FEDERAL COURT OF AUSTRALIA

Ethicon Sàrl v Gill [2021] FCAFC 29

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| File number: |  |
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| Judgment of: | **JAGOT, MURPHY AND LEE JJ** |
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| Date of judgment: | 5 March 2021 |
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| Catchwords: | **CONSUMER LAW** - defective goods - urogynaecological medical devices - whether primary judge erred in finding safety of devices not such as persons generally were entitled to expect - whether primary judge erred in finding devices not of merchantable or acceptable quality, or not reasonably fit for purpose within meaning of *Trade Practices Act 1974* (Cth) or the *Australian Consumer Law* - whether primary judge erred in finding respondents’ damage caused by defect  **CONSUMER LAW** - misleading or deceptive conduct - information in connection with devices, instructions for use and marketing - whether primary judge erred in finding appellants engaged in misleading or deceptive conduct - whether primary judge erred in finding third respondent’s damage caused by misleading or deceptive conduct  **NEGLIGENCE** - medical devices - duty of care - whether primary judge erred in finding appellants breached duty of care - inadequate pre-market and post-market evaluations of safety of devices - inadequate warnings of material risks of devices - standard of care - breach - regulatory environment - causation - onus of proof - application of ss 5C and 5D of the *Civil Liability Act 2002* (WA) and ss 51 and 52 of the *Wrongs Act 1958* (Vic)  **LIMITATION OF ACTIONS** - whether primary judge erred in finding that first and third respondents’ claims in negligence were not statute barred - onus of proof - application of *Limitation Act 1935* (WA) and ss 39(3) and (4) of *Limitation Act 2005* (WA)  **OTHER RELIEF** - whetherprimary judge erred in granting injunction enjoining appellants from supplying, distributing, marketing or promoting devices in Australia without warning or advice |
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| Legislation: | *Civil Liability Act 2002* (WA)  *Competition and Consumer Act 2010* (Cth)  *Evidence Act 1995* (Cth)  *Federal Court of Australia Act 1976* (Cth)  *Judiciary Act 1903* (Cth)  *Limitation Act 1935* (WA)  *Limitation Act 2005* (WA)  *Therapeutic Goods Act 1989* (Cth)  *Trade Practices Act* *1974* (Cth)  *Trade Practices Amendment Bill 1992* (Cth)  *Trade Practices Amendment (Personal Injuries and Death) Act 2004 (No 2)* (Cth)  *Trade Practices Amendment (Australian Consumer Law) Act (No. 2) 2010* (Cth)  *Wrongs Act 1958* (Vic)  *Federal Court Rules 2011* (Cth)  *Therapeutic Goods (Medical Devices) Regulations* 2002 (Cth)  Explanatory Memorandum, *Trade Practices Amendment Bill 1992* (Cth)  Federal Food, Drug and Cosmetic Act 1938 (US)  Federal Rules of Civil Procedure (US) |
|  |  |
| Cases cited: | *A v National Blood Authority* [2001] 3 All ER 289  *Aldi Foods Pty Ltd v Moroccanoil Israel Ltd* [2018] FCAFC 93; (2018) 261 FCR 301  *Amaca Pty Ltd v Hannell* [2007] WASCA 158; (2007) 34 WAR 109  *AstraZeneca Pty Ltd v GlaxoSmithKline Australia Pty Ltd* [2005] FCA 1645  *Australian Competition and Consumer Commission v 4WD Systems Pty Ltd* [2003] FCA 850; (2003) 200 ALR 491  *Australian Executor Trustees (SA) Limited v Kerr* [2021] NSWCA 5  *Axon v Axon* [1937] HCA 80; (1937) 59 CLR 395  *Banque Commerciale SA en Liquidation v Akhil Holdings Ltd* [1990] HCA 11; (1990) 169 CLR 279  *Bennett v Minister of Community Welfare* [1992] HCA 27; (1992) 176 CLR 408  *Betfair Pty Ltd v Racing New South Wales and Anor* [2010]FCAFC 133; (2010) 189 FCR 356  *Black v Lipovac (by his next friend Lipovac)* [1998] FCA 699; (1998) 217 ALR 365  *BMW Australia Limited v Australian Competition and Consumer Commission* [2004] FCAFC 167; (2004) 207 ALR 452  *Branir v Owston Nominees (No 2)* [2001] FCA 1833; (2001) 117 FCR 424  *Butcher v Lachlan Elder Realty Pty Ltd* [2004] HCA 60; (2004) 218 CLR 592  *Campbell v Backoffice Investments Pty Ltd* [2009] HCA 25; (2009) 238 CLR 304  *Carey-Hazell* *v Getz Bros & Co (Aust) Pty Ltd* [2004] FCA 853; (2004) ATPR 42-014  *Chappel v Hart* [1998] HCA 55; (1998) 195 CLR 232  *Commercial Union Assurance Co of Australia Ltd v Ferrcom Pty Ltd* (1991) 22 NSWLR 389  *Commonwealth v McLean* [1996] NSWSC 657; (1996) 41 NSWLR 389  *Dyczynski v Gibson* [2020] FCAFC 120; (2020) 381 ALR 1  *Ethicon Sàrl* *v Gill* [2018] FCAFC 137; (2018) 264 FCR 394  *Femcare Ltd v Bright* [2000] FCA 512; (2000) 100 FCR 331  *Forrest v Australian Securities and Investments Commission* [2012] HCA 39; (2012) 247 CLR 486  *Fox v Percy* [2003] HCA 22; (2003) 214 CLR 118  *Gill v Ethicon SÀRL* [2018] FCA 470  *Gill v Ethicon Sàrl* *(No 3)* [2019] FCA 587; (2019) 369 ALR 175  *Gill v Ethicon Sàrl (No 5)* [2019] FCA 1905  *Gill v Ethicon Sàrl (No 6)* [2020] FCA 279  *Gill v Ethicon Sàrl (No 8)* [2020] FCA 771  *Graham Barclay Oysters Pty Ltd v Ryan* [2002] HCA 54; (2002) 211 CLR 540  *Hollis v Dow Corning Ltd* [1995] 4 SCR 634  *Hunt & Hunt Lawyers v Mitchell Morgan Nominees Pty Limited* [2013] HCA 10; (2013) 247 CLR 613  *ICI Australia Operations Pty Ltd v Trade Practices Commission* [1992] FCA 707; (1992) 38 FCR 248  *Jones v Dunkel* [1959] HCA 8; (1959) 101 CLR 298  *Lee v Lee* [2019] HCA 28; (2019) 266 CLR 129  *March v E & MH Stramare Pty Ltd* [1991] HCA 12; (1991) 171 CLR 506  *McLean v Tedman* [1984] HCA 60; (1984)155 CLR 306  *Merck Sharp & Dohme (Australia) Pty Ltd v Peterson* [2009] FCAFC 26; (2009) 355 ALR 20  *Merck Sharp & Dohme (Australia) Pty Ltd v Peterson* [2011] FCAFC 128; (2011) 196 FCR 145  *Naxakis v Western General Hospital* [1999] HCA 22; (1999) 197 CLR 269  *Parkdale Custom Built Furniture Pty Ltd v Puxu Pty Ltd* (1982) 149 CLR 191  *Peterson v Merck Sharpe & Dohme (Aust) Pty Ltd* [2010] FCA 180; (2010) 184 FCR 1  *Pilato v Metropolitan Water Sewerage & Drainage Board*  (1959) 76 WN (NSW) 364  *Precision Plastics Pty Limited v Demir* (1975) 132 CLR 362  *Purkess v Crittenden* [1965] HCA 34; (1965) 114 CLR 164  *Rogers v Whitaker* [1992] HCA 58; (1992) 175 CLR 479  *Rosenberg v Percival* [2001] HCA 18; (2001) 205 CLR 434  *Rural Press Ltd v Australian Competition and Consumer Commission* [2003] HCA 75; (2003) 216 CLR 53  *Scope Machinery Pty Ltd v Ross* [2009] WASCA 100  *State Rail Authority of New South Wales v Earthline Constructions Pty Limited (in liq)* [1999] HCA 3; (1999) 160 ALR 588  *Strong v Woolworths Ltd* [2012] HCA 5; (2012) 246 CLR 182  *Taco Company of Australia Inc v Taco Bell Pty Ltd* [1982] FCA 170; (1982) 42 ALR 177  *Timbercorp Finance Pty Ltd (in liquidation) v Collins* [2016] HCA 44; (2016) 259 CLR 212  *Trade Practices Commission v Mobil Oil Australia Ltd* [1984] FCA 403; (1984) 4 FCR 296  *Vairy v Wyong Shire Council* [2005] HCA 62; (2005) 223 CLR 422  *Vale v Sutherland* [2009] HCA 26; (2009) 237 CLR 638  *Wallace v Kam* [2013] HCA 19; (2013) 250 CLR 375  *Wilkes v DePuy International Ltd* [2016] EWHC 3096 (QB); [2017] 3 All ER 589  *Wyong Shire Council v Shirt* [1980] HCA 12; (1980) 146 CLR 40 |
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|  | Young PW, *Declaratory Orders* (2nd ed, Butterworths, 1984) |
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| Division: | General Division |
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| Registry: | New South Wales |
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| National Practice Area: | Commercial and Corporations |
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| Sub-area: | Regulator and Consumer Protection |
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| Number of paragraphs: | 928 |
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| Dates of hearing: | 1-9 February 2021 |
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| Counsel for the Appellants: | B Walker SC with K Morgan and D Wong |
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| Solicitor for the Appellants: | Clayton Utz |
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| Counsel for the Respondents: | A Bannon SC with A Naylor, C Colquhoun and Z Hillman |
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| Solicitor for the Respondents: | Shine Lawyers |

ORDERS

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|  | | NSD 391 of 2020 |
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| BETWEEN: | ETHICON SÀRL  First Appellant  ETHICON INC  Second Appellant  JOHNSON & JOHNSON MEDICAL PTY LIMITED ACN 000 160 403  Third Appellant | |
| AND: | KATHRYN GILL  First Respondent  DIANE DAWSON  Second Respondent  ANN SANDERS  Third Respondent | |

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| order made by: | JAGOT, MURPHY AND LEE JJ |
| DATE OF ORDER: | 5 MARCH 2021 |

THE COURT ORDERS THAT:

1. Subject to order 2, the appeal be dismissed.

2. By 4pm on 19 March 2021 the parties provide:

(a) any competing submissions as to the costs of the appeal;

(b) an agreed or competing form of order addressing the issue referred to in [812] to [818] of the reasons of the Full Court (**s 33ZB order**); and

(c) any submissions, limited to five pages, relied upon by to support any dispute as to the appropriate costs order and form of s 33ZB order (with any such dispute to be thereafter resolved by the Full Court on the papers).

Note: Entry of orders is dealt with in Rule 39.32 of the *Federal Court Rules 2011*.

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REASONS FOR JUDGMENT

THE COURT:

##### 1. THE APPEAL

###### 1.1 The proceedings before the primary judge

1 In *Gill v Ethicon Sàrl (No 5)* [2019] FCA 1905 (**TJ**) the primary judge held the appellants (the respondents in the proceedings below) liable for damages in connection with the supply of nine medical devices in Australia (the **devices**). Five of the devices were intended for use in the treatment of female stress urinary incontinence (**SUI**). They are known as Gynecare Tension-free Vaginal Tape System (**TVT**), Gynecare TVT Obturator System (**TVT-O**), Gynecare TVT Secur System (**TVT Secur**), Gynecare TVT Exact Continence System (**TVT Exact**) and Gynecare TVT Abbrevo Continence System (**TVT Abbrevo**), and are together referred to as the **SUI devices**. The other four devices were intended for use in the treatment of female pelvic organ prolapse (**POP**). They are known as Gynecare Gynemesh Prolene Soft (**Gynemesh PS**), Gynecare Prolift Pelvic Floor Repair System (**Prolift**), Gynecare Prolift+M Pelvic Floor Repair System (**Prolift+M**) and Gynecare Prosima Pelvic Floor Repair System (**Prosima**), and are together referred to as the **POP devices**.

