**FEDERAL COURT OF AUSTRALIA**

**Gill v Ethicon Sàrl & Ors (No 5) [2019] FCA 1905**

**SUMMARY**

In accordance with the practice of the Federal Court in some cases of public interest, importance or complexity, the following summary has been prepared to accompany the orders made today. This summary is intended to assist in understanding the outcome of this proceeding and is not a complete statement of the conclusions reached by the Court. The only authoritative statement of the Court’s reasons is that contained in the published reasons for judgment which will be available on the Court’s website.

This is a representative (or class) action brought by three women: Kathryn Gill, Diane Dawson, and Ann Sanders, each of whom suffered complications after surgery involving the transvaginal implantation of synthetic mesh.

At the centre of the case are nine medical devices made from knitted polypropylene, a thermoplastic polymer. Five of the devices are indicated for use as surgical implants for women with stress urinary incontinence, four for use as surgical implants for women with pelvic organ prolapse.

Stress urinary incontinence is the involuntary leakage of urine. Its only symptom is leakage during activities accompanied by increased abdominal pressure, such as coughing, sneezing, lifting, laughing or exercising.

Pelvic organ prolapse is the downward displacement of a pelvic organ, which in the case of a woman means the uterus, the compartments of the vagina, or the neighbouring organs such as the bladder, rectum or bowel. Prolapse occurs when the muscles, ligaments, and the network of supporting tissues that hold the organs in place fall or slip out of place.

Both conditions can affect the quality of the sufferer’s life. They can undoubtedly be distressing but they are never life-threatening. Treatment is always elective and various forms of treatment are available, including surgery that does not involve the implantation of synthetic mesh.

Kathryn Gill was born in 1970. She has tertiary qualifications in science and education. She met her future husband, Steven, in 1997. They were a happy couple who led a healthy and active life. They have two children. After the birth of her second child, Mrs Gill was diagnosed with prolapse in multiple compartments of her vagina. In January 2007 she underwent surgery to treat her condition. The operation involved the implantation through her vagina into her pelvis of a large quantity of polypropylene mesh known as “Prolift Total”. She was only 36 years old at the time. She was very fit. She expected to recover well from surgery. But that was not to be.

Following her surgery, Mrs Gill experienced a great deal of pain. Around six months later, she could feel something sharp inside her vagina and a tearing sensation resulting in sharp pain. It transpired that the mesh had eroded and a piece of mesh was piercing the front wall of her vagina. She felt confused and did not understand what was happening to her. In September of the same year she underwent the first of three operations to remove portions of the mesh in order to alleviate her pain and suffering. Each time she hoped for a full recovery. Each time her hopes were dashed. To make matters worse, her prolapse recurred and she has suffered a host of other symptoms, including a multitude of colorectal problems. In 2017 more mesh was found to have eroded but she was counselled against further surgery. The complications of the mesh surgery have taken a great physical and emotional toll on her. She now lives with constant pelvic pain, which varies in intensity from moderate to severe. Sometimes the pain is so bad she struggles to breathe. The pain saps her energy. It can affect her memory and her ability to concentrate and articulate. It has affected her relationship with her husband. She has had to make adjustments to her daily life to avoid aggravating the pain, both in and outside the home. Pain has prevented her from returning to full-time work, as she had planned to do when her children started high school, and she struggles to manage working three days a week. She has had to ration the time she spends engaging in activities with her family which causes her considerable distress.

Diane Dawson was born in 1959. She married her husband, Geoff, in 1978. They were both passionate gardeners and enjoyed travelling. They have three children and seven grandchildren. Mrs Dawson was diagnosed with pelvic organ prolapse in 1999, and in 2001 she underwent a traditional form of surgical repair. About seven years later, however, the prolapse recurred, and in May 2009 Mrs Dawson agreed to undergo further surgery to repair it, this time involving the use of a polypropylene mesh known as “Gynemesh PS”. Initially, Mrs Dawson was pleased with the results. Before long, however, she began to experience a number of complications, including excruciating pain across her buttocks, pain deep inside her vagina, and pain that radiated down her legs. In October 2009 an eroded piece of mesh was surgically removed from the front wall of her vagina. In September 2013 her condition was such that she was advised that her best option was to have further surgery to remove as much of the mesh as possible, although even this course would not necessarily cure her pain or other symptoms. Despite a total of five operations to date to deal with the complications, she is beset by chronic pain and multiple other symptoms. Her enjoyment of life has been substantially diminished. She is understandably angry, frustrated, and distressed by her plight. Her sense of self has altered. Her self-esteem and self-confidence have greatly diminished. She does not see herself as the woman she once was. She has managed to stay at work, thanks to a sympathetic employer, but in discomfort, if not overt pain, most of the time.

Ann Sanders was born in 1946. In 1967 she opened her own hair salon, which she operated for about seven years. She married her husband, Peter, in 1973. They have two children and two grandchildren. Mr and Mrs Sanders had a strong relationship and enjoyed spending their time outdoors. In 1993 Mrs Sanders began to experience symptoms of stress urinary incontinence. In March 2001 she attended a hospital in Perth where she was implanted with a polypropylene mesh known as “TVT”. Mrs Sanders was very happy with the results of her surgery — until 2007. Around the beginning of that year she began to experience discomfort urinating. In early 2008 she felt as if there was a blade in her vagina. Later, she developed other symptoms, including chronic pain and recurrent infections. In 2011 she was diagnosed with a mesh erosion and underwent surgery to remove some of the mesh. The operation failed to alleviate her symptoms and her incontinence returned. Consequently, she, like Mrs Gill and Mrs Dawson, now lives with chronic pain and numerous other symptoms that restrict her activities and limit her ability to socialise. While her relationship with her husband is strong, she feels like she is letting him down, and spoiling things for him and the rest of their family. She is frightened about what the future holds for her.

