(d) of the 5FASOC would have made any material difference to the matters outlined in sub-paragraphs 40(b) and (c) of the Defence;

otherwise deny the allegations contained in that paragraph.

(iii) Mrs Sanders' Implant

49. In answer to paragraph 49 of the 5FASOC, the Respondents state that on or about 17 October 2000, Mrs Sanders attended a consultation with Dr John Taylor, during which:

(a) Dr Taylor recorded that Mrs Sanders reported that she has had typical stress incontinence for 7 years, with some urgency and occasional urge incontinence;

(b) on examination, Dr Taylor found that Mrs Sanders had a cystocoele and rectocoele;

(c) Dr Taylor recorded that urodynamic investigations showed a stable bladder with a small, after micturition, urinary residue;

(d) Dr Taylor recorded that the ultrasound scan of the urinary tract Mrs Sanders brought with her was normal;

(e) on request from Mrs Sanders for a surgical cure, was placed on the waiting list for a TVT mesh type sling; and

otherwise do not know and cannot admit the allegations contained in that paragraph.

PARTICULARS

1) Letter from Dr John Taylor to Dr Clare Matthews dated 17 October 2000 **[SAN.MESH.00000194]**

2) Consultation notes of Dr John Taylor, King Edward Memorial Hospital for Women (**KEMH**) dated 19 October 2000 **[SAN.MESH.00000195] at [00000195]**

50. In answer to paragraph 50 of the 5FASOC, the Respondents:

(a) state that Mrs Sanders had, prior to 17 October 2000, been informed of and had treatment for stress urinary incontinence, being pelvic floor exercises, as pleaded in paragraph 47 of the 5FASOC;

(b) state that Mrs Sanders informed her treating doctor, Dr Taylor, on or about 17 October 2000, that she had no benefit from pelvic floor exercises in treating her clinical condition; and

otherwise do not know and cannot admit the allegations contained in that paragraph.

PARTICULARS

1) Letter from Dr John Taylor to Dr Clare Matthews dated 17 October 2000 **[SAN.MESH.00000194]**

2) Consultation notes of Dr John Taylor, King Edward Memorial Hospital for Women (KEMH) dated 19 October 2000 **[SAN.MESH.00000195] at [00000195]**

51. In answer to paragraph 51 of the 5FASOC, the Respondents state that, on or about 12 March 2001, Dr Sandra McNeill, Registrar, performed surgery on Mrs Sanders at KEMH, which included implantation of a GYNECARE TVT Device (with product code 510041) and a cystoscopy, and otherwise do not know and cannot admit the allegations contained in that paragraph.

PARTICULARS

1) Letter from Dr Sandra McNeill to Dr Clare Matthews dated 12 March 2001 **[SAN.MESH.00000193]**

2) Operation Record dated 12 March 2001 **[SAN.MESH.00000203]**

52. In answer to paragraph 52 of the 5FASOC, the Respondents repeat paragraphs 40 and 49 of the Defence, and otherwise do not know and cannot admit the allegations contained in that paragraph.

53. In answer to paragraph 53 of the 5FASOC, the Respondents:

(a) state that the Respondents have not been provided with any medical records of Mrs Sanders relating to any of the conditions described in paragraph 53 of the 5FASOC dated between 31 May 2001 and 21 January 2011;

(b) state that some of the conditions described in paragraph 53 of the 5FASOC may occur as the result of different factors including childbirth injury, multiple vaginal deliveries and menopause, as described in paragraphs 6 and 6A of the Defence, which Mrs Sanders had;

(c) state that, on or about 21 January 2011, Mrs Sanders consulted Dr Juliet Tan during which consultation:

(i) Mrs Sanders reported she had dysuria and haematuria;

(ii) on examination, Dr Tan found Mrs Sanders had a ring pessary at vaginal orifice level;

(iii) Dr Tan advised Mrs Sanders that the ring pessary needed to be removed as it was obstructing urine flow;

(iv) Dr Tan referred Mrs Sanders to KEMH for an outpatient appointment;

(d) state that, on or about 28 January 2011, Mrs Sanders presented to KEMH Emergency Department for treatment of a painful sensation in her vagina from the ring pessary which was at the vaginal orifice level; and

otherwise do not know and cannot admit the allegations contained in that paragraph.