2 The respondents to the appeal (the applicants in the proceedings below) succeeded on all the pleaded causes of action. The three representative applicants in the class action (the respondents to the appeal), Kathryn Gill, Diane Dawson, and Ann Sanders, were awarded damages for loss and injury caused to them by the device with which they had been implanted. Mrs Gill had POP and was implanted with a Prolift device on 12 January 2007. Mrs Dawson also had POP and was implanted with Gynemesh PS on 8 May 2009. Mrs Sanders suffered from SUI and was implanted with TVT on 12 March 2001.

3 In *Gill v Ethicon Sàrl (No 6)* [2020] FCA 279 (**RJ**) the primary judge quantified the damages payable to the representative applicants ($1,276,113 to Mrs Gill, $555,555 to Mrs Dawson and $757,372 to Mrs Sanders), answered common questions in the proceedings, and granted an injunction (the **Injunction**). The common questions and the answers to them are set out in **Schedule A**. The Injunction is set out in **Schedule B**. The Injunction relates to the four SUI devices which remain on the market. None of the POP devices is currently on the Australian Register of Therapeutic Goods (**ARTG**) so that those devices can no longer be sold in Australia. One of the SUI devices, TVT Secur, was also removed from the ARTG and has not been sold in Australia since 2008.

###### 1.2 The issues in the appeal

4 The appellants (also referred to as **Ethicon** below, where it is not necessary to distinguish between them) challenge the trial judgment in which the primary judge held them liable for contraventions of the *Trade Practices Act* *1974* (Cth) (the **TPA**) and Sch 2 to the *Competition and Consumer Act 2010* (Cth) (the **CCA**), the *Australian Consumer Law* (the **ACL**) and for negligence.

5 The primary judge held the appellants liable for contraventions of:

 s 75AD of the TPA in that the devices were supplied with a “defect” and s 138 of the ACL because they were supplied with “a safety defect”;

 s 74D of the TPA in that the devices were not of merchantable quality and did not comply with the guarantee given by s 54 of the ACL in that they were not of acceptable quality;

 s 74B of the TPA in that the devices were not reasonably fit for the particular purpose for which they were acquired by the group members and not fit for the disclosed purpose under s 55 of the ACL; and

 s 52 of the TPA and s 18 of the ACL in that the information the respondents released in connection with the devices, including the instructions for use accompanying the devices (the **IFUs**), and the way in which they were marketed and promoted was misleading or deceptive or likely to mislead or deceive consumers: TJ [15].

6 Insofar as the common law claims for negligence are concerned, the primary judge held the appellants liable for breaching their duty of care to Mrs Gill, Mrs Dawson and Mrs Sanders by:

 failing to undertake any, or any adequate, clinical or other evaluation of the devices before releasing them in Australia;

 failing to conduct any, or any adequate, evaluation of safety and effectiveness of the devices after their release in Australia; and

 failing to inform them, their treating doctors, and/or the hospitals in which the treatments were administered, of the inadequate evaluations about, and the risks of, or susceptibilities to, complications of the kinds from which they suffered: TJ [16].

7 The appellants contend that the primary judge erred on 17 grounds as follows.

1.2.1 Defects

8 ***Ground 1***: the primary judge erred (including at TJ [3458], [3496], [3499]) in finding that the safety of each of the nine devices was not such as persons generally were entitled to expect because the primary judge:

(1) did not properly consider or give sufficient weight to the evidence of the pelvic surgeons in relation to clinical considerations and the different safety profiles of each of the devices, and their safety profiles relative to other surgical and nonsurgical alternatives;

(2) preferred the evidence of non-clinical experts and relied on the findings about the appellants’ awareness (including relevant clinical significance) of the pleaded complications; and

(3) did not properly consider or give sufficient weight to the differences between the five SUI devices and the four POP devices (comprising the three pelvic floor repair systems and Gynemesh PS).

Had this evidence been properly considered, the primary judge would not have concluded that each of the devices had a defect or a safety defect because that evidence established, when viewed in the context of clinical considerations, the benefit-risk profile for each device was such as persons generally were entitled to expect.

9 ***Ground 2***: the primary judge erred:

(1) in using the conclusions of non-compliance with the requirements for Conformité Européenne marking (**CE marking** or the **CE Mark**) to find that (at TJ [3458], [3496], [3499]) the safety of each of the devices was not such as persons generally were entitled to expect because:

(a) the case pleaded, particularised or advanced by the respondents was not based on the CE Mark or any representation said to be made by the CE Mark; and/or

(b) using conclusions of non-compliance with the requirements for CE marking was inconsistent with the primary judge’s finding that most surgeons would not have any appreciation of the path of regulatory clearance for medical devices (TJ [3250]); and/or

(c) the primary judge had no evidence as to any Australian surgeon’s or patient’s understanding or appreciation of the CE Mark and made no relevant finding (other than at TJ [3250]) as to a person’s understanding or appreciation of the CE Mark; and/or

(d) contrary to the primary judge’s finding (at TJ [3270], [3272]) the CE Mark and clearance for sale was not a representation in Australia that the devices met “regulatory requirements and standards”, and

(2) in the alternative, in placing too much weight (at TJ [3272]) on the conclusion of any non-compliance with the requirements for CE marking in finding that each device had a defect or a safety defect within the meaning of the TPA or the ACL.

10 ***Ground 3***: as a consequence of grounds 1 and/or 2 above, the primary judge erred in finding that each of the devices was not of merchantable or acceptable quality, or was not reasonably fit for purpose within the meaning of the TPA or the ACL.

11 ***Ground 4***: as a consequence of grounds 1 and/or 2 above, the primary judge erred in finding that:

(1) because Mrs Gill suffered damage caused by her Prolift, she suffered damage caused by the defect, because it was not of merchantable quality, or because it was not reasonably fit for purpose (TJ [3544], [4428], [4429]);

(2) because Mrs Dawson suffered damage caused by her Gynemesh PS, she suffered damage caused by the defect, because it was not of merchantable quality, or because it was not reasonably fit for purpose (TJ [3544], [4498]); and

(3) because Mrs Sanders suffered damage caused by her TVT, she suffered damage caused by the defect, because it was not of merchantable quality, or because it was not reasonably fit for purpose (TJ [3544], [4517]).

1.2.2 Negligence

12 ***Ground 5***:the primary judge erred (including at TJ [3878]) in finding that the appellants breached their duty of care to warn in respect of each device because the primary judge:

(1) did not properly consider or give sufficient weight to the evidence of the pelvic surgeons in relation to clinical considerations and the different safety profiles of each of the devices, and their safety profiles relative to other surgical and nonsurgical alternatives; and

(2) preferred the evidence of non-clinical experts and relied on the findings about the appellants’ awareness (including relevant clinical significance) of the pleaded complications; and

(3) did not properly consider or give sufficient weight to the differences between the five SUI devices and the four POP devices (comprising the three pelvic floor repair systems and Gynemesh PS).

Had this evidence been properly considered, the primary judge would not have concluded that the appellants breached their duty of care to warn in respect of each device because that evidence established, when viewed in the context of clinical considerations, that the warnings provided in connection with each device were reasonable and appropriate in the circumstances.

13 ***Ground 6***: the primary judge erred in finding that the first appellant and second appellant breached their duty of care to take reasonable care to avoid injury to patients by finding that the appellants’ pre-market and post-market evaluations of each of the devices was deficient in circumstances where (see TJ [3699]):

(1) the respondents did not advance a case that the regulatory environment informs the first appellant’s and second appellant’s obligations; and

(2) the respondents did not advance a case as to how any non-compliance with the regulatory environment has relevantly affected the appellants’ obligations.

14 ***Ground 7***: the primary judge erred in finding that the first appellant and second appellant breached their duty to take reasonable care to avoid injury to patients by finding that their pre-market evaluation of each of the devices was deficient (common question and answer 15; TJ [3762]) because:

(1) the evidence did not establish:

(a) the first appellant’s and second appellant’s engagement with any regulator was insufficient;

(b) the first appellant’s and second appellant’s risk analyses and design validation studies were insufficient;

(c) the first appellant and second appellant did not satisfy the European Council Directive 93/42/EEC issued on 14 June 1993 and amended from time to time thereafter (**European Directive**) (TJ [3688]-[3689]); and

(d) the first appellant and second appellant did not have enough evidence to obtain CE marking for each of the devices (TJ [3687]); and

(2) the evidence did establish that the first appellant and second appellant appropriately and reasonably relied on studies conducted on, and experience associated with, the use of polypropylene and polypropylene-based meshes in the body, as well as the surgical technique and benefit-risk profile of earlier Ethicon devices before each device was supplied in Australia.

15 ***Ground 8***: the primary judge erred in finding that the first appellant and second appellant breached their duty to take reasonable care to avoid injury to patients by finding that their post-market evaluation of each of the devices was deficient (TJ [3776]-[3778], [3784], [3794]; common question and answer 16) because:

(1) the evidence did not establish:

(a) the first appellant’s and second appellant’s post-market evaluation on the devices, both in terms of clinical studies and ongoing review of the scientific literature was deficient;

(b) the first appellant’s and second appellant’s complaint handling and event reporting to regulatory authorities was deficient;

(c) the first appellant’s and second appellant’s responses to enquiries raised by regulators was deficient; and

(2) as a consequence of the matters outlined at ground 5 above, the evidence did establish that the adverse events (including the impact of those events on patients) and the warnings accompanying each of the devices were reasonable and appropriate in the circumstances.

16 ***Ground 9***: the primary judge erred in finding that, but for the first appellant’s and second appellant’s allegedly negligent pre-market and post-market evaluations:

(1) none of the devices would have been on the Australian market at any time (common question and answer 19(a));

(2) no group member would have received a device and suffered damage from its implantation (common question and answer 19(b)); and

(3) Mrs Gill (at TJ [4445]-[4446]), Mrs Dawson (at TJ [4502]) and Mrs Sanders (at TJ [4521]) would not have suffered their injuries because the evidence does not establish that:

(a) registration in Australia would have been withheld for each device had the first appellant and second appellant disclosed certain facts about the testing process for each device; or

(b) withholding or withdrawing each device from the market was the only course reasonably open to the first appellant, second appellant, and any regulator.

17 ***Ground 10***: the primary judge erred in finding that:

(1) Mrs Gill’s injuries were caused by the appellants’ pre-market and post-market evaluations (TJ [4445]-[4446]) because the primary judge failed properly to apply ss 5C and 5D of the *Civil Liability Act 2002* (WA) (the **CLA**) and reversed the onus of proof;

(2) Mrs Dawson’s injuries were caused by the appellants’ pre-market and post-market evaluations (TJ [4502]) because the primary judge failed properly to apply ss 51 and 52 of the *Wrongs Act 1958* (Vic) (the **Wrongs Act**) and reversed the onus of proof; and

(3) Mrs Sanders’ injuries were caused by the appellants’ pre-market and post-market evaluations (TJ [4521]) because the primary judge failed properly to apply ss 5C and 5D of the CLA or the common law and reversed the onus of proof.