In this proceeding, Mrs Gill, Mrs Dawson and Mrs Sanders call into question the safety of the devices with which they were implanted.

They are by no means alone. They brought this case, not merely for their own benefit, but also on behalf of other Australian women in similar positions. The number of such women is unknown. At the beginning of the trial, I was informed that some 700 women had registered as group members. But since the group is an open one and more than 90,000 of the respondents’ devices have been supplied in Australia, it is highly likely that there are many more.

The medical devices used for the treatment of stress urinary incontinence which are the subject of this proceeding are known by trade names. I abbreviate those names in the judgment to TVT (an acronym for tension-free vaginal tape), TVT-O, TVT Exact, TVT Abbrevo, and TVT Secur. The tapes were designed to be inserted between the middle of the urethra and the skin of the vagina to provide support for damaged or weakened muscles and ligaments and reduce, if not stop, leakage. In this summary and in the judgment, when I refer to the devices collectively, I call them “the **SUI devices**”.

The relevant medical devices used for the treatment of pelvic organ prolapse are known by the trade names Gynemesh PS, Prolift, Prolift+M, and Prosima. I call them “the **POP devices**”. All of these, except for Gynemesh PS, were sold as kits with special instruments. Different kits were available for different forms of prolapse. Prolift Total, the device Mrs Gill received, was a combination of the two meshes supplied with the Prolift Anterior and Prolift Posterior kits. The purpose of these devices was to provide reinforcement and long-lasting stabilisation of the fascial structures of the pelvic floor.

The action is brought against three related companies, all members of the Johnson & Johnson group. The first respondent is Ethicon Sàrl, a Swiss corporation, and the manufacturer of all but one of the devices in question. The second respondent is Ethicon Inc., an American corporation and the manufacturer of the other Ethicon device, Gynemesh PS. Ethicon Inc. was also involved in other respects, including in the marketing of all the relevant devices. In this summary, as in the judgment, where it is unnecessary to distinguish between them, I refer to both Ethicon companies simply as “**Ethicon**”. When I refer to all the devices they manufactured, I call them “the **Ethicon devices**”.

Ethicon Sàrl and Ethicon Inc. supplied the Ethicon devices to the third respondent, Johnson & Johnson Medical Pty Limited (**JJM**), an Australian company, which promoted and supplied the Ethicon devices to Australian doctors and hospitals.

This was a large case. And it was complex.

All the respondents denied liability and the action was vigorously defended.

The applicants brought seven claims, four under Commonwealth consumer protection laws and three at common law in negligence. Numerous issues were raised. Some were common to the applicants and some or all members of the group they represented. Others were unique to the individual applicants.

The impugned conduct giving rise to the claims took place over more than two decades. During this period, different laws applied at different times.

What is more, Mrs Gill and Mrs Sanders live in Western Australia and Mrs Dawson in Victoria. These are the places where their alleged injuries occurred. Although it has been 118 years since Federation and it is said there is only one common law in Australia, the Commonwealth, states and territories have enacted legislation, which is not uniform and which in a number of respects affects the applicants’ claims, particularly the time they had to bring proceedings and the amount of damages or compensation they can recover.

The trial began at the beginning of July 2017 and did not conclude until the end of February 2018.

Evidence was adduced from some 48 witnesses, 37 of whom were experts hailing from multiple disciplines. They included urogynaecologists, urologists, and gynaecologists; pathologists; biomechanical engineers; epidemiologists and biostatisticians; regulatory experts; colorectal surgeons; psychiatrists; occupational therapists, and a specialist in occupational medicine.

In addition to reports and affidavits from the witnesses, more than 5,000 documents were tendered, consisting of over 164,000 pages.

Mercifully, the trial was conducted electronically, which means that the pleadings, the documentary evidence, the transcripts, and the submissions were uploaded to a searchable database. To a not insignificant extent, this eased the burden on the Court.

Extensive written submissions were filed. The applicants’ closing submissions alone were over 1,100 pages; the respondents’ ran to 730. Closing oral argument took place over four weeks. After the trial, the parties filed a series of supplementary submissions dealing with a number of discrete issues. I received the last of those submissions on 15 March this year.

All this accounts for the time it has taken to produce a judgment and for the length of my reasons at nearly 1,500 pages.

Before I announce my decision, I need to refer to some additional contextual matters.

TVT was first sold in Australia in October 1999, TVT-O in March 2004, TVT Exact in July 2010, and TVT Abbrevo in October 2010. The mesh used in all these devices was and, so far as I am aware continues to be, made from Prolene, a polypropylene resin manufactured by Ethicon. TVT Secur was first sold in Australia in April 2007. It was also made from Prolene, but is no longer on the market.

Gynemesh PS was first sold in Australia in July 2003, Prolift in June 2005, Prolift+M in December 2009, and Prosima in April 2010. Gynemesh PS, Prolift and Prosima are made from Prolene Soft, which was developed by Ethicon for use in abdominal hernia repair. Like Prolene, it was made from knitted filaments of polypropylene, but it has a smaller filament diameter, which is said to give it a softer feel, and it has a different knit design. The mesh in Prolift+M is Prolene Soft combined with an absorbable fibre known as Monocryl.

The use of the meshes, and the techniques required to implant them, exposed patients to risks of significant and serious injury.

The law seeks to protect people from harm that can be caused by medical devices. It does so in a number of ways.

*First*, no medical device can be sold in Australia unless it has been approved by the Therapeutic Goods Administration (**TGA**) for inclusion on the Australian Registerof Therapeutic Goods (**ARTG**). The TGA also has the power to cancel or suspend an entry on the ARTG and to impose conditions which, if breached, can lead to suspension or cancellation.