PARTICULARS

1) Progress Notes of Dr Juliet Tan dated 21 January 2011 **[SAN.MESH.00000098] at [00000099]**

2) Request for Outpatient Appointment to KEMH from Dr Tan dated 21 January 2011 **[SAN.MESH.00000102]**

3) KEMH Emergency Medicine Summary dated 28 January 2011 **[SAN.MESH.00000103]**

54. In answer to paragraph 54 of the 5FASOC, the Respondents state that, on or about 19 May 2011, Mrs Sanders consulted Dr Alanagh Gilbert, during which consultation:

(a) Dr Gilbert found, on examination, that Mrs Sanders had an area of mesh erosion anteriorly, that she did not have stress incontinence and that she had mild urge incontinence;

(b) Dr Gilbert arranged for Mrs Sanders to have an examination under anaesthetic, a cystoscopy and removal of vaginal mesh; and

otherwise do not know and cannot admit the allegations contained in that paragraph.

PARTICULARS

1) Consultation notes of Dr Alanagh Gilbert dated 19 May 2011 **[SAN.MESH.00000195] at [00000197]**

2) Letter from Dr Alanagh Gilbert to Dr Juliet Tan dated 19 May 2011 **[SAN.MESH.00000054]**

55. In answer to paragraph 55 of the 5FASOC, the Respondents state that, on or about 8 August 2011, Dr John Phillipe Daborn performed surgery on Mrs Sanders at KEMH, which included an examination under anaesthetic, excision of vaginal mesh and cystoscopy, and otherwise do not know and cannot admit the allegations contained in that paragraph.

56. In answer to paragraph 56 of the 5FASOC, the Respondents:

(a) state that Mrs Sanders consulted Dr Nicolas Tsokos on or about 22 September 2011, during which consultation:

(i) Mrs Sanders reported her condition to Dr Tsokos;

(ii) Dr Tsokos examined Mrs Sanders and recorded his findings;

(b) state that Mrs Sanders consulted Dr Clare Matthews including on or about 13 October 2011, 27 October 2011, 23 September 2014 and 23 April 2015, during which consultations:

(i) Mrs Sanders reported her condition to Dr Matthews;

(ii) Dr Matthews examined Mrs Sanders and recorded her findings;

(c) state that Mrs Sanders consulted Dr Tim Jeffery on or about 27 October 2011, during which consultation:

(i) Mrs Sanders reported her condition to Dr Matthews;

(ii) Dr Jeffery examined Mrs Sanders and recorded his findings; and

otherwise do not know and cannot admit the allegations contained in that paragraph.

PARTICULARS

1) Letter from Dr Nicolas Tsokos to Dr Juliet Tan dated 22 September 2011 **[SAN.MESH.00000052]**

2) KEMH Outpatients' Case Notes dated 22 September 2011 **[SAN.MESH.00000195] at [00000198]**

3) Progress Notes of Dr Clare Matthews **[SAN.MESH.00000001]**

4) Letter from Dr Tim Jeffery to Perilya Road Medical Centre dated 27 October 2011 **[SAN.MESH.00000050]**

57. The Respondents deny the allegations contained in paragraph 57 of the 5FASOC.

58. The Respondents do not know and otherwise cannot admit the allegations contained in paragraph 58 of the 5FASOC.

(iv) Claims under the Trade Practices Act and the Competition and Consumer Act

59. In answer to paragraph 59 of the 5FASOC, the Respondents admit that the devices referred to in paragraphs 5(b)(v) to 5(b)(ix) of the Defence are goods for the purposes of section 4 of the TPA and section 2 of Schedule 2 of the CCA and otherwise admit paragraph 59 of the 5FASOC.

60. The Respondents admit the allegations contained in paragraph 60 of the 5FASOC.

61. In answer to paragraph 61 of the 5FASOC, the Respondents repeat paragraphs 40 to ~~0~~48 of the Defence and otherwise deny the allegations contained in that paragraph.