18 ***Ground 11***: the primary judge erred in finding that:

(1) Mrs Gill’s injuries were caused by deficiencies in the appellants’ warnings accompanying Prolift (including at TJ [4492], [4496]) because the primary judge failed properly to apply ss 5C and 5D of the CLA and reversed the onus of proof;

(2) Mrs Dawson’s injuries were caused by deficiencies in the appellants’ warnings accompanying Gynemesh PS (including at TJ [4508], [4514]-[4515]) because the primary judge failed properly to apply ss 51 and 52 of the Wrongs Act and reversed the onus of proof; and

(3) Mrs Sanders’ injuries were caused by deficiencies in the appellants’ warnings accompanying TVT (including at TJ [4530], [4556], [4558]) because the primary judge failed properly to apply ss 5C and 5D of the CLA or the common law and reversed the onus of proof.

1.2.3 Misleading or deceptive conduct

19 ***Ground 12***: the primary judge erred in finding that the appellants engaged in misleading or deceptive conduct (see TJ [3604]-[3607], common question and answer 22) in relation to a case not pleaded, particularised or advanced by the respondents.

20 ***Ground 13***: the primary judge erred in finding that the appellants engaged in misleading or deceptive conduct because:

(1) the primary judge:

(a) did not properly consider or give sufficient weight to the evidence of the pelvic surgeons in relation to clinical considerations and the different safety profiles of each of the devices, and their safety profiles relative to other surgical and non-surgical alternatives;

(b) preferred the evidence of non-clinical experts and relied on the findings about the appellants’ awareness (including relevant clinical significance) of the pleaded complications; and

(c) did not properly consider or give sufficient weight to the differences between the five SUI devices and the four POP devices (comprising the three pelvic floor repair systems and Gynemesh PS).

Had this evidence been properly considered, the primary judge would not have concluded that the appellants engaged in misleading or deceptive conduct in respect of each device because that evidence established, when viewed in the context of clinical considerations, that the conduct of the appellants in respect of each device (including the information provided in connection with each device) was not misleading:

(2) the evidence did not otherwise establish the surrounding facts and circumstances of the supply of each device in Australia, including by medical practitioners to potential patients in each relevant period (TJ [3581], [3584], [3586], [3591]-[3592], [3594]-[3600], [3602], [3604]-[3605], common question and answer 22).

21 ***Ground 14***: the primary judge erred in finding that, because Mrs Sanders suffered damage caused by her TVT, she suffered damage caused by the misleading or deceptive conduct (TJ [4560]) because the evidence does not establish that:

(1) Dr O’Neill, Dr Giele and/or Dr Taylor would have provided different advice, including a different or additional warning (TJ [4530], [4558]); and/or

(2) Mrs Sanders would not have undergone surgery to implant her TVT (TJ [4556]).

1.2.4 Limitation periods

22 ***Ground 15***: the primary judge erred in finding that Mrs Gill’s claim in negligence was not statute barred by failing properly to apply ss 39(3) and (4) of the *Limitation Act 2005* (WA) (the **2005 Limitation Act**) by reversing the onus of proof (TJ [4831]).

23 ***Ground 16***: the primary judge erred in finding that Mrs Sanders’ claim in negligence was not statute barred by:

(1) applying the 2005 Limitation Act (rather than the *Limitation Act 1935* (WA) (the **1935 Limitation Act**)) and granting Mrs Sanders an extension of time under ss 39(3) and (4), by:

(a) failing to place sufficient weight on the contemporaneous medical records (TJ [4840]); and

(b) finding that the first symptom or other manifestation of personal injury (beyond *de minimis*) occurred in 2007 or 2008 (at TJ [4853]).

(2) in the alternative, failing properly to apply ss 39(3) and (4) of 2005 Limitation Act by reversing the onus of proof (TJ [4861]).

1.2.5 Injunction

24 ***Ground 17***: the primary judge erred in granting the Injunction (at TJ [5822], RJ [50]) enjoining the appellants from supplying, distributing, marketing or promoting any of the SUI devices (other than TVT Secur) anywhere in Australia without including a warning or advice in the terms set out in orders 2 and 3 of the orders of 6 March 2020 in the patient information leaflets, instructions for use or any promotional material because:

(1) there was no evidence before the Court as to the knowledge of treating surgeons or persons generally as at 21 November 2019 (the date reasons were published in the trial judgment) or 6 March 2020 (the date reasons were published in RJ and the Injunction ordered); and/or

(2) the Injunction was ordered in the absence of hearing from the Therapeutic Goods Administration (embodied by the Commonwealth) (the **TGA**) despite it being the entity having the expertise and statutory responsibility for regulating the provision of medical devices (and the warnings and advice provided in relation to medical devices) in Australia.

25 The respondents filed a notice of contention to the effect that, if the primary judge’s conclusion in relation to the existence of a defect/safety defect in any product the subject of the proceeding below relied on the Court’s findings of non-compliance with the requirements for CE marking, then the primary judge’s conclusion as to defect should be upheld for each product on the basis of those of the primary judge’s findings other than non-compliance with CE marking requirements.

###### 1.3 Summary of conclusions

26 We have decided that the appeal must be dismissed, subject to us being satisfied it is appropriate to vary the order by which the primary judge’s findings are binding on group members and providing greater specificity to the answer to common question 22. Our reasons follow.

##### 2. KEY ASPECTS OF THE PROCEEDINGS BELOW

27 As the primary judge recorded, the proceedings were brought under Pt IVA of the *Federal Court of Australia Act 1976* (Cth) (the **FCA Act**) by three applicants, both on their own behalf and on behalf of other women who claim to have suffered complications from the implantation of one or other of the devices during the relevant period. The class of applicants is open and more than 90,000 of the devices have been supplied in Australia: TJ [13].

28 The hearing began in July 2017 and ended in February 2018 involving hearing days on 4-14, 19-20, 24-28 July 2017, 2, 9-17, 21-23, 30-31 August 2017, 4, 12-19, 28-29 September 2017, 3-12, 16-26 October 2017, 1-8, 14-16, 20-24, 29 November 2017, 29-31 January 2018 and 1-22 February 2018.

29 Evidence was adduced from 48 witnesses, 35 of whom gave oral evidence. Of the 48 witnesses, 37 were experts from nine different disciplines: TJ [19]. More than 5,500 documents were tendered, running to over 164,000 pages: TJ [20].

30 Mrs Gill, Mrs Dawson and Mrs Sanders, and each of their husbands gave evidence: TJ [21].

31 The respondents (the applicants below) also called evidence from:

(1) four urogynaecologists (a surgical subspecialty of urology and gynaecology, which involves the diagnosis and treatment of female pelvic floor disorders) – Andrew Korda, Wael Agur, Jerry Blaivas, and Michael Thomas Margolis: TJ [22]. They also tendered a report from a urogynaecologist on whom the appellants (the respondents below) proposed to rely – Malcolm Frazer: TJ [23];

(2) Bilal Chughtai, a urologist, Uwe Klinge, a general surgeon and biomaterials researcher, Bernd Klosterhalfen and Vladimir Iakovlev, pathologists, Russell Dunn and Scott Guelcher, biomechanical engineers, Derrick Beech, Bryan Allman, Peggy Pence and Anne Holland, regulatory experts, Howard Hu, Cara Krulewitch, and Mark Woodward, epidemiologists, Ian Gordon, a biostatistician, Alan Meagher and Anthony Eyers, colorectal surgeons, Patricia Jungfer, a psychiatrist, Joseph Slesenger, a specialist in occupational medicine, and Lindy Williams and Timothy Walsh, occupational therapists: TJ [24]; and

(3) Robyn Leake, an obstetrician and gynaecologist who treated Mrs Gill, James Swan, an obstetrician and gynaecologist who treated Mrs Dawson, and Sandra McNeill, an obstetrician and gynaecologist who assisted in the operation in which Mrs Sanders was implanted with TVT: TJ [26].

32 The appellants (the respondents below) called evidence from:

(1) six urogynaecologists – Piet Hinoul, Pierre Collinet, Jan Deprest, Alan Lam, Jan-Paul Roovers, and Anna Rosamilia; and

(2) Steven McLean, an engineer, Paul Santerre, a professor of biomaterials, Thomas Wright, a pathologist, Lisa Brown, Anthony Samuels and Rosalie Wilcox, psychiatrists, and Susan Borthwick, an occupational therapist: TJ [27].

33 Dr Hinoul was the only witness from the appellants to give evidence. He holds a PhD in bio-medical sciences from the University of Amsterdam. Since June 2014 he has held the position of Vice President – Medical Affairs at Ethicon Inc., based in Somerville, New Jersey, USA: TJ [28]. Dr Hinoul joined Ethicon in 2008, when he was appointed Director of Medical Affairs – Europe, Middle East and Africa (Women’s Health and Urology), based in Paris, France. As Director of Medical Affairs, Dr Hinoul was responsible for Ethicon’s pelvic floor repair and incontinence repair products: TJ [29]. In December 2010 Dr Hinoul became the Worldwide Director of Medical Affairs (Women’s Health and Urology) for Ethicon Inc., based in Somerville, New Jersey. In June 2012 his responsibilities increased to cover other aspects of the Ethicon business and from April 2013, until his promotion to Vice-President – Medical Affairs, he held the position of Worldwide Director of Medical Affairs (Ethicon Endo-Surgery (Energy Franchise)): TJ [30].

34 The primary judge made adverse credit findings against Dr Hinoul. She said:

Dr Hinoul presented as a company spokesman. His affidavit was lengthy (363 pages) but not full and frank. It cast Ethicon’s conduct in the most favourable light. In cross-examination, Dr Hinoul was inclined not to give responsive answers to potentially uncomfortable questions and tended to be evasive where direct answers would not suit the respondents’ interests. At times he steadfastly defended the indefensible: TJ [31].

35 A key figure in the development of the devices, Dr Axel Arnaud, remains with Ethicon. He was a predecessor of Dr Hinoul as Ethicon’s Director of Medical Affairs. He investigated the TVT procedure in 1996 and TVT-O in 2002 and was a moving force in the development of the POP devices. He was not called to give evidence. No explanation for his failure to give evidence was provided. Nor was any explanation given for the fact that other Directors of Medical Affairs at Ethicon were not called to give evidence: TJ [32].

36 The primary judge also made adverse credit findings against a number of the other witnesses called by the appellants, Professor Wright (TJ [305]-[309]), Professor Santerre (TJ [310]-[313]), Professor Deprest (TJ [314]-[323]) and, to a lesser extent, Dr MacLean (TJ [324]-[325]).

37 The respondents pleaded that the SUI devices could cause the following complications (called the **Tape Complications**):

 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 and/or apareunia (avoidance of sexual intercourse);

 difficulty voiding;

 offensive vaginal discharge;

 *de novo* 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: TJ [184].

38 The respondents alleged that the POP devices could cause the same complications and also cause difficulty defecating and recurrence of prolapse (called the **Mesh Complications**): TJ [185].

39 The respondents also alleged that the devices were difficult, if not impossible, to remove safely from patients suffering from one or more of the pleaded complications, that one or more surgical procedures might be required, and that removal carried the risk of new complications or of aggravating existing complications. These were referred to as the “Tape Removal Complications” (for SUI devices) and the “Mesh Removal Complications” (for POP devices), as the case may be: TJ [187].