*Second*, legislation passed by the Commonwealth Parliament imposes a number of obligations on companies that manufacture and/or supply medical devices. Orders, including orders for the payment of damages or compensation, declarations, and injunctions may be made against manufacturers and suppliers of medical devices who do not comply with these obligations. The *Trade Practices Act 1974* (Cth)and, since 2010, the Australian Consumer Law, which is part of the *Competition and Consumer Act 2010* (Cth), contain provisions making corporations that supply goods that they manufacture liable to compensate people who are injured because of defects in those goods, because the goods are not fit for the particular purpose for which they are acquired, or because they are not of merchantable quality. “Goods” include medical devices. “Manufacturer” has an extended meaning under the legislation. Relevantly it includes corporations who import goods into Australia. It was not in dispute that JJM was a manufacturer for the purposes of the Act. “Defect” also has a special meaning, to which I will come in due course. As is well known, this legislation also prohibits corporations from engaging in misleading or deceptive conduct about the attributes of their goods.

*Third*, the common law, developed over centuries by the courts, imposes on manufacturers, and in some cases suppliers, duties to consumers of their goods to take reasonable care for their safety and allows people to sue for damages if they are injured because of a breach of such a duty. This is the cause of action in negligence.

In the present case, the applicants claimed damages for the injuries they allegedly suffered because of contraventions of the relevant provisions of the Trade Practices Act and because the respondents breached their duties of care in a number of respects. These claims were interrelated. The applicants argued that the devices cause a number of potentially serious complications but the respondents were so driven by commercial interests that they neglected to undertake the investigations reasonably necessary to inform themselves and the community of the extent, if not also the nature, of the risks posed by the devices and to take appropriate or sufficient remedial action. To the extent that the respondents were aware, the applicants argued, they failed to make adequate disclosure.

Shortly put, the applicants mounted the following case.

*First*, all of the Ethicon devices had a defect within the meaning of that term in the Trade Practices Act and none was fit for the particular purpose for which it was acquired or of merchantable quality. The Trade Practices Act provided that goods have a defect if their safety is “not such as persons generally are entitled to expect”. I will say more about this subject a little later. Except for the addition of the word “safety” before “defect”, the relevant provision of the Australian Consumer Law is identical.

*Second*, the information provided by the respondents in the instructions for use supplied with the devices and in promotional material they disseminated did not warn of certain risks of which the respondents knew or ought to have known and, in numerous respects, was misleading because of those omissions and because of false statements and half-truths contained in the documentation.

*Third*, the respondents failed to take reasonable care to evaluate the safety of the Ethicon devices both before and after they were taken to market.

*Fourth*, the applicants were injured because of the defect in the devices the respondents supplied to them and were therefore entitled to compensation.

*Fifth*, the applicants were injured because of the other contraventions of the legislation and the breaches by the respondents of their duties of care, and were therefore entitled to damages.

In substance, I have found that the applicants made out their case.

In my judgment I determine both the issues which were common to some or all members of the group and those issues which were unique to the individual applicants.

In this relatively brief summary, it is impossible to capture all my findings, let alone all my reasons. The summary is not a substitute for those reasons or a supplement to them. I encourage those who are interested in the case to read the judgment. I will limit my remarks to some of the more important matters and the most significant findings.

The meshes used in all the Ethicon devices are biomaterials, in that they are materials used in medical devices which are intended to interact with biological systems. It is generally accepted that a biomaterial will be biocompatible if it is able to perform with an appropriate host response in a specific situation. Importantly, the nature of the response to a particular material and its suitability for a particular application can vary from one situation to another. Where, as here, a biomaterial is intended for permanent implantation, for a biomaterial to be biocompatible it should not degrade in the body and should not have an adverse effect on the body’s tissues or systems. That a biomaterial may be suitable for implantation in one part of the body does not necessarily mean that it is suitable for implantation in another part.

The meshes are net-like in appearance. They contain multiple pores (or holes). They are designed in this way so as to allow the body’s tissues to grow through the mesh. Upon implantation, the mesh generates an inflammatory response, known as a foreign body reaction, which causes a layer of scar tissue to form through and around the mesh. The greater the amount of mesh used, the greater the foreign body reaction. In the case of a permanent implant, like the Ethicon devices, the inflammatory response lasts as long as the implant remains in the body.

The scar tissue enables the mesh to adhere to the healthy tissue. But the tissue reaction is not always predictable or uniform. It may vary in intensity from one patient to the next. For one reason or another, the immune system may generate an excessive reaction and serious complications may occur. The evidence established that the chronic inflammatory response is the primary cause of significant complications arising from the use of all synthetic meshes. The evidence also established that all the Ethicon meshes, or more accurately the integrated mesh and tissue, contract or shrink. The respondents disputed that mesh contraction was of clinical significance. But the evidence was overwhelmingly against them. It showed that mesh contraction can cause a number of complications including shortening and narrowing of the vagina, chronic pain, and pain with sexual intercourse. Some of that evidence was given by the respondents’ own expert witnesses. Some of it appeared in their own records.

The applicants pleaded that all the Ethicon devices could cause the following complications about which the respondents had provided no, or no adequate, warning:

* a chronic inflammatory reaction of the tissues surrounding or attached to the implants;
* extrusion or erosion of the mesh into surrounding organs, including the vaginal wall, bladder or urethra;
* infection;
* chronic pain;
* dyspareunia (the medical term for pain with sexual intercourse) and/or apareunia (avoidance of sexual intercourse);
* difficulty voiding;
* offensive vaginal discharge;
* new or recurrent urinary incontinence;
* damage to surrounding organs, nerves, ligaments, tissue and/or blood vessels;
* haemorrhage;
* leg weakness;
* reoperation or revision surgery associated with complications; and
* psychiatric injury.

The applicants pleaded that the POP devices could also cause these complications, as well as difficulty defaecating and the recurrence of prolapse. They also pleaded that all the Ethicon devices were difficult, if not impossible, to remove safely, that one or more surgical procedures might be required, and that removal carried the risk of new complications or of aggravating existing complications. In addition, the applicants pleaded that the respondents failed to give any or any sufficient information or warning to group members, their treating doctors and hospitals that “the chronic inflammatory response to the implants could be affected by conditions which affect the immune response and healing, including autoimmune and connective tissue disorders”.