62. In answer to paragraph 62 of the 5FASOC, the Respondents:

    (a) repeat paragraphs 40 to ~~0~~48 of the Defence;

    (b) state that Mrs Sanders and each Tape Sub-Group Member did not rely, or it was not reasonable for Mrs Sanders or any Tape Sub-Group Member to rely, on the skill or judgment of any of the Respondents in acquiring one or more of the devices listed in paragraphs 5(b)(v) to 5(b)(ix) of the Defence; and

    otherwise deny the allegations contained in that paragraph.

63. In answer to paragraph 63 of the 5FASOC, the Respondents:

    (a) repeat paragraphs 40 to ~~0~~48 of the Defence;

    (b) state that Mrs Sanders and each Tape Sub-Group Member did not rely, or it was not reasonable for Mrs Sanders or any Tape Sub-Group Member to rely, on the skill or judgment of any of the Respondents in acquiring one or more of the devices listed in paragraphs 5(b)(v) to 5(b)(ix) of the Defence; and

    otherwise deny the allegations contained in that paragraph.

64. The Respondents deny the allegations contained in paragraph 64 of the 5FASOC.

65. In answer to paragraph 65 of the 5FASOC, the Respondents:

(a) deny the allegations contained in that paragraph;

(b) repeat paragraphs 3 and 4 of the Defence and state that neither Ethicon Sàrl nor Ethicon, Inc. carried on business in Australia and are not subject to the consumer protection provisions of the TPA or Schedule 2 of the CCA relied upon by each of the Tape Sub-Group Members; and

(c) state that neither Ethicon Sàrl nor Ethicon, Inc. are liable to compensate any of the Tape Sub-Group Members pursuant to the provisions of the TPA or Schedule 2 of the CCA.

(v) Claims in Negligence

66. In answer to paragraph 66 of the 5FASOC, the Respondents:

(a) state that:

(i) the Commonwealth Government has established a legislative scheme for the registration of medical devices which is embodied in the *Therapeutic Goods Act* 1989 (Cth) and the delegated legislation made under that Act;

(ii) under that legislative scheme, medical devices are included on the ARTG in accordance with a risk-based assessment;

(iii) each of the devices described in paragraphs 5(b)(v) to 5(b)(ix) of the Defence was, at all material times:

A. included on the ARTG as a class IIb or III medical device;

B. available only on recommendation of a permitted surgeon;

C. marketed to surgeons;

(iv) as manufacturers of the devices described in paragraphs 5(b)(v) to 5(b)(ix) of the Defence, Ethicon Sàrl and Ethicon, Inc. made available to JJM Australia information about each of those devices for provision to surgeons;

(v) before any implant surgery, each Tape Sub-Group Member's treating surgeon would, as a matter of course, have:

A. consulted with each Tape Sub-Group Member and assessed each Tape Sub-Group Member's clinical needs and relevant medical and surgical history;

B. synthesised and assessed all relevant information;

C. provided each Tape Sub-Group Member with information, advice and warnings tailored for each Tape Sub-Group Member; and

D. determined the most appropriate course or method of treatment, including implantation with one or more of the devices referred to in paragraphs 5(b)(v) to 5(b)(ix) of the Defence, alternative treatments with or without another implant, alternative surgeries or no surgery, depending on each Tape Sub-Group Member's individual circumstances, the information that each Tape Sub-Group Member made available to their treating surgeon, personal preference and the treating surgeon's surgical training and experience;

(vi) it was reasonable for the Respondents to expect that, prior to implanting one or more of the devices referred to in paragraphs 5(b)(v) to 5(b)(ix) of the Defence, each Tape Sub-Group Member would be informed, by their respective treating surgeon(s), to the degree the surgeons judged appropriate, that such use carried risk, including the risk that the implantation of one or more of the devices may not alleviate the patient's stress urinary incontinence, may not improve the patient's quality of life, or may require revision;

(b) state that, as a consequence of the matters pleaded in paragraph 66(a) of the Defence:

(i) neither Ethicon Sàrl nor Ethicon, Inc. owed any Tape Sub-Group Member the duty of care as alleged in paragraph 66 of the 5FASOC; or

(ii) in the alternative, satisfied any applicable standard of care; and

otherwise deny the allegations contained in that paragraph.