40 After the hearing, the respondents applied for and were granted leave to amend their pleadings to add an allegation that the appellants failed to give any or any sufficient information or warning 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: see *Gill v Ethicon Sàrl* [2018] FCA 470 at [81]-[107]: TJ [196].

41 The primary judge referred to these complications together as the **pleaded complications**: TJ [197].

42 The appellants pleaded that “all surgical procedures present risks”. They also pleaded that non-absorbable polypropylene mesh, which formed a component of each of the POP and SUI devices, was designed to allow for an inflammatory response that is necessary for tissue ingrowth. They otherwise denied the existence of the pleaded complications: TJ [188]. They did not plead that either pelvic surgeons generally or the particular treating surgeons of the representative respondents were aware at all relevant times of the pleaded complications.

43 However, as the primary judge recorded:

189 In cross-examination, Dr Hinoul acknowledged that, from the time each of the devices was first supplied anywhere in the world, Ethicon knew of its potential to cause each of the pleaded complications. He conceded that, from the time of first supply, Ethicon was aware that a 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. Furthermore, he admitted that from that time Ethicon knew that there was a risk of mesh exposure and extrusion into the vaginal canal or another organ, that mesh exposure or extrusion could be difficult to treat, and that it could cause pain or discomfort. He also admitted that at the date of first supply Ethicon knew that both mesh erosion or extrusion and pain could occur many years after any of the devices had been implanted. Moreover, he admitted that Ethicon knew at that time that implantation carried a lifelong risk of erosion and pain, as well as risks of: dyspareunia and, as a consequence, apareunia; difficulty voiding; difficulty defecating; offensive discharge; leg weakness; and damage to surrounding organs, ligaments, tissues, and blood vessels.

190 Dr Hinoul also conceded that Ethicon knew at that time that both acute and chronic pain could be caused by each of the devices, 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. He agreed that the mesh could be difficult, if not impossible, to remove safely or without complications and that, in the case of Prolift, it could be disastrous. He said that Prolift could be removed safely but admitted that there was always a risk in so doing of causing damage to surrounding structures. He also admitted that, at the time each of the Ethicon devices was launched, Ethicon knew that, in the event of complications, the original condition (stress urinary incontinence or pelvic organ prolapse) could recur.

191 Ultimately, then, there was no dispute that all of the complications could be caused by implantation of the Ethicon devices. What is more, lead counsel for the respondents, Mr Finch SC, told the Court in closing argument that the respondents accepted that each of the pleaded complications was clinically significant.

44 This last statement is a reference to the fact that in closing submissions senior counsel for the appellants conceded that each of the pleaded complications, if one of them occurred, was clinically significant in terms of incidence and consequence. The appellants now dispute the extent of the concession but, for the reasons we later explain, we consider the appellants made that concession in clear terms.

45 The appellants’ concession, prompted by Dr Hinoul’s oral evidence, was important to the primary judge’s process of reasoning: TJ [192], [198], [280]-[281], [300], [1134], [1540], [2839], [2990], [3063], [3362], [3405].

46 Dr Hinoul, it should be noted, gave evidence after all of the respondents’ experts (excluding experts in respect of issues of quantification of damages) gave evidence.

47 Three observations should be made about these events immediately, as they partly explain the nature of the challenges to the reasoning of the primary judge and how those challenges should be assessed.

48 The first observation represents the way the appellants’ defence evolved. The case advanced by the respondents since this case began (as long as nine years ago) involved two fundamental and connected propositions: (a) the factual contention that each of the devices caused the pleaded complications, and (b) the factual and legal contention that the appellants should have warned of the risks of the pleaded complications, but failed to do so as required.

49 As noted above, the response was straightforward – the appellants pleaded that all surgery presents risks, but otherwise expressly denied that the devices caused the pleaded complications: defence at [23] and [45]. Consistently with this approach – and obviously enough, given the denial – the appellants did not suggest that pelvic surgeons knew of the risk of the pleaded complications (notwithstanding they did state their expectation of the nature of the risks that would be the subject of warning by surgeons in their defence at [18(c)] and [40(c)]).

50 These opposed positions as to the existence or otherwise of the pleaded complications marked out the primary forensic battleground in the many years leading up to the hearing and during much of the hearing. A vast array of expert evidence was marshalled to support each position. Lay evidence was also filed, including 363 pages of narrative affirmed by Dr Hinoul. No-one reading that long, dense and carefully constructed affidavit would have understood from it the true position, which was only revealed when Dr Hinoul was cross-examined. As it turned out, not only did the pleaded complications exist, but at all relevant times they were known by the appellants to exist. Moreover, they were all clinically significant.

51 It is important to remember this history when one comes to the way the appellants now advance their case. With what can only be described as considerable forensic dexterity, the appellants now suggest that the pleaded complications were known to pelvic surgeons generally, such that the respondents did not establish that it was necessary for them to warn pelvic surgeons about them or that, at the least, the respondents had not proved that the pleaded complications were not known to pelvic surgeons generally, with the same consequence.

52 This volte-face forced upon the appellants by a witness telling the truth in cross-examination was described by senior counsel for the respondents, not unfairly, as an adventitious attempt to try to extract a plausible defence from a case that until the eleventh hour had been premised on a theory of the case that had become untenable. Reduced to its core, the argument put in final submissions below (and on appeal) was essentially a focus on s 140(1) of the *Evidence Act 1995* (Cth) (**Evidence Act**) and, more specifically, on the notion, as Sir Owen Dixon emphasised, that a party bearing the onus will not succeed unless the whole of the evidence establishes a “reasonable satisfaction” on the preponderance of probabilities such as to sustain the relevant issue (*Axon v Axon* [1937] HCA 80; (1937) 59 CLR 395 at 403, 407), and the “facts proved must form a reasonable basis for a definite conclusion affirmatively drawn of the truth of which the tribunal of fact may reasonably be satisfied”: ***Jones v Dunkel*** [1959] HCA 8; (1959) 101 CLR 298 at 305.

53 The second observation is connected to the first. The hearing below was both very long and hard fought. Of the 48 witnesses, 37 were experts giving opinion evidence in nine broadly distinguishable areas of specialised knowledge. Unlike in most complex class actions, there were no orders for concurrent evidence of experts after the conclusion of the lay evidence, nor was any dispute of a scientific or technical nature made the subject of inquiry and report. Another feature was that by the consent of the parties, the hearing was unusually structured. According to senior counsel for the respondents (that is, the applicants) who appeared below, lay affidavits by the representative respondents (applicants) were read but cross-examination was deferred. Then the experts called on behalf of the respondents (applicants) gave evidence. Dr Hinoul thereafter gave his highly significant and (from the perspective of the appellants) damaging lay evidence. None of this is meant as a criticism of the primary judge who was presented with this unique way of doing things by the parties who, no doubt, were required to work around the availability of a large number of busy professionals. But it is worth mentioning, because when it comes to drawing any inference about the respondents’ failure to call witnesses in chief or the failure to adduce certain evidence in chief from witnesses who were called, it is necessary to bear in mind the case was a very different one before, as compared to after, the cross-examination of Dr Hinoul.

54 The third observation involves a reiteration of the statements in *Gill v Ethicon Sàrl* *(No 3)* [2019] FCA 587; (2019) 369 ALR 175 at [3]-[15]. That is, there was a regrettable failure of the parties to identify with precision, in advance, the precise issues to be determined at the hearing. Indeed confusion about what was resolved and the consequences of setting aside the impugned findings of fact and law by the primary judge remained, up until the oral hearing of this appeal, and complicated any questions of relief.

55 The binding of class members to a determination of the court or a settlement approved by the court is foundational to the operation of a class action regime. A Federal Court in the United States is required, by Rule 23 of the Federal Rules of Civil Procedure (US), to designate those persons whom the court finds to be members of the class, so as to identify the claimants potentially bound by the outcome of the court’s determination or any settlement: see r 23(c)(3). In a proceeding governed by Pt IVA of the FCA Act, effectively the same result is arrived at by reason of the operation of s 33ZB. This provides that a judgment given in a class action must describe or otherwise identify the group members affected by it and binds all such persons other than any person who has opted-out. This provision creates its own kind of “statutory estoppel”: ***Timbercorp Finance*** *Pty Ltd (in liquidation) v Collins* [2016] HCA 44; (2016) 259 CLR 212 at [52]-[53] per French CJ, Kiefel, Keane and Nettle JJ. It was described by the Full Court in *Femcare Ltd v Bright* [2000] FCA 512; (2000) 100 FCR 331 at [25] per Black CJ, Sackville and Emmett JJ as, in one sense, the “pivotal provision” in Pt IVA.

56 A routine misconception is that the common questions specified in the originating application or supporting documentation define the common questions for the balance of the proceeding. This cannot be the case. For one thing, issues which are common may narrow considerably upon a joinder of issue by way of pleadings. Similarly, issues which are common to the claims may arise by way of a positive averment made in a subsequent pleading, whether it be a defence, a reply, a rejoinder or so on. Further common issues of fact may arise upon the filing of lay or expert affidavit evidence.

57 By whatever means common questions arise, what is critical for the orderly conduct of a Pt IVA proceeding is that prior to an initial trial starting there is specificity in what common questions are being determined. In *Merck Sharp & Dohme (Australia) Pty Ltd v Peterson* [2009] FCAFC 26; (2009) 355 ALR 20 at [6], the Full Court explained that at the conclusion of an initial trial, the court should pronounce formal orders regarding the common questions, perhaps by way of formal declarations or answers to questions.

58 In the early stages of Pt IVA litigation, the discipline of identifying the issues to be determined at an initial trial had not developed. Significant controversy often arose following the delivery of a judgment (as it did here), with the parties parsing the judgment trying to divine which of the findings amounted to the determination of a common issue of law or fact. The accumulated experience of this Court in having to deal with the needless controversy that such a course involved was the impetus for ensuring that prior to an initial trial there was no such confusion.

59 Nowadays, a “*Merck* order” is made, almost always wholly or largely by consent, which identifies that at an initial trial the whole of the claim of the applicant or some other group representatives are determined, together with a list of questions identified in a schedule to the order. These questions reflect common issues or issues of commonality the answers to which, following judgment, can be the subject of s 33ZB orders (thus identifying the metes and bounds of the statutory estoppel).

60 Unfortunately, in this proceeding, the primary judge was provided with what was said to be an agreed statement of the common questions, but no order was made. Senior counsel for the respondents (the applicants below) started the hearing in July 2017 apparently on the basis of a perceived consensus as to the common questions, but was apparently disabused of his misapprehension over five months later when a document was provided by the appellants (SBM.020.002.0003) which stated that, as to the “self-styled…agreed statement of the common questions” filed on 12 July 2017, there:

…is no agreement between the parties that the questions are common. There is also no agreement that the questions can be answered in a meaningful and sensible way.

61 Precisely why this occurred is difficult to discern. Although the appellants’ failure to speak out in a timely way about the lack of consensus is particularly troubling, both sides share some responsibility for an order not being made at the outset of the initial trial making it clear (either by way of agreement or determination) what precisely was being decided. But whatever else is unclear, this lack of clarity ought not to be a course repeated in any complex Pt IVA proceeding in the future.