In their defence, the respondents asserted that “all surgical procedures present risks”, but otherwise denied these allegations. The basis for the respondents’ denial was obscure. It was not apparent from their affidavit evidence, and early in the cross-examination of the first of their witnesses to testify, it quickly became clear that their denial was unsustainable.

The witness in question was Dr Piet Hinoul. Dr Hinoul was the only person to give evidence who worked (or had worked) for any of the three respondents. Dr Hinoul is a urogynaecologist. At the time of the trial he was the Vice-President of Medical Affairs at Ethicon Inc. He joined the Ethicon business in 2008 when he was appointed Director of Medical Affairs for Europe, the Middle East and Africa. Two years later he became the Worldwide Director of Medical Affairs (Women’s Health and Urology) for Ethicon Inc. Dr Hinoul’s evidence in chief cast the respondents’ conduct in the most favourable light. Although he was disinclined to make reasonable concessions, at times steadfastly defending the indefensible, there were a number of matters he could not deny. Those matters included what Ethicon knew about the complications of mesh implantation at the relevant times.

In cross-examination Dr Hinoul admitted that, from the time each of the Ethicon devices was supplied anywhere in the world, Ethicon knew that it could cause each of the pleaded complications. Those admissions were consistent with the information in Ethicon’s own records. In closing submissions the respondents informed the Court that they accepted that each of the pleaded complications was clinically significant.

Dr Hinoul also admitted in cross-examination that from the time each of the Ethicon devices was supplied anywhere in the world, Ethicon knew that:

* the foreign body reaction to surrounding tissue would create a scar, that the mesh could be subjected to a contracting force applied by surrounding scar tissue, that the response of the host tissue was variable, and that any significant degree of contraction could lead to pain as could the scarring itself;
* there was a risk of mesh exposure and extrusion into the vaginal canal or an organ;
* mesh exposure or extrusion could be difficult to treat, and that it could cause pain or discomfort;
* mesh erosion, extrusion and pain could occur many years after implantation, indeed that implantation carried a lifelong risk of erosion, pain, and the other pleaded complications;
* all the devices could cause both acute and chronic pain, that chronic pain could be very damaging and debilitating, indeed “life altering”, and that multiple operations might be necessary to attempt to alleviate the pain;
* the mesh from which the devices were made could be difficult, if not impossible, to remove safely or without complications and that, in the case of Prolift, it could be disastrous; and
* in the event of complications, the original condition — stress urinary incontinence or pelvic organ prolapse as the case may be — could recur.

Dr Hinoul maintained that many of the complications were rare. The foundation for his opinion was not clear. It is true that complaints made directly to the respondents about the devices amounted to a tiny fraction of the numbers of devices that were sold. But Dr Hinoul conceded that adverse events were under-reported and the weight of the evidence, including the scientific literature tendered by both sides, indicated that most of these complications were not rare.

Numerous reports of scientific studies were tendered. Some were concerned with the Ethicon devices. Some related to the performance of similar devices and similar and other modes of treatment. The evidence from the published studies was not always consistent and the quality of the studies was variable. After reviewing the evidence, giving weight to the higher quality studies and meta-analyses, I was satisfied that a number of the pleaded complications are not uncommon and that some are in fact common. The highest rates of complications have been reported with transvaginal prolapse surgery using the POP devices, where the quantities of mesh used were much greater than the quantities used in the SUI devices, and with the POP kits, in particular, where, in addition, the surgical techniques were difficult to master.

In my judgment I provide an account of the history of the use of polypropylene medical devices. It is sufficient in this summary to observe that Prolene was first used as a suture material, where it has been very successful. Later, Prolene, and later still Prolene Soft, were knitted into meshes for use in the abdominal wall for the repair of hernias. During the 1990s, surgeons experimented with the use of hernia mesh in the female pelvic floor in the hope of achieving more durable results from incontinence surgery. A number of single arm clinical trials were conducted by surgeons in Scandinavia. It was just a matter of time before similar experiments were undertaken using the same materials to reinforce the pelvic floor in prolapse repair. Ethicon capitalised on the work of the surgeons. Both Prolene mesh and Prolene Soft, however, were created for the purpose of reinforcing the abdominal wall without regard to the biomechanics or environment of the female pelvis. They were designed to sit flat against the abdominal wall in largely tension-free conditions. Ethicon assumed that the conditions in the female pelvis would not be materially different. In contrast to the abdomen, however, the pelvic floor is an area subject to a great deal of stress and strain. After Prolift was launched, a confidential PowerPoint presentation prepared by Ethicon researchers, apparently for internal use, acknowledged that “today’s vaginal implants do not consider the patients’ biomechanical needs” and recognised that “unmet biomechanics” lead to “misfunction, pain & shrinkage”, which in turn, leads to a “handicapped patient”. Ethicon began work on the design of a mesh adapted to the pelvic floor, but nothing eventually came of it and the project was abandoned in 2011.

The female genital area is also much more sensitive than the abdominal wall. And the environmental conditions are not the same. As two of Ethicon’s medical directors put it in a 2003 internal presentation, there is a “high risk of infection since [the] vagina is a septic cavity”.

Ethicon neglected to define the different physiological forces at work in the female pelvis or incorporate these considerations into the development of the Ethicon devices. To a considerable extent, that accounts for the problems encountered with the devices.

So how was this possible?

One reason was that the respondents saw the commercial opportunities presented by the new devices and were keen to exploit them before their competitors beat them to it. In the case of TVT and TVT-O, they were content to rely on studies conducted by the surgeon inventors on select groups of women without exploring whether similar results would be achieved in the wider population for which they designated and promoted the devices and without waiting for long-term results. In the case of Prolift, Ethicon started studies on a prototype but pressed ahead with the launch, without waiting until the studies had been completed. Senior Ethicon employees privately acknowledged that Prolift had been launched without clinical evidence and Prolift+M with little clinical evidence.