67. In answer to paragraph 67 of the 5FASOC, the Respondents repeat paragraphs 40, 41, 42, 43, 44 and 47A of the Defence, and otherwise deny the allegations contained in that paragraph.

68. In answer to paragraph 68 of the 5FASOC, the Respondents repeat paragraphs 40, 41, 42, 44, 45 and 46 of the Defence, and otherwise deny the allegations contained in that paragraph.

68A. In answer to paragraph 68A of the 5FASOC, the Respondents repeat paragraphs 40, 41, 42, 44, 45, 46 and 68 of the Defence and otherwise deny the allegations contained in paragraph 68A of the 5FASOC.

68B. The Respondents deny the allegations contained in paragraph 68B of the 5FASOC.

68C. The Respondents deny the allegations contained in paragraph 68C of the 5FASOC.

69. In answer to paragraph 69 of the 5FASOC, the Respondents repeat paragraphs 40, 45 to 0 and 68 of the Defence, and otherwise deny the allegations contained in that paragraph.

70. Not used.

71. Not used.

72. The Respondents deny the allegations contained in paragraph 72 of the 5FASOC.

73. In answer to paragraph 73 of the 5FASOC, the Respondents:

(a) state that the common law does not relevantly operate to impose obligations that are more onerous or extensive than those imposed on the Respondents by sections 74B, 74D, 75AC and 75AD of the TPA and sections 9, 54, 55, 138, 271 and 272 of Schedule 2 of the CCA;

(b) deny that the Respondents were negligent; and

(c) do not know and therefore cannot admit that any Tape Sub-Group Member suffered loss or damage.

74. In answer to paragraph 74 of the 5FASOC, the Respondents:

(a) state that:

(i) the Commonwealth Government has established a legislative scheme for the registration of medical devices which is embodied in the *Therapeutic Goods Act* 1989 (Cth) and the delegated legislation made under that Act;

(ii) under that legislative scheme, medical devices are included on the ARTG in accordance with a risk-based assessment;

(iii) each of the devices described in paragraphs 5(b)(v) to 5(b)(ix) of the Defence was, at all material times:

A. included on the ARTG as a class IIb or III medical device;

B. available only on recommendation of a permitted surgeon;

C. marketed to surgeons;

(iv) before any implant surgery, each Tape Sub-Group Member's treating surgeon would, as a matter of course, have:

A. consulted with each Tape Sub-Group Member and assessed each Tape Sub-Group Member's clinical needs and relevant medical and surgical history;

B. synthesised and assessed all relevant information;

C. provided each Tape Sub-Group Member with information, advice and warnings tailored for each Tape Sub-Group Member; and

D. determined the most appropriate course or method of treatment, including implantation with one or more of the devices referred to in paragraphs 5(b)(v) to 5(b)(ix) of the Defence, alternative treatments with or without another implant, alternative surgeries or no surgery, depending on each Tape Sub-Group Member's individual circumstances, the information each Tape Sub-Group Member made available to their treating surgeon, personal preference and the treating surgeon's surgical training and experience;

(v) it was reasonable for the Respondents to expect that, prior to implanting one or more of the devices referred to in paragraphs 5(b)(v) to 5(b)(ix) of the Defence, each Tape Sub-Group Member would be informed, by their respective treating surgeon(s), to the degree the surgeons judged appropriate, that such use carried risk, including the risk that the implantation of one or more of the devices may not alleviate the patient's stress urinary incontinence, may not improve the patient's quality of life, or may require revision;

(b) state that, as a consequence of the matters pleaded in paragraph 74(a) of the Defence:

(i) JJM Australia did not owe Mrs Sanders or any Tape Sub-Group Member the duty of care as alleged in paragraph 74 of the 5FASOC; or

(ii) in the alternative, satisfied any applicable standard of care; and

otherwise deny the allegations contained in that paragraph.