##### 3. KEY FINDINGS OF THE PRIMARY JUDGE

62 The summary below includes only those facts where it should be concluded from the primary judge’s reasons for judgment as a whole that the primary judge was satisfied about the fact to the requisite civil standard of proof. It includes findings which the primary judge made by accepting the evidence of an expert or experts and identifying that evidence. The summary below does not identify the expert who provided the opinion which supported the finding except where it is necessary to do so. The summary mainly consists of direct quotes from the primary judge’s reasons. Accordingly, first person references in the summary are to the primary judge. Further, to avoid confusion, the primary judge’s references to the respondents as quoted or referred to below have been amended to refer instead to the appellants.

###### 3.1 The representative respondents - overview

3.1.1 Mrs Gill

63 Mrs Gill was born in 1970: TJ [3885]. She has psoriasis, an autoimmune condition: TJ [3888].

64 After her second child Mrs Gill suffered a vaginal prolapse in 2004: TJ [3900]. She developed urge incontinence and pain with intercourse and constipation: TJ [3901]. Her symptoms increased. She needed to insert her fingers into her vagina and push her vaginal wall backwards to defecate. Her sexual relationship with her husband deteriorated significantly: TJ [3910].

65 Mrs Gill was implanted with a POP device, Prolift Total, in January 2007 when she was 36: TJ [3919]. Her post-surgical pain never resolved: TJ [3921]. It was becoming painful for her to defecate and she became ill in February 2007: TJ [3923]-[3925]. She had a post-surgical infection and was hospitalised: TJ [3928]. On release from hospital in March she was still in pain, very tired, and could not have sex: TJ [3931]. She did not improve and needed help with daily tasks: TJ [3935]. She continued to suffer pain which she said was of three types (a constant, aching pain in the region of her coccyx which she rated at 6 out of 10 in severity, sporadic severe pain akin to period pain with coughing or on sudden movements rated at 8 or 9 out of 10, and “terrible” pain on defecation, fluctuating in intensity but with a difficult bowel movement rating around 9 out of 10 in severity): TJ [3936]. She had non-menstrual vaginal bleeding: TJ [3937]. She spent a lot of time sleeping and just lying in bed as even sitting in a chair was a problem: TJ [3938]. Sex was impossible: TJ [3939].

66 By June 2007 she had mesh erosion into her vagina: TJ [3942]-[3943]. She had her first mesh excision surgery in September 2007: TJ [3949]. Her pain continued. She was diagnosed with depression in March 2008: TJ [3953]. She resumed sexual intercourse but had dyspareunia. By May 2008 she had another mesh erosion into the vagina: TJ [3955]. In June 2008 she had her second mesh excision surgery in which part of the mesh was removed to relieve her pain: TJ [3959]. Her symptoms improved: TJ [3965]-[3966]. She remained stable until mid-2013 apart from heavy period and associated treatment: TJ [3967]-[3970]. Her depression worsened after her husband had an accident in 2010: TJ [3972]-[3974].

67 In mid-2013 Mrs Gill could feel something sharp and lumpy in her vagina. Pain and bleeding with intercourse occurred. Bowel movements again became painful and she had some urge incontinence: TJ [3987]. She had her third mesh excision surgery in August 2013: TJ [3997]. Afterwards she continued to have pain including a new pain originating in her lower right pelvic area and travelling down the front of her right groin and leg: TJ [3999].

68 In December 2015 or January 2016 Mrs Gill’s prolapse recurred: TJ [4017]. Examination in July 2017 disclosed that the right Alcock canal (also known as the pudendal canal) was exquisitely tender and that residual mesh was palpable to a few millimetres above the canal and about one centimetre caudal from the ischial spine: TJ [4054]. An examination in January 2018 disclosed “tender +++on [right] anterior wall/apex where mesh fibres are exposed”: TJ [4060]. Mrs Gill continues to suffer serious and chronic pain, faecal urgency and flatal and faecal incontinence, aggravation of her depression and an anxiety disorder, and recurrent prolapse all of which the primary judge found was caused by the device with which she was implanted: TJ [4063], [5049]. Her revision surgeries were also caused by the device: TJ [4916]-[4918]. Sexual intercourse has ceased due to pain: TJ [4063].

3.1.2 Mrs Dawson

69 Mrs Dawson was born in 1959: TJ [4070]. She suffered from POP: TJ [4081]. She had prolapse repair surgery and a hysterectomy in 2001: TJ [4082]-[4083]. By 2003 she had a problem with painful sexual intercourse: TJ [4086]. She had surgery in 2004 for adhesions and cyst removal: TJ [4087]-[4089]. Post-surgery she and her husband resumed sexual intercourse on average once every one to two weeks: TJ [4091].

70 In 2008 she developed mild pain in her lower back, bottom and pelvis after prolonged sitting. By 2009 the pain had worsened. Her bowel function deteriorated. She needed to digitate and push her vagina back to defecate. She experienced urge incontinence: TJ [4092]. She had superficial dyspareunia. She had symptoms of recurrent prolapse: TJ [4094].

71 She was implanted with the POP device, Gynemesh PS, in May 2009 (when she was 50): TJ [4097]. A review in June 2009 indicated excellent results from the surgery: TJ [4103]. Shortly after, however, she began to experience terrible (10 out of 10) pain which she had never experienced before inside and across her bottom, as well as pain down her legs and inside her vagina. Her bowel problems returned. Sexual intercourse was painful. She could not tolerate sitting for any long period. Coping with the pain for the rest of her life felt unimaginable: TJ [4105]. She saw a number of doctors about the pain: TJ [4107], [4111]. She had a local steroid injection to deal with the pain in her sacro-coccygeal joint in July 2009: TJ [4114]. The injection did not work: TJ [4115]. In August 2009 examination of the coccyx externally caused “exquisite discomfort”: TJ [4117]. She continued to see doctors. Examination in September 2009 revealed a 1 x 6mm erosion in the mid anterior vaginal wall: TJ [4120]. Medications for neuropathic pain did not resolve the issue: TJ [4127].

72 In October 2009 Mrs Dawson had mesh excision surgery of an area of mesh erosion of 2mm x 1cm: TJ [4123]. Her bottom remained painful affecting her ability to sit: TJ [4125]. She continued to see doctors and take medication, but the pelvic pain was ongoing: TJ [4129]. In 2012 examination showed she had SUI, severe dyspareunia, detrusor instability (associated with urge incontinence), inability to defecate without digital support, and persistent leg and buttock pain: TJ [4131]. Medications were prescribed to re-oestroganise her vagina and reduce the detrusor instability: TJ [4132]. She obtained some relief: TJ [4133]. By March 2013 she still had apareunia, was now complaining of pain with a full rectum, continued to experience difficulty initiating and completing defecation, and her buttock pain had returned: TJ [4134]. In January 2014 she had her second mesh excision surgery: TJ [4141]. She experienced some improvement: TJ [4143]. Sexual intercourse remained impossible, however: TJ [4145]. Mesh erosion issues continued: TJ [4148]. In May 2015 she had her third mesh excision surgery: TJ [4151]. By July 2015 Mrs Dawson was again experiencing pain in her bottom and back passage: TJ [4156]. Further mesh exposure was discovered: TJ [4157]. The pain continued making it very difficult for her to sit: TJ [4161]. She had her fourth mesh excision surgery in October 2015: TJ [4164]. By her examination in March 2016 her pain was much worse, she had difficulty sitting and walking for long periods, and had to strain to defecate: TJ [4168]. In June 2016 she was examined by Professor Korda who “confirmed a narrowed introitus and a contracted, narrowed vagina with a fibrosis around the left anterior and left posterior portion of the vagina. Her vagina was rigid, not pliable, and only admitted one finger. A tender remnant of the mesh was palpable on both the anterior and posterior walls. The right ischiorectal fossa was tender and she indicated that this was the spot where she had to push in order to complete defaecation”: TJ [4170], [4172]. By March 2017 she was in a great deal of pain. She said she was “hardly able to walk or sit and “had a bulge coming outside of [her] bottom”, which she sometimes had to push in order to defecate and which “felt like touching a balloon”: TJ [4192]. She had surgery to divide her vaginal scar tissue which was caused by the initial mesh insertion and subsequent mesh erosion revision surgeries: TJ [4191]-[4193]. The relief given by this surgery was short-lived: TJ [4216].

73 Mrs Dawson had not been able to have successful intercourse since the implant surgery: TJ [4208]. Since the operation in 2009 she had had intercourse with her husband five, possibly six times. She said that it felt like someone was cutting her inside and she would scream with pain. When Mr and Mrs Dawson attempted to have sexual intercourse on about 18 September 2017 she experienced knife-like pain pushing up and down inside her vagina and pain radiating down the right leg and a burning and pulling sensation under her right buttock. The next day she spent a great deal of time on the toilet with increasing rectal mucus. As a result of the pain she vowed never to have intercourse with her husband again: TJ [4221]. She has continuing pain in the nature of a burning sensation in the top of her legs and underneath her buttocks, a needle-like sensation inside her bottom, and a burning pain in and around her vagina: TJ [4216]. Her bottom and pelvis continue to ache after a day’s work. She reduced her work to four days a week and did not know how she would manage work in the future: TJ [4217]. She was depressed at the significant changes in her life since the implant surgery: TJ [4227]. Each of her revision surgeries was caused by the device with which she was implanted: TJ [5336]-[5337]. The primary judge also found that the device caused Mrs Dawson’s pudendal neuropathy, chronic pain syndrome, coccygeal pain, chronic and severe pelvic pain, and apareunia, and also aggravated her pre-existing defecation disorder: TJ [5354]-[5461].

3.1.3 Mrs Sanders

74 Mrs Sanders was born in 1946: TJ [4228]. She was implanted with an SUI device, TVT, on 12 March 2001 (when she was 54) to treat her SUI: TJ [4235]-[4236]. The surgery effectively treated her SUI and she recovered well and remained well until 2007: TJ [4237]-[4239]. In 2007 she experienced discomfort urinating: TJ [4240]. In 2008 she found sexual intercourse painful. So did her husband who could feel something sharp in her vagina: TJ [4241]. She also developed constant groin pain: TJ [4242]. In 2008 to 2009 she experienced a sharp pain in her vagina which could radiate down her legs which adversely affected her quality of life: TJ [4243]. In 2010 her urinary symptoms increased and she had to regularly take antibiotics. She had also started to take regular painkillers: TJ [4244]-[4246]. The vaginal pain caused her to see a doctor in January 2011 and mesh exposure in the vagina was discovered. By this time she felt that she could not cope with the pain and was relieved to be told she needed to have the mesh excised: TJ [4247]-[4259]. She had mesh excision surgery on 8 August 2011: TJ [4263]. Only part of the mesh could be removed. She was told she might need more surgery: TJ [4268].

75 After the mesh excision surgery, her symptoms of painful, difficult and frequent urination and leakage continued: TJ [4270]. These symptoms got worse and the dull pain and sharp pain returned: TJ [4272]-[4273]. She continued to be prescribed antibiotics: TJ [4274]-[4278]. She developed hip pain for which she had hip replacement surgery in 2016: TJ [4327]. The hip surgery resolved her hip pain: TJ [4330]. She also developed shoulder pain due to previous shoulder injuries: TJ [4333]-[4335]. Mrs Sanders continues to experience severe pain in her groin and vagina and throughout her pelvis: TJ [4345]. She continues to take an antibiotic tablet every day, as well as two paracetamol (Panadol) and two ibuprofen (Advil) tablets every night: TJ [4344]. She was and continues to be troubled by incontinence and has no bladder control: TJ [4346]. She and her husband have not had sex since 2008 because intercourse is painful for her: TJ [4350]. She has been both anxious and depressed and grieves for the life she once enjoyed: TJ [4354]. Her prognosis is uncertain as she has incipient vaginal mesh erosion: TJ [4356]. The device caused her revision surgeries and scarring of her vagina. It also caused her adjustment disorder with mixed anxiety and depressed mood: TJ [5606]. The device caused her overactive bladder symptoms of urgency and frequency, her dyspareunia, apareunia, and chronic pelvic pain: TJ [5676].