Another reason was that the respondents did not inform doctors or patients of the limitations of the available information, all the risks that could eventuate, how they could be effectively managed, or how they could be remedied.

The respondents were not oblivious to the importance of patient safety. They knew that doctors and patients wanted to be assured that their products were both safe and effective. They introduced changes to their devices which they believed or hoped would reduce the risk of injury. But they continued to promote and sell the older devices after the new and “improved” versions were introduced and they remained publicly coy about what they knew and did not know about all of them.

The Ethicon devices are subject to the Australian regulatory regime for therapeutic goods, administered by the TGA. As I mentioned earlier, in order for a medical device to be supplied in Australia it must be included in the ARTG. There are different ways of acquiring and maintaining registration. To secure inclusion on the ARTG for the Ethicon devices, JJM (as the Australian company supplying the goods) relied on the fact that the devices carried a “CE” mark, signifying that they had been cleared for sale in the European Union. “CE” is an acronym for the French words for European conformity.

In the European Union, medical devices must comply with certain directives. The Ethicon devices are subject to Directive 93/42/EEC, as amended from time to time. Included in this European Directive is a list of “essential requirements”. There are 14 such requirements, designed to protect patients and users from harm. The first requirement, for example, stipulates that a medical device is to be designed and produced in a way that ensures that it does not compromise health or safety when used on a patient under the conditions and for the purposes for which it is intended and that any risks associated with their use are outweighed by their intended benefits and compatible with a high level of protection of health and safety. The essential requirements cover such matters as design and construction safety, risk management, performance, and clinical evaluation. The presence of the CE mark on a medical device constitutes a representation by the manufacturer that the device conforms to the requirements of the European Directive and its essential requirements.

Nevertheless, the medical devices industry is largely self-regulating, at least to the following extent. The decision about whether the conditions for affixing CE marking and maintaining them have been satisfied is made by the manufacturer and it is the manufacturer who applies the mark. There is an independent audit process, but only of the manufacturer’s systems. While the auditors might review clinical data, verification of conformity is conducted on a sampling basis for most of the devices. The obligation to establish and maintain compliance with the regulatory requirements rests exclusively with the manufacturers. That was the position at all relevant times.

Moreover, when the Ethicon devices were entered in the ARTG, all but one class of device that had received CE marking were accepted for registration without the TGA conducting any independent assessment of their safety or efficacy and without the need for the manufacturer to demonstrate that independent pre-market testing of their safety and efficacy had been carried out. That meant that, with the exception of TVT Secur, the sole documentary requirement for inclusion in the ARTG for all of the Ethicon devices was evidence that they bore the CE mark. To register TVT Secur, JJM was also required to provide the TGA with further information, including an audit file.

The evidence about the regulatory requirements and the respondents’ compliance with them came from four well-qualified experts in the field, all of whom gave evidence for the applicants. They included a former director of the Therapeutic Devices Branch of the TGA, and three independent consultants in regulatory compliance, one from the United Kingdom and two from the United States, all with extensive industry experience. That evidence revealed widespread and systematic non-compliance with regulatory requirements, standards, and guidelines. The respondents called no experts to rebut this evidence. Three of the applicants’ regulatory experts were cross‑examined, but their evidence easily withstood the cross-examination. The respondents tried to marginalise the evidence, arguing that it was of peripheral relevance or not relevant at all. But they were wrong. Regulatory compliance or non-compliance was directly relevant to both the statutory and the common law claims.

The expert evidence established that none of the Ethicon devices satisfied all the requirements for CE marking either at the time the marks were applied or at any relevant time thereafter.

Amongst other things, before a medical device is allowed on the market, regulatory requirements and standards impose obligations on manufacturers to conduct sufficient pre-market evaluation of the device to justify its release to the market and, in particular, to demonstrate that any risks to health and safety which may be associated with its intended use are outweighed by the benefits it offers. Appropriate pre-market evaluation includes collecting clinical data; testing design controls; performing design validation; undertaking risk management assessments; and conducting comprehensive reviews and critical analyses of the scientific literature.

The evidence established that the pre-market evaluation of the devices undertaken by Ethicon was deficient in numerous respects, including the following.

*First*, Ethicon conducted no or no adequate clinical trials on the devices before taking them to market. TVT, TVT-O, Prolift, and Prosima, for example, were all developed on the basis of studies conducted by surgeons on select groups of patients. No clinical trials were conducted on Gynemesh PS. Although the Ethicon meshes were intended for permanent implantation and indicated for use in a wide range of patients, before they were made available for sale, none of the Ethicon devices was subjected to a comparative trial, let alone a randomised controlled trial, to assess its relative safety and efficacy in comparison to other forms of surgical repair. Nor did Ethicon conduct a trial in a large enough population group representative of all the women for whom the device was indicated and for a sufficient period of time to enable reliable conclusions to be drawn about its long-term safety or efficacy. Email correspondence revealed that even JJM’s Medical Director, no less, expressed concern that TVT Secur had been launched without enough clinical data to justify the roll-out.

*Second*, critical documents that manufacturers are required to create and maintain were missing from Ethicon’s design history and technical files.

*Third*, no overarching, cohesive risk management system was in place. Risk management assessments were largely treated as a box-ticking exercise. Some harms and hazards associated with the devices, of which Ethicon was well aware, were not assessed, and, as a result, were not mitigated. Where harms and hazards were assessed, they were rarely escalated for further review or action and were therefore not remediated.

*Fourth*, the clinical evaluations of all the devices which were relied upon to support CE marking did not satisfy the requirements of the Directive.