75. In answer to paragraph 75 of the 5FASOC, the Respondents repeat paragraphs 40, 41, 42,44 and 47A of the Defence, and otherwise deny the allegations contained in that paragraph.

76. In answer to paragraph 76 of the Defence, the Respondents repeat paragraphs 40, 41, 42, 44, 45 and 46 of the Defence, and otherwise deny the allegations contained in that paragraph.

77. In answer to paragraph 77 of the 5FASOC, the Respondents repeat paragraphs 40, 45 to 0 and 76 of the Defence, and otherwise deny the allegations contained in that paragraph.

78. Not used.

79. The Respondents deny the allegations contained in paragraph 79 of the 5FASOC.

80. In answer to paragraph 80 of the 5FASOC, the Respondents:

(a) state that the common law does not relevantly operate to impose obligations that are more onerous or extensive than those imposed on the Respondents by sections 74B, 74D, 75AC and 75AD of the TPA and sections 9, 54, 55, 138, 271 and 272 of Schedule 2 of the CCA;

(b) deny that the Respondents were negligent; and

(c) do not know and therefore cannot admit that any Tape Sub-Group Member suffered loss or damage.

81. The Respondents deny that they were negligent and that they are thereby liable for loss or damage, if any, suffered by any Tape Sub-Group Member.

(vii) Misleading Conduct Claims under the TPA and CCA

82. In answer to paragraph 82 of the 5FASOC, the Respondents repeat paragraphs 5, 15, 16, 17, 40, 41, 42, 45, 46, 47, 47A, 48, 67, 68, 69, 75, 76 and 77.

83. The Respondents deny the allegations contained in paragraph 83 of the Defence.

84. The Respondents deny the allegations in paragraph 84 of the Defence.

85. In answer to paragraph 65 of the 5FASOC, the Respondents:

(a) state that pursuant to section 82(1AAA) of the TPA and sections 137C and 137E of the CCA the Tape Sub-Group Members may not recover the amount of any loss or damage from personal injury;

(b) repeat paragraphs 3 and 4 of the Defence;

(c) state that neither Ethicon Sàrl nor Ethicon, Inc. carried on business in Australia and are not subject to Part V of the TPA or Schedule 2 of the CCA relied upon by each of the Tape Sub-Group Members;

(d) state that neither Ethicon Sàrl nor Ethicon, Inc. are liable to compensate any of the Tape Sub-Group Members pursuant to the provisions of the TPA or Schedule 2 of the CCA; and

otherwise deny the allegations contained in that paragraph.

State of scientific or technical knowledge

86. Further, or in the alternative, in answer to the allegations pleaded in paragraphs 26 and 61of the 5FASOC, the Respondents state that, at all material times, the state of scientific or technical knowledge was not such as to enable it to discover the matters alleged in paragraphs 26 and 61 of the 5FASOC, if found to exist (which is denied), such that:

(a) section 75AK(1)(c) of the TPA affords a complete defence to the claim under section 75AD of the TPA;

(b) section 142 of Schedule 2 of the CCA affords a complete defence to the claim under section 138 of Schedule 2 of the CCA;

(c) the state of scientific or technical knowledge is one of the relevant circumstances for the purpose of section 74D(3) of the TPA to which the Court must have regard in determining whether the implants were of merchantable quality;

(d) the state of scientific or technical knowledge is one of the relevant circumstances for the purpose of section 54(3) of Schedule 2 of the CCA to which the Court must have regard in determining whether the implants were of acceptable quality;

(e) the Respondents did not breach any duty of care owed under the general law.