###### 3.2 The relevant conditions

3.2.1 Stress urinary incontinence

76 SUI is the involuntary leakage of urine during activities such as coughing, sneezing, lifting, laughing or exercising: TJ [43]. The condition affects the sufferer’s quality of life but is never life-threatening: TJ [44]. Treatment is always elective: TJ [49].

77 Non-surgical treatments for SUI, which are not always successful, include general lifestyle changes, pelvic floor exercises, and the use of continence devices such as a pessary: TJ [51].

78 Traditional surgical treatments for SUI include:

(1) Burch colposuspension which is used to correct urodynamic stress incontinence;

(2) needle suspension procedures;

(3) sling procedures using either the patient’s own connective tissue (fascia) (known as autologous slings) or foreign graft material; and

(4) use of urethral bulking agents, involving injection of a variety of different substances around the bladder neck and into the urethral sphincter, to thicken the urethral wall so as to provide greater urethral resistance during increases in abdominal pressure: TJ [52].

79 All of the surgical treatment options for SUI are attended by risks, although the nature and extent of the risks vary from procedure to procedure: TJ [60].

80 It is common ground that, before deciding on the most appropriate course or method of treatment, a treating surgeon would consult with the patient, obtain her medical and surgical history, and assess her clinical needs: TJ [62].

3.2.2 Pelvic organ prolapse

81 POP is the downward displacement of a pelvic organ, which, in the case of a woman means the uterus, the different vaginal compartments or neighbouring organs such as the bladder, rectum or bowel: TJ [107]. In a prolapse of the anterior compartment of the vagina, either the bladder or uterus (or, in the absence of a uterus the vaginal vault) bulges into the front wall of the vagina. This is referred to as a cystocoele or urethrocoele. In a posterior compartment prolapse, the rectum (the lower part of the large bowel) or part of the small intestine bulges into the upper part of the back wall of the vagina. The former is known as a rectocoele and the latter as an enterocoele: TJ [109].

82 Prolapse can affect sexual function and cause dyspareunia, inability to penetrate the vagina due to obstruction, vaginal laxity, and loss of libido: TJ [116]. It is not a life-threatening condition but can drastically affect a woman’s quality of life: TJ [117].

83 Non-surgical treatments for POP include lifestyle interventions, pessaries and pelvic physiotherapy, as well as the use of vaginal oestrogen in post-menopausal women, avoidance of constipation and chronic cough, and training the pelvic floor muscles: TJ [119].

84 Traditional surgical treatments for POP include reconstructive surgery and vaginal closure or removal surgery (also known as obliterative procedures): TJ [120]. Surgery which uses the patient’s own tissue is commonly referred to as “native tissue repair”: TJ [127].

85 All surgical treatment options for POP are associated with risks, although the evidence indicates that complications from native tissue repair are generally short-lived and treatable: TJ [130].

###### 3.3 The devices

86 The first appellant (Ethicon Sàrl, a Swiss corporation) made all of the devices but for Gynemesh PS which was made by the second appellant (Ethicon Inc., an American corporation): TJ [8]. The first and second appellants supplied the devices to the third appellant, a related Australian company, Johnson & Johnson Medical Pty Limited (**JJM**). JJM promoted and supplied the devices to Australian hospitals and doctors: TJ [9].

87 According to statements made on the ARTG, the purpose of each of the SUI devices was to treat SUI and female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The purpose of the POP devices was to provide “tissue reinforcement and long-lasting stabilisation of fascial structures of the pelvic floor in vaginal wall prolapses”: TJ [11].

88 The devices are all made using a knitted polypropylene, a thermoplastic polymer: TJ [1].

89 Prolene, a polypropylene resin, has been widely used in sutures which the primary judge accepted to be “functional, safe and effective”: TJ [40].

90 In the early 1970s, Ethicon developed Prolene sutures into a knitted flat mesh and, in 1997, into a three-dimensional form known as the “Prolene Hernia System”. The first of the devices was cleared for sale on the back of the regulatory approval of Prolene sutures and, in part, because of its supposed “substantial equivalence” to the Prolene Hernia System, despite the differences in design, use, anatomy, and site-specific considerations: TJ [42].

3.3.1 The SUI devices

91 TVT gained regulatory approval in Europe in 1997 and was cleared by the United States Food and Drug Administration (the **FDA**) on 28 January 1998. On 21 July 1998 it was approved by the TGA as a class IIB device for supply in Australia. It was first sold here in October 1999: TJ [85].

92 TVT-O received regulatory approval in Europe and the United States in December 2003. It was first supplied in Australia in March 2004: TJ [92]. It remains on the market in Australia.

93 TVT Secur was cleared for sale in the United States on 28 November 2005 and in Europe on 4 May 2006. It was launched in Australia in April 2007, but sales were halted in March 2008 and its registration was cancelled by the TGA in June 2012: TJ [100].

94 TVT Exact was released to the Australian market in July 2010: TJ [103]. It remains on the market in Australia.

95 TVT Abbrevo gained regulatory clearance in the United States on 1 July 2010, and in Europe in September 2010. It was first supplied in Australia in October 2010: TJ [104]. It remains on the market in Australia.

3.3.2 The POP devices

96 Gynemesh PS received regulatory clearance in the United States on 8 January 2002, in Europe on 20 March 2003, and in Australia on 26 May 2003. It was first supplied to the Australian market in July 2003: TJ [137]. On 16 March 2013 the indication for use of Gynemesh PS was narrowed to “a bridging material for apical vaginal and uterine prolapse where surgical treatment (laparotomy or laparoscopic approach) is warranted”. In other words, it was no longer indicated for transvaginal use but only for prolapse repair using an abdominal approach: TJ [140]. On 17 August 2017, JJM notified the TGA that it would be discontinuing Gynemesh effective immediately and on 22 August 2017 the TGA cancelled its entry on the ARTG: TJ [141].

97 Prolift was cleared for sale in Europe on 2 March 2005, around the same time in the United States, and in Australia on 30 March 2005. It was supplied in Australia in and from June 2005 until 15 August 2012. Registration was cancelled by the TGA on 21 April 2015: TJ [142].

98 Prolift+M obtained regulatory clearance in Europe on 18 March 2008, in the United States on 15 May 2008, and was first supplied in Australia in December 2009. Registration was cancelled by the TGA on 21 April 2015: TJ [162] and [168].

99 Prosima was first supplied in Australia in April 2010. It was not supplied after 15 August 2012 and, along with the other mesh kits (that is, the POP devices), the TGA cancelled its registration on 21 April 2015: TJ [168].

###### 3.4 Risks associated with mesh implantation

100 As noted, the appellants ultimately conceded that all of the pleaded complications could be caused by implantation of the devices, they knew of the potential to cause each of the pleaded complications from the time of first supply of a device, and each of the pleaded complications was clinically significant: TJ [191].

101 Mesh can extrude or “erode” into the bladder, urethra and vaginal canal: TJ [214]. This can occur immediately, soon after surgery or years later: TJ [216]. Exposure may have serious consequences. Since the vagina is never free of organisms (bacteria), once the mesh is exposed or erodes, the vagina “inevitably” becomes infected and the nidus (focus) of the infection is virtually impossible to treat because antibiotics have great difficulty penetrating through the mesh. Chronic inflammation is the result of exposed mesh and exposure may also aggravate chronic inflammation, particularly when bacteria colonise the exposed mesh: TJ [223].

102 Pain can be both more severe and more enduring after repair with procedures involving the use of mesh than after procedures which do not: TJ [228]. In contrast with native tissue repair, pain after mesh repair can arise well after surgery, sometimes years later: TJ [232]. All the devices may cause pain, including chronic pain, and there are various mechanisms that may be responsible for it: TJ [787(6)].

103 The mesh is difficult, if not impossible, to remove entirely as it is or becomes integrated in the connective tissue, and removal surgery may not relieve pain: TJ [246].

104 All meshes used in the devices must be inserted without tension. However, achieving the requisite amount of tension is not easy and even the most experienced surgeons can occasionally fail. If the mesh tension is too tight each complication is more likely to occur: TJ [263] and [264].

105 In the implantation of the SUI devices, the retropubic space is vulnerable to damage. Major vascular injury can occur and is potentially fatal. Haemorrhage can be “dramatic” and is difficult to manage: TJ [258]. Bladder perforation is a well-recognised risk of the retropubic procedures: TJ [259]. Obstructive voiding symptoms (including, rarely, retention) can also occur, possibly in association with a “higher than desirable tension”: TJ [260].

106 The implantation of the POP devices may involve injuries to the bladder, urethra, rectum and pelvic nerves: TJ [262].

107 There is no good evidence that the surgical learning curve accounts to any significant extent for “the inherent mesh complications”: TJ [270].

108 Transvaginal mesh kits like Prolift were “notoriously difficult for a surgeon to get right every time” even for a surgeon skilled in prolapse surgery: TJ [272].

109 Tension was the critical factor in the success of Prolift and if implants were put in too tightly patients often experienced pain and dyspareunia: TJ [272]. However, mesh may become too tight because of variations in the patient’s response to it: TJ [273]. The Prolift technique involved “a blind approach”, which made it difficult to determine whether or not there would be sufficient or excessive tension after the operation was complete: TJ [275].

110 The development of a haematoma after mesh implantation can become a far greater problem than a haematoma after native tissue repair because of healing difficulties in the presence of mesh: TJ [274].

111 Immunocompromised patients were at particular risk of harm from the chronic inflammatory response and the appellants either knew or ought to have known that was so at least from the time the very first device was launched. The proposition that this was not a matter of clinical significance must be rejected: TJ [281].

112 The immune response to any foreign material has been described as “complex, dynamic, and patient specific”. It was uncontroversial that the individual host response is unpredictable. The evidence established that a heightened chronic inflammatory response to implantation with non-absorbable polypropylene may occur in patients who have autoimmune disorders or have been using immune-suppressants for a long time and that the appellants knew this at the time the first of the devices was released to the market: TJ [282].

###### 3.5 Biocompatibility

113 The biomechanical properties of the mesh and mesh stiffness in particular are amongst the main reasons for the post-surgery complications of mesh implantation: TJ [299].

114 When a biomaterial such as polypropylene is implanted in the body, it provokes an inflammatory response in the host tissue. This inflammatory response is known as the “foreign body reaction” or “foreign body response”. It causes a layer of scar tissue to form around the implant or the pores of the implant, which is weaker and more rigid than normal healthy tissue: TJ [341]. In a foreign body reaction the inflammatory cells may persist for years, even decades, becoming “a chronic inflammatory response”: TJ [345].

115 For a permanent implant, like each of the devices, the foreign body response endures for the duration of the time the implant remains in the body: TJ [345].

116 The foreign body reaction can vary in intensity, and the intensity of the foreign body reaction, more particularly the extent of the inflammatory response, correlates with the extent of the fibrosis (scarring): TJ [347].

117 Until relatively recently, in the IFUs issued for all the devices the foreign body reaction was described as “transitory”: TJ [352]. However, the appellants knew that as long as the implant remains in the body, the foreign body or inflammatory response to polypropylene implants, including the devices in question, is not “transient” or “transitory” but chronic and permanent. Indeed, this was an intended outcome, as some fibrosis (scarring) is required to enable the device to adhere to the tissue and remain in place: TJ [353].

118 The respondents proved that the foreign body reaction is clinically significant and can cause many, if not all, of the pleaded complications: TJ [354].

119 The evidence establishes that every woman implanted with a device could suffer from all of the pleaded complications: TJ [405].

120 The appellants accepted that pore size is a critical component of the biocompatibility of any mesh used in the body: TJ [450]. The changes in pore size in vivo that occurs with the devices is significant: TJ [787(1)].

121 Bridging fibrosis can occur following implantation of all of the devices: TJ [533], [787(4)]. Bridging fibrosis is where the fibrous tissue around one filament comes in contact with the fibrous tissue around the next one: TJ [526]. The filling out of the distance between fibres by scar tissue forms a rigid “scar/mesh compound” or “scar plate”, which leads to a number of complications including loss of elasticity and pain associated with the rigidity, shrinkage or contraction of the mesh, mesh erosion, nerve entrapment, bacterial encasement, chronic pain and dyspareunia: TJ [521]. Bridging fibrosis is of clinical significance: TJ [537] and [787(4)].

122 “Mesh contraction” or “mesh shrinkage” is a complication of the use of polypropylene meshes. It involves a reduction in the surface area originally covered by the mesh brought about by the retraction of the fibrotic tissues around the mesh: TJ [538].

123 The evidence establishes that contraction has clinical significance: TJ [564]. The appellants’ records show that they accepted that contraction was clinically significant: TJ [576]. The appellants’ submissions to the contrary were inconsistent with their own documents, the opinions of the TVM Group (a group of experts who were developing a standardised technique for the surgical management of POP with mesh via a vaginal approach and attempting to better understand the mechanism of vaginal erosion which was associated with the use of synthetic materials in order to reduce its occurrence), and the position of the FDA: TJ [593]. Polypropylene mesh, including those meshes used in the devices, contracts in the way Professors Klinge, Klosterhalfen and Deprest explained, and contraction of the mesh has clinical significance. It can increase the risk of recurrence of the condition which it was designed to arrest and it can cause a number of complications such as mesh exposure/erosion and chronic pain, including at rest and with sexual intercourse: TJ [610], [787(5)].

124 It is inappropriate to transfer results of experimental studies on polypropylene fibres or sutures to polypropylene meshes: TJ [631]. A suture is a single fibre with only one compartment (loop). All the meshes in question consist of a considerably larger amount of foreign material and multiple compartments (pores). Consequently, the nature and extent of the reaction to a mesh implant will be different from the nature and extent of the reaction to a suture or sutures: TJ [633].

125 Hernia mesh is used as a flat mesh in largely tension-free conditions whereas the pelvic floor is an area subject to a great deal of stress and strain: TJ [634].

126 The clinical studies conducted by the Aachen Group confirmed that the more foreign body implanted or surface area covered, the greater the degree of inflammation: TJ [635].

127 The effect of polypropylene mesh on tissue differs according to the environment in which it is implanted: TJ [636].

128 The mesh cannot expand or contract and, in order to function properly, several organs in the pelvis need to expand and contract. The mobility and function of the anterior abdominal wall, on the other hand, are much more limited: TJ [637].

129 The devices are designed to be implanted superficially under sensitive mucosa and can easily erode through the mucosa. In contrast, erosions of hernia meshes are rare: TJ [637]. There is some evidence that the appellants recognised this: TJ [638].

130 Hernia repair meshes are only in direct contact with the abdominal fascia. Pelvic meshes, on the other hand, are placed in an environment with a wide range of soft tissues, including smooth and striated muscle, various kinds of connective tissue, and specialised organs: TJ [647].

131 The vagina is regarded as a “clean-contaminated” field. When polypropylene is implanted transvaginally, it is seeded with bacteria which contribute to infection and inflammation in the tissues: TJ [648]. There is no dispute and no doubt on the evidence that the mesh can both cause an infection and exacerbate an existing infection: TJ [652].

132 In numerous other respects the environment of the pelvic floor is very different from the wall of the abdomen or, for that matter, the groin: TJ [653]. The female genital area has a much higher nerve density in comparison with the anterior abdominal wall and the groin: TJ [660]. There are several sensory nerves in the female pelvis, including the pudendal nerve. The chance of mesh coming into contact with sensory nerves is high, particularly if it moves or erodes: TJ [681]. It is uncontentious that all the devices may cause pain, including chronic pain, and that there are various mechanisms that may be responsible for it: TJ [684].

133 There was a vastly higher rate of mesh exposure/erosion with vaginal implants compared to abdominal wall implants: TJ [660]. Accordingly:

(1) erosion through the vaginal mucosa is one of the most common complications of implantation with polypropylene mesh but it is rare to encounter mesh erosion through abdominal skin or into internal organs with hernia mesh: TJ [664];

(2) chronic pain is a complication of both hernia and vaginal mesh. The differences are mainly in the distribution and pattern of radiation. Since the arms of the POP devices and the ends of the SUI devices cross many structures in the pelvis, “pain distribution can involve areas from suprapubic to vaginal, introital, deep pelvic/vaginal, obturator/hip/groin, and into the buttock”. Pain can also radiate into the medial thigh: TJ [665];

(3) with hernia mesh, pain on intercourse can occur in cases of mesh migration into the spermatic cord, but dyspareunia is more prevalent as a complication of vaginal mesh: TJ [666];

(4) urinary obstruction is a complication “almost unique to vaginal implants”: TJ [667];

(5) other *de novo* urinary symptoms, such as overactive bladder and urge incontinence, are much more frequent for vaginal mesh implants: TJ [668]; and

(6) mesh excision is much more problematic in the case of vaginal implants as it is difficult to readily access the obturator and other “deep parts”. In addition, removal of mesh that has migrated into the bladder or rectum poses a risk of fistulas: TJ [669].

134 Polypropylene is subject to oxidation: TJ [685]. The IFUs provided with all the devices, however, stated that Prolene is not subject to degradation or weakening by the action of tissue enzymes: TJ [686]. It is because polypropylene is subject to oxidation that the appellants added antioxidants to it in the manufacture of Prolene (and Prolene Soft): TJ [691]. The weight of evidence indicates that polypropylene is subject to oxidation in vivo despite the addition of antioxidants during the manufacturing process: TJ [693]. Ethicon’s own scientists concluded that Prolene is subject to oxidative degradation in vivo: TJ [713]. Polypropylene, including Prolene, undergoes oxidation in vivo and the antioxidants added to the polypropylene during the manufacturing process, do not provide permanent protection from the risk of degradation: TJ [779].

135 When Prolene undergoes oxidation in vivo this is reflected in the surface cracking detected by Professor Kosterhalfen and Dr Iakovlev and others using scanning electron microscopy. When this occurs it may lead to an increase in inflammation and scar tissue formation but it has not been proved that when Prolene does oxidise in vivo it has any clinically significant effect and, in particular, that it causes a significant reduction in the tensile strength of the polymer: TJ [786].

###### 3.6 The performance of the devices

3.6.1 The evidence

136 Witnesses who were pelvic floor surgeons but who lacked epidemiological or statistical expertise placed weight on study findings which were not statistically significant or which drew heavily on studies that were affected by one or more kinds of bias: TJ [805]. Ethicon’s contention that the Court should (invariably) prefer the evidence of pelvic surgeons to evidence of the epidemiologists and biostatisticians in assessing how the published literature should be interpreted and applied is rejected: TJ [806].

3.6.2 Complication rates

137 The primary judge applied the following descriptions taken from the Royal College of Obstetricians and Gynaecologists: TJ [808].

|  |  |  |
| --- | --- | --- |
| Term | Number of people | Size of group/area |
| Very common | 1/1 to 1/10 | One person in a family |
| Common | 1/10 to 1/100 | One person in a street |
| Uncommon | 1/100 to 1/1000 | One person in a village |
| Rare | 1/1000 to 1/10,000 | One person in a small town |
| Very rare | 1/10,000 and above | One person in a large town |

138 Inappropriate placement is not the sole cause of exposure or erosion. Bunching and folding may also occur as a result of the scar tissue contracting around the mesh: TJ [836].

139 For the Prolift procedure, as counsel for the appellants conceded in closing argument, the evidence shows that, even in the most experienced hands, complications, including mesh erosion and exposure, will still occur: TJ [837].

140 It was common ground that mesh-related adverse events may occur years after vaginal mesh surgery: TJ [839].

141 The weight of the evidence makes it tolerably clear that many, if not all, of the complications associated with incontinence surgery using polypropylene mesh, including all the SUI devices, were at least in part attributable to the mesh. Even Ethicon accepted as much. The Nilsson et al (2013) (Nilsson C et al, “Seventeen years’ follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence” (2013) 24(8) Int Urogynecol J 1265–1269 (ETH.MESH.19876896)) results were exceptional; the study’s findings could not be generalised to other patient and surgeon populations where the same exclusion criteria were not employed, less skilled surgeons were involved, and all other conditions were not equal. In any case the study population was a small one: TJ [912].

142 The Morling study (Morling R et al, “Adverse events after first, single, mesh and non-mesh surgical procedures for stress urinary incontinence and pelvic organ prolapse in Scotland, 1997-2016: a population based cohort study” (2016) *The Lancet* 1–12 (SHI.MESH.00024517)) is significant, not least because it cast doubt over the widespread perception that the risk of recurrence of POP following native tissue procedures is high: TJ [1121].

143 The evidence indicates that the following complications are common after surgery with the SUI devices (that is, occurring in 1% to 10% of patients):

 mesh exposure/extrusion/erosion;

 recurrent urinary tract infections;

 chronic pain;

 dyspareunia;

 difficulty voiding;

 *de novo* urinary incontinence;

 recurrence of stress urinary incontinence;

 bladder perforations (with retropubic slings) (uncommon but not rare with transobturator slings); and

 reoperation or revision surgery associated with complications: TJ [1139].

144 After surgery with the POP devices, these complication rates were higher: TJ [1140].

3.6.3 SUI devices

145 Erosion is common to all the SUI devices, but most of these erosions are cases of vaginal exposure: TJ [1151].

146 The evidence does not allow for a definitive conclusion to be reached on the incidence of chronic pain after implantation of an SUI device. Having regard to the findings in the various reviews and studies discussed above, however, the incidence appears to be between 1% and 10%. It is therefore common, and not rare as Dr Hinoul and others have claimed: TJ [1167].

147 Dyspareunia and apareunia following implantation of the SUI devices is likely to be common: TJ [1174].

148 Reoperation or revision surgery is likely to be common following implantation with the SUI devices: TJ [1177].

149 Voiding difficulties are not uncommon after implantation with the SUI devices: TJ [1183].

150 *De novo* or recurrent urinary incontinence is a common outcome of surgery using the SUI devices, but unlikely to be any more frequent than it is after traditional surgery: TJ [1192].

151 Bladder and vaginal perforations are common after implantation with the retropubic SUI devices and uncommon after implantation with the transobturator SUI devices. The evidence is insufficient to enable a finding about the incidence of damage to other surrounding organs or vessels or to nerves, ligaments, tissue and blood vessels: TJ [1199].

3.6.4 POP devices

152 On any view of the matter, erosion, at least in the sense of exposure, is at least common after transvaginal implantation of any and all of the devices: TJ [1216].