After a medical device enters the market, manufacturers have continuing obligations to monitor and study its performance. There are extensive regulatory requirements and guidelines for conducting appropriate post-market surveillance of medical devices. Appropriate surveillance includes conducting clinical studies and follow-up; reviewing design performance; undertaking risk management assessments; reviewing user complaints; investigating adverse events; and deciding on corrective or preventative actions.

The evidence showed that Ethicon’s post-market surveillance was also deficient in multiple respects.

*First*, post-market surveillance was essentially passive or reactive, when it should have been proactive. Sponsored studies were conducted primarily for marketing purposes.

*Second*, the problems with Ethicon’s risk management continued. The procedures did not conform to regulatory requirements. Furthermore, no genuine risk analyses were carried out and certainly none that complied with the regulatory requirements and standards.

*Third*, clinical evaluation reports did not comply with regulatory requirements and were not routinely or regularly prepared. In the case of TVT, for example, 10 years or more passed before the first post-market report was produced. In the case of Gynemesh PS, it was seven years, and for Prolift, five. Conclusions were formulaic and were not justified by the material upon which they relied. In some instances, it was clear that text from one report had been copied and pasted into another without regard to the relevance of the new context. For the most part, these reports could scarcely be described as evaluations at all, let alone critical analyses. Instead, they were generally highly selective and often, if not invariably, overlooked the limitations of the data and the unfavourable parts of the articles they cited and the reservations or qualifications that were made in them. The methodology was also problematic.

*Fourth*, Ethicon’s system for complaints reporting and analysis was inadequate. The complaints to Ethicon from surgeons and patients were not fully evaluated, acted upon, or properly fed back into the risk management process. In some cases, they were ignored altogether.

On the basis of these failings and others, outlined at length in my judgment, the expert witnesses concluded that Ethicon’s post-market evaluation of the devices was inadequate and did not meet regulatory standards. I accepted their evidence. Not only was there no independent expert evidence to contradict it, but their conclusions were also supported by a number of documents tendered by the applicants that showed that deficiencies in Ethicon’s post-market evaluation of the devices had been identified and raised with the respondents on multiple occasions by its own auditors, the TGA, and other regulatory bodies.

That brings me to the warnings and information the respondents provided about the Ethicon devices.

For almost all of the time with which this proceeding is concerned, few of the pleaded complications or the inadequacies of Ethicon’s clinical evaluations were disclosed in the instructions for use issued with the devices or in any of the promotional material that was tendered in evidence. Substantial amendments to the instructions for use were made in 2015 after intervention, first by the Canadian regulator, Health Canada, and later by the TGA, but I found that the amended versions still provided inadequate and, in some respects, misleading accounts of the effects of implantation and the risks of the pleaded complications. The promotional material, which included product brochures produced by both Ethicon and JJM, minimised the harm the devices could cause while at the same time exaggerating their benefits.

A few examples will suffice.

In all the instructions for use supplied with all the Ethicon devices, the respondents represented that the mesh elicited a minimal to slight inflammatory reaction which was “transient” or “transitory” when they knew that the reaction was not invariably minimal to slight and that it was never transient or transitory. As the Associate Medical Director of Ethicon’s Worldwide Customer Quality division said in an email to a colleague, “from what I see each day, these patient experiences are not ‘transitory’ at all”.

The first version of the instructions for use issued with TVT did not warn of the risk of mesh erosion. Although later versions did list erosion and extrusion as potential adverse reactions, they did so in a way that was misleading or deceptive. The respondents represented that extrusion and erosion were possible consequences of the so-called transitory foreign body response. In so doing, there was a real chance that a not insignificant number of doctors and patients would conclude that those consequences could only occur soon after the devices were implanted when the respondents knew that they could occur years later.

It was not until April 2015, and then only after the intervention of the regulators, that the respondents first warned that any of the devices could *cause* infection. Before then, the warning they gave was that infection could be “potentiated”, that is to say that the effect or potency of an existing infection could be increased. Yet the evidence was that the meshes used in all the Ethicon devices were susceptible to an increased risk of secondary, mesh-related infections as a result of bacteria that colonises the mesh during implantation and that, when the mesh erodes or is exposed, the vagina “inevitably” or “almost certainly” becomes infected.

Furthermore, while the instructions for use stated that the mesh could potentiate an infection, a brochure published by JJM boasted that Prolene Soft, which it will be recalled was the mesh used in Prolift, Gynemesh PS and Prosima “does not potentiate infection”.

The 2015 versions of the instructions for use for all the SUI devices that were still on the market added a warning in these terms: “As with all surgical procedures, there is a risk of infection”. But this warning was also deficient. It minimised the significance of the risk in three ways: *first*, it intimated that the risk of infection was no greater than with any other surgical procedure; *second*, it implied that implantation of the mesh could not cause infection; and *third*, it failed to mention the risk of late-onset infections.

In product brochures for TVT, TVT-O and TVT Abbrevo, the answer given to the question “Will I have pain after the operation?” was that “some mild pain” may occur over 24 or 48 hours after surgery, which “may be controlled by simple pain relief”. Thus, not only was the risk of chronic pain not disclosed, but the clear inference was that there was no possibility of chronic pain, severe pain, or pain months or years after implantation when, to the knowledge of the respondents, the reality was otherwise. It was not until 2015, by which time TVT had been on the market for over 16 years and the POP devices were no longer being supplied, that the respondents warned of the risk of chronic pain, and then only at the behest of the TGA.

The respondents did not inform doctors or patients that the chronic inflammatory response to implantation could be affected by the presence of autoimmune, connective tissue and like disorders which affect the immune response to healing. The first allusion in any of the instructions for use appeared in the Prolift+M document first in use in December 2008. But it merely stated that “in patients with compromised immune systems or other conditions that would compromise healing the risks and benefits should be carefully weighed”. The first reference to a warning suggestive of the possibility that some patients are more susceptible to complications than others appeared in the September 2015 edition of the instructions for use for TVT Exact. It counselled physicians to use their surgical experience and judgment to determine if Prolene mesh was appropriate for certain patients and stated that “patient-specific factors may impair wound healing, which may increase the likelihood of adverse reactions”, but it offered no guidance as to what those factors might be.