Limitations

87. Further, pending receipt of further particulars of the Group Members' claims, in answer to the allegations pleaded in paragraphs 24 to 39 and 59 to 81 of the 5FASOC, the Respondents state that the Group Members' causes of action will be subject to, and the Respondents are relying upon, the limitation periods prescribed by the:

(a) *Limitation Act* 1969 (NSW);

(b) *Limitation of Actions Act* 1958 (Vic);

(c) *Limitation of Actions Act* 1974 (QLD);

(d) *Limitation Act* 2005 (WA);

(e) *Limitation Act* 1935 (WA);

(f) *Limitation Act* 1985 (ACT);

(g) *Limitation Act* 1974 (TAS);

(h) *Limitation of Actions Act* 1936 (SA);

(i) *Limitation Act* 1981 (NT);

(j) *Trade Practices Act* 1974 (Cth); including ss 74J(1) and (3), 75AO(1) and (2), 82(2), 87F, 87G and 87H; and

(k) *Competition and Consumer Act* 2010 (Cth)(**CCA**), including ss 87F, 87G and 87H of the CCA and ss143(1) and (2) and 236(2) of Schedule 2 of the CCA (being the *Australian Consumer Law*).

88. Further, and in answer to Mrs Gill's claim for common law damages (which is not admitted), the Respondents state that:

(a) Mrs Gill's alleged cause of action accrued more than 3 years before the commencement of these proceedings; and

(b) pursuant to subsection 14(1) of the *Limitation Act* 2005 (WA) (**WA Act 2005**), her cause of action cannot be maintained, subject to the Court extending time in accordance with section 39 of the WA Act 2005.

89. Further, and in answer to Mrs Gill's claim for compensation under the TPA and CCA (which is not admitted), the Respondents state that:

(a) Mrs Gill's alleged cause of action accrued more than 3 years before the commencement of these proceedings; and

(b) pursuant to section 87F of the TPA/CCA, her cause of action is statute barred.

90. In answer to the Mrs Sanders' claim for common law damages (which is not admitted), the Respondents state that:

(a) Mrs Sanders' alleged cause of action accrued more than 6 years before the commencement of these proceedings; and

(b) pursuant to section 38(1)(c)(vi) of the *Limitation Act* 1935 (WA), her common law claim for damages is statute barred.

91. Further, and in answer to Mrs Sanders' claim for compensation under the TPA and CCA (which is not admitted), the Respondents state that:

(a) Mrs Sanders' alleged cause of action accrued more than 6 years before the commencement of these proceedings; and

(b) pursuant to sections 82 and 87F of the TPA/CCA, her cause of action is statute barred.

Claim subject to tort reform

92. Further, pending receipt of further particulars, in answer to the whole of the 5FASOC, the Respondents state that the Applicant's common law cause of action and claims for damages and compensation must be determined in accordance with the *Civil Liability Act* 2002 (NSW) and Part VIB of the *Trade Practices Act* 1974 (Cth).

93. Further, pending receipt of further particulars of the Group Members' claims, in answer to the whole of the 5FASOC, the Respondents state that the Group Members' common law causes of action and claims for damages and compensation must be determined in accordance with the:

(a) *Civil Liability Act* 2002 (NSW);

(b) *Wrongs Act* 1956 (Vic);

(c) *Civil Liability Act* 2003 (QLD);

(d) *Civil Liability Act* 2002 (WA);

(e) *Civil Law (Wrongs) Act* 2002 (ACT);

(f) *Civil Liability Act* 2002 (TAS);

(g) *Civil Liability Act* 1936 (SA);

(h) *Personal Injuries (Liabilities and Damages) Act* 2003 (NT);

(i) Part VIB of the *Trade Practices Act* 1974 (Cth); and

(j) Part VIB of the *Competition and Consumer Act* 2010 (Cth).

Date: 20/04/18

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Signed by Colin Bruce Loveday
Lawyer for the respondents

This pleading was prepared by Colin Bruce Loveday, Lawyer for the respondents.

Certificate of lawyer

I Colin Bruce Loveday certify to the Court that, in relation to the Defence filed on behalf of the respondents, the factual and legal material available to me at present provides a proper basis for:

(a) each allegation in the pleading; and

(b) each denial in the pleading; and

(c) each non admission in the pleading.

Date: 20/04/18

.....

Signed by Colin Bruce Loveday
Lawyer for the respondents