153 Whatever the true rate of chronic pain for the POP devices, it does not appear to be rare, is likely to be higher than experienced by women who received only an SUI device, and the highest rates are likely to occur following multiple-compartment repair using synthetic polypropylene mesh, including Prolene Soft: TJ [1226].

154 *De novo* dyspareunia and apareunia are likely to be common after implantation of the POP devices: TJ [1234].

155 *De novo* SUI is also common after mesh surgery: TJ [1243].

156 While recurrence of POP after native tissue repair is a given, permanent mesh repair does not prevent it. Indeed, the evidence indicates that it is common after both kinds of repair: TJ [1248].

157 Injury to the bladder appears to be more common with mesh surgery than native tissue repair: TJ [1253].

3.6.5 Gynemesh PS used abdominally in vault repair

158 It therefore seems that mesh erosion is a common outcome of sacrocolpopexy but in the short to medium term the rates are lower than they are after transvaginal implantation: TJ [1269].

###### 3.7 Comparative outcomes

159 The two hypotheses considered were TJ [1285]:

(1) treatment of stress urinary incontinence with the SUI devices causes equivalent or fewer complications than surgical treatment of stress urinary incontinence using the alternative treatments (the **safety hypothesis**); and

(2) treatment of stress urinary incontinence with the SUI devices causes an equivalent or better outcome than surgical treatment of stress urinary incontinence using the alternative treatments (the **efficacy hypothesis**),

Where the alternative treatments identified were open colposuspension, laparoscopic colposuspension and fascial sling repair.

(Original emphasis).

160 Neither in October 1999, when TVT was first supplied in Australia, nor at any time thereafter were any of the SUI devices proven to be safer or more effective in the long-term than the alternative treatments: TJ [1336].

161 Neither in July 2003 when Gynemesh PS was first supplied in Australia nor at any time thereafter were any of the POP devices proven to be safer or more effective in the long-term than the alternative treatments: TJ [1336].

###### 3.8 Regulatory requirements

162 The evidence of Dr Allman, Ms Holland and Dr Pence is accepted: TJ [1353].

163 Each of the devices is a medical device within the meaning of the *Therapeutic Goods Act 1989* (Cth) (**TG Act**), s 41BD: TJ [1367].

164 At all material times JJM was the Australian sponsor of the devices, s 3 TG Act: TJ [1368].

165 Ethicon Sàrl and Ethicon Inc. were the manufacturers of the devices: TJ [1479].

166 TVT-O, TVT Abbrevo, and TVT Exact were all included in the same ARTG registration as TVT on the basis that they were the same kind of device. Similarly, the Prolift+M and Prosima devices were included in the same entry as Prolift. Gynemesh PS had a separate entry, as did TVT Secur, with its unique classification as a class III device: TJ [1377].

167 In order to secure registration on the ARTG for these devices (save for TVT) JJM, as the Australian sponsor, had to make an application under s 41FC of the TG Act, certifying the following relevant matters set out in s 41FD (TJ [1378]):

(1) that the device is correctly classified according to the medical device classifications;

(2) that it complies with the essential principles established under the TG Act and set out in Sch 1 of the MDR [the *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) (**Medical Devices Regulations** or **MDR**)];

(3) that appropriate “conformity assessment procedures” or other comparable procedures have been applied to devices of that kind;

(4) that either the sponsor has sufficient information to substantiate compliance with (b) and (c) above, or that the sponsor has procedures in place, including a written agreement with the manufacturer, to ensure that such information can be obtained from the manufacturer within the period specified in the regulations; and

(5) that particular advertising requirements have been complied with.

168 The *Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between Australia and the European Community* (**EC Mutual Recognition Agreement**) came into force on 1 January 1999. It committed Australia to recognising conformity assessment results, like testing and certification, performed by the European Union’s designated conformity assessment bodies. It covered a wide range of goods including medical devices: TJ [1389].

169 Apart from class III medical devices, at the time the devices were entered onto the ARTG, products that had received a “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. “CE” is an acronym for Conformité Européenne (meaning “European Conformity”). All the sponsor needed to do in order to have the devices registered on the ARTG was to produce the CE certificates: TJ [1391].

170 The presence of the CE Mark on a medical device constitutes a representation that the device conforms to the requirements of the particular European directive which applied to that type of product at the time of certification and thereafter and is an indication to the world at large that it may lawfully be sold in all member states of the European Union: TJ [1392].

171 Each of the devices carries a CE Mark. The mark was placed on TVT in 1997 (the evidence does not reveal the precise date but it is likely to have been in about November or late October), TVT-O in December 2003, TVT Secur on 4 May 2006, TVT Exact in June 2010, TVT Abbrevo in September 2010, Gynemesh PS on 20 March 2003, Prolift on 2 March 2005, Prolift+M on 18 March 2008, and Prosima on 12 April 2007: TJ [1398].

172 TVT was listed on the ARTG on 21 July 1998, TVT Secur on 18 October 2006, Gynemesh PS on 26 May 2003, and Prolift on 30 March 2005: TJ [1399].

173 With the exception of TVT Secur, each of the devices was classified as a class IIb device as each was a surgically invasive and implantable medical devices intended for long-term use. TVT Secur was classified as a class III device because of the Vicryl and PDS fleece which were designed to be wholly absorbed by the patient’s body: TJ [1400].

174 The European Directive required a critical evaluation of the relevant scientific literature relating to the safety, performance, design characteristics and intended purpose of the device where the device is demonstrated to be equivalent to the device to which the data relates and the data adequately demonstrate compliance with the relevant essential requirements or a critical evaluation of the results of all clinical investigations made or a critical evaluation of both the relevant scientific literature and clinical investigations: TJ [1413]. For implantable devices and devices in class III, however, clinical investigations were mandatory unless it was “duly justified to rely on existing clinical data”: TJ [1414].

175 Ethicon adopted the “literature” route for all devices. When clinical investigations were not undertaken the decision to rely on existing clinical data was not always “duly justified”. When clinical investigations were undertaken, Ethicon rarely waited for them to be completed before applying the CE Mark and did not critically evaluate them. The clinical evaluation reports for all the devices revealed a distinct lack of critical evaluation of the studies on which they relied and the literature to which they referred. Some of them disclosed no evaluation at all. In addition, in some instances the literature to which the data related and upon which the reports relied concerned devices that were not demonstrated to be equivalent to the device in question: TJ [1415].

176 Although Ethicon had procedures in place that were intended to meet regulatory requirements for obtaining CE marking for each of the devices, it did not in fact have adequate clinical evidence and therefore did not have sufficient justification to affix a CE Mark to any of them. Ethicon did not comply with the steps that a reasonable manufacturer would undertake to ensure that it was appropriate for the devices to maintain their CE marking once released onto the market: TJ [1480].

177 Ethicon did not adhere at any time to European Union or United States industry requirements and regulatory standards in any of the following areas: design validation; evaluation of complaints; management responsibility or risk management. During the development of both the SUI and the POP devices, no overarching, cohesive risk management system was in place. Ethicon’s design validation process was flawed because it did not adequately represent the population of surgeons using the devices and feedback from surgeons was not fully evaluated or implemented: TJ [1501].

178 Certain information required to be included in the IFUs of all devices was not provided. There were significant deficiencies with respect to the information provided about potential complications, adverse reactions, and warnings. A significant and extensive amount of information regarding the safety of the devices was omitted from the various IFUs. Ethicon’s failure to include the required information in the IFUs was contrary to the essential principles/requirements with which Ethicon had certified compliance as part of the process of obtaining registration of the devices on the ARTG: TJ [1540].

###### 3.9 Development and pre-market evaluations

179 There is no disagreement that any clinical experience with Prolene sutures and mesh should be considered when evaluating future devices of the same material. However, the evaluation should not have solely relied on prior history of similar devices for safety and effectiveness due to the new indication and use in pelvic floor repair versus the abdominal wall (hernia). What was not considered in these risk assessments was the impact of polypropylene mesh on anatomical location with respect to differing biomechanical properties (erosion/adhesion risk), microbiological flora (infection risk), as well as inflammatory response: TJ [1551].

3.9.1 SUI devices

3.9.1.1 TVT

180 Ethicon did not wait for the long-term results or for more widespread use before releasing TVT to the market. Dr Hinoul conceded as much in cross-examination. TVT was released in Europe in 1997, before the one year results of the Nordic multi-centre study had been published, and well before any long term results were available. At that point in time Ulmsten et al (1996) (Ulmsten U et al, “An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence” (1996) 7(2) Int Urogynecol J Pelvic Floor Dysfunct 81-85 (ETH.MESH.19935677)) was the only published article on the use of transvaginal tape using Prolene mesh. It was cleared for sale in the United States in January 1998: TJ [1573]-[1575].

181 If Dr Hinoul intended to represent that Ethicon carried out a thorough analysis of the similarities and differences between the two products (ProteGen and TVT), I cannot agree. The technical file, which he referenced, does contain a table which compared the two products. What it does not contain, however, is any assessment and demonstration of the significance these might have on safety and performance. If ProteGen were indeed substantially equivalent to TVT, then one might also reasonably have expected that the literature review in the clinical evaluation report would refer to, and critically analyse, the literature on ProteGen. Yet it did not: TJ [1577]. Further:

(1) Dr Hinoul went on to say that ProteGen was recalled in 1999 after many patients experienced complications, though he did not say what these complications were. I was not taken to any evidence to indicate that the experience with ProteGen triggered a review by Ethicon of TVT, as one might have expected of a reasonably prudent manufacturer: TJ [1578];

(2) Dr Allman’s opinion, which was not challenged, was that the two devices did not meet the European definition of equivalence: TJ [1580]; and

(3) as Dr Allman observed, it is logically difficult to sustain an argument that the safety and performance of ProteGen could be used to define the safety and performance of TVT: TJ [1580].

182 It was common ground that there had been no comparative, let alone randomised controlled trials, assessing the safety and efficacy of TVT at the time of its launch in Australia in 1999: TJ [1600].

183 The clinical evaluation conducted by Ethicon was not sufficient to justify CE marking for TVT. Ethicon should have conducted “Ethicon-controlled” clinical investigations before CE marking was obtained or instituted post-market clinical follow-up studies at the time of CE marking: TJ [1601].

184 Ethicon’s risk assessments of the TVT device were manifestly inadequate: TJ [1602]. Ethicon had not complied with the requirements for quality management systems for the design of a medical device. The design history and technical files from 1999 and 2000 disclosed that critical documentation regarding the TVT system design and associated processes were missing: TJ [1606]. A design Failure Mode and Effect Analysis (**dFMEA**) was not created until 2000-2002, three and five years after the CE Mark was applied to TVT and two and four years after it was first sold in Australia: TJ [1607]. This retrospective dFMEA was not credible: TJ [1608].

3.9.1.2 TVT-O

185 TVT-O was launched worldwide on 22 December 2003 and was first supplied in Australia in March 2004: TJ [1654].

186 The launch was the result of Ethicon cutting corners including by compromising on safety evaluation: TJ [1655].

3.9.1.3 TVT Secur

187 Ethicon’s comparison of TVT Secur, which utilises different materials and has a different size, shape factor, and surgical approach, with TVT, was not a valid method to determine a specification for the TVT Secur: TJ [1666]. It is true that the indications of use were the same as the currently marketed TVT mesh products but there were significant differences between the devices in material, construction, and dimensions. Supplementary submissions filed by the appellants on 20 June 2018 acknowledged as much: TJ [1688]. The data from TVT and TVT