Brochures for the SUI devices intimated, despite what Ethicon actually knew, that the use of those devices would cause “no late onset adverse events”, no tape erosion, and no tissue reactions.

A 2005 Prolift brochure represented that Prolene Soft was “specially designed for placement through the vagina to support [prolapsed] pelvic organs”, when in fact it was the same mesh designed to reinforce the abdominal wall. In an internal email the Director of Worldwide Risk Management for Ethicon Inc. said of this representation:

This mesh was not “specifically designed” for Prolift application, we pulled a mesh out of our existing bag of tricks. This statement is unsupportable from (*scil*) a design history standpoint.

In an internal presentation some three years after Prolift was launched, Ethicon researchers observed that there was still no evidence of a device created specifically for the female pelvis.

The respondents argued that surgeons would be expected to inform themselves of the risks associated with the use of the Ethicon devices, so that the shortcomings of the documents were of little moment. Not only did that argument pay no heed to the regulatory requirements, but it also ignored the fact that in their product brochures the respondents directed readers to the instructions for use “for *complete* contraindications, warnings, precautions, and adverse reactions” (emphasis added). Furthermore, when Dr Hinoul was cross-examined on the statements about pain made in the brochure for the SUI devices, he agreed that the respondents would have no reason to expect that a surgeon would deliver a different message about a device than the information given in the product brochure, including as to the risk of pain.. He also agreed that an ordinary, reasonable patient reading the brochure would expect not to suffer long-term pain as a complication.

And now to my findings on liability.

I will deal first with the applicants’ statutory claims.

The applicants’ central statutory claim was that the devices were supplied with a defect within the meaning of the Trade Practices Act. It was common ground that, if the applicants succeeded on their defective goods claim, then they were entitled to succeed on two other statutory counts, the first that the devices were unfit for the particular purpose for which they were acquired; and the second that they were of unmerchantable quality. Consequently, it is sufficient for me to refer only to the defective goods claim.

In determining whether a product has a defect, in that its safety is less than persons generally are entitled to expect, all relevant circumstances must be taken into account. The Act stipulates that those circumstances include the manner in which, and the purposes for which, the goods have been marketed; their packaging; the use of any mark in relation to them; any instructions for, or warnings with respect to doing, or refraining from doing, anything in relation to them; what might reasonably be expected to be done with, or in relation to, them; and the time when they were supplied by the manufacturers.

In this case, the relevant goods were marketed as safe and effective in the treatment of the conditions for which they were indicated. Risks were minimised or not mentioned at all. The use of the CE mark constituted a representation that the Ethicon devices met the requirements for CE marking and that the manufacturers had taken the necessary steps to enable them to apply the mark. I held that persons generally are entitled to expect as much.

The case law establishes that a product may have a defect even if the defect is one which only affects some people. While the law does not require that goods be absolutely free of risk, it does require that manufacturers and suppliers disclose the risks. Unless a manufacturer provides frank warnings about the risks associated with the use of its products, medical devices included, persons generally are entitled to expect that the products do not carry those risks.

I rejected the respondents’ submission that, if particular complications could arise from any form of pelvic floor surgery, it was reasonable for manufacturers to expect that treating surgeons knew about them and that they need not refer to them in the instructions for use supplied with the devices. I considered that the submission did not reflect the position at law.

Having regard to all the relevant circumstances, a snapshot of which appears in the earlier part of this summary, I was satisfied that at all relevant times all the Ethicon devices had a defect. It follows from the common position taken by the parties that at all such times all the Ethicon devices were also unfit for the particular purposes for which they were acquired and of unmerchantable quality. While there were some differences between the various devices, the techniques used to implant them, and the extent of the harm they could cause, the differences were not material for present purposes. All the devices carried risks of complications the respondents admitted were clinically significant, against which no adequate warnings were given, and about which doctors and patients alike could have been misled. None of them satisfied all the essential requirements for CE marking. In essence, the Ethicon devices were oversold, that is to say, they were promoted to doctors as suitable for most patients when they had not been adequately evaluated, when they carried significant risks, and when the respondents had not provided sufficient guidance about the nature or extent of the risks, the management of those risks, or the patients who were most at risk.

I was also persuaded that the POP kits were only ever suitable for use in the context of a clinical trial, and then only with appropriate warnings about the nature and extent of the potential complications. Even if they could be said to have been suitable for use in treatment of severe cases of pelvic organ prolapse or where alternative surgical treatment had failed or where there was a high risk of recurrence or in highly experienced hands and for a highly select group of patients, they were sold without such limitations.

I rejected the statutory defence pleaded by the respondents that the state of scientific or technical knowledge at the time the Ethicon devices were supplied was not such as to enable the defects to be discovered. While the evidence showed that with the passage of time there was an increase in knowledge about certain matters, the respondents did not prove that the knowledge that was available at the relevant times was not such as to enable the defects to be discovered. Indeed, before any of the devices were supplied, the respondents were admittedly aware of the relevant risks. The inadequate information they provided about them was a problem of their own making.

Consequently, I found that the respondents were liable to compensate any applicant and/or group member who suffered an injury because of the defect for the amount of the loss and damage she sustained as a result of that injury.

I found that Mrs Gill was injured because of the defect in Prolift Total, that Mrs Dawson was injured because of the defect in Gynemesh PS, and that Mrs Sanders was injured because of the defect in TVT.

Based on the representations made in the instructions for use and the marketing material, I also found that the respondents engaged in misleading or deceptive conduct.

Each of the sections of the Trade Practices Act and the Australian Consumer Law alleged to have been contravened applies to conduct by corporations in trade or commerce.

In their defence, the Ethicon companies denied that their conduct was in trade or commerce. But “trade or commerce” is defined in both the Trade Practices Act and the Competition and Consumer Act to mean “trade or commerce within Australia or between Australia and places outside Australia”. I held that the phrase plainly includes the export to Australia of foreign‑made goods.

The Ethicon companies also argued that none of the statutory causes of action applied to them because neither of them had a place of business in Australia and because the applicants had not established that they carried on business in Australia during the relevant period.

I did not accept either argument. I considered that the first was based on a misinterpretation of the legislation. As to the second, I noted the admission in the defence that the Ethicon companies supplied the devices to JJM for sale in Australia throughout the period covered by the applicants’ pleading and found that, amongst other things, by supplying the Ethicon devices on a regular basis to an Australian company and, together with that company, promoting them for the purpose of sale to Australian consumers, the Ethicon companies were carrying on business in Australia.

I now turn to the applicants’ claims in negligence.

I found that all three respondents were obliged to exercise reasonable care in the supply and marketing of the devices. I held that that duty extended to providing accurate information about the performance and safety of the devices and information that was not apt to mislead, including warnings about all but one of the pleaded complications. I held that the duty was not confined to the period before the devices were made or placed on the market, but was a continuing obligation to evaluate their safety, keep abreast of information about the nature and extent of potential complications, and to convey that information to users of the devices.

In the case of the two Ethicon companies, I found that they also had a duty to take reasonable care in the design, testing and evaluation of the devices. I was not persuaded, either as a matter of law or fact, however, that the scope of JJM’s duty was that extensive. Rather, the duty of care owed by JJM, as the supplier but not the manufacturer, was to take reasonable steps to ensure that the information they conveyed about the devices was accurate, not misleading, and sufficient to alert both medical practitioners and prospective patients about the true risks associated with the use of the devices.

The applicants claimed the respondents breached their duties of care in three ways.

The first alleged breach was that the respondents failed to conduct adequate pre-market evaluation of the Ethicon devices.

I found that the pre-market evaluations conducted by Ethicon evinced a want of reasonable care for the safety of the women for whose benefit they were intended and promoted. As I have observed, the expert evidence established that none of the Ethicon devices satisfied the requirements to justify applying a CE mark in order to release them to market. Its clinical evaluation reports were manifestly inadequate. It had no cohesive risk management system and its design control and validation processes were flawed. Amongst other things, Ethicon failed to address all known hazards. It failed to eliminate or reduce risks as far as possible. And it failed to inform users of all residual risks. I held that a reasonably prudent manufacturer would not have acted in this way.

The second alleged breach was that the respondents failed to conduct adequate post-market evaluation of the devices.

I found that Ethicon’s post-market evaluation of all the devices was also deficient and fell well below the standard of care required of a reasonably prudent manufacturer. Post-market clinical evaluation was haphazard and for years the requirement for preparing clinical evaluation reports was overlooked, if not ignored. The reports that were eventually prepared were wanting in numerous respects. Ethicon’s procedures for risk management and clinical evaluation did not conform to regulatory requirements. Its complaints review system was flawed. It tended to minimise the significance of complaints and to avoid responsibility for adverse events.

The third alleged breach was that the respondents failed to provide any or any adequate information, advice or warnings about the pleaded complications and the absence of any, or any adequate, clinical or other evaluation of the risks.

I found that the information about the potential risks in the instructions for use and promotional material provided by the respondents did not conform to the standard required of a reasonably prudent manufacturer or supplier in their position. It fell well short of capturing all known, let alone reasonably foreseeable, risks and was apt to mislead both doctors and patients about the safety and efficacy of the various devices.

In the light of these findings and other matters discussed in the reasons for judgment, I held that each of the respondents was negligent. The risks were known, not insignificant, and on the respondents’ own admission, could cause significant and serious harm if they eventuated. A far more cautious approach was warranted than the respondents took.

The respondents pleaded that all the claims made by Mrs Gill and Mrs Sanders were out of time and argued that, on the assumption that the Court had power to extend the period, the Court should not exercise the power in their favour. With one exception, I found against the respondents on both matters.

With the exception of Mrs Sanders’ claim for damages for misleading or deceptive conduct, I found that none of the claims either of them brought under the Trade Practices Act was out of time. I rejected the respondents’ contention that Mrs Sanders’ other statutory claims had to fail because this proceeding was commenced more than 10 years after she was supplied with TVT, since the point was never pleaded against her and no application to amend the defence to do so was ever made. Notwithstanding their submission to the contrary, I determined that, since they had not raised the matter in their defence, it was not open to them to rely on it.

I found that Mrs Gill’s common law action was out of time, but I decided that the Court had the power to extend the limitation period and that it is appropriate to exercise that power in her favour. I concluded that extending the time would not cause significant prejudice to the respondents and that the delay in the commencement of the action would not unacceptably diminish the prospects of the respondents receiving a fair trial.

I found that Mrs Sanders’ action in negligence was out of time, too, but I also found that she was entitled to apply for an extension of time, as she did. I was satisfied that I had the power to grant an extension. As was the case with Mrs Gill, the respondents did not suggest they would be prejudiced if I were to exercise that power and made no submissions on how the discretion should be exercised.

In the circumstances, I extended the limitation periods to enable both Mrs Gill and Mrs Sanders to prosecute their claims in negligence.

I assessed damages for all three applicants while leaving some of the arithmetic to the lawyers. I also considered that orders should be made for both declaratory and injunctive relief. Before I make any final orders, however, as is commonplace in this kind of litigation I intend to give the parties a reasonable opportunity to read the judgment and to agree upon the orders necessary to give effect to my reasons. In the meantime, each of the applicants will need to make an election as to whether she wishes to receive damages under the Trade Practices Act or at common law. Consequently, I will now make programming orders to ensure that these steps are taken. That means that final orders, including the awards with respect to damages, are unlikely to be made before mid-February next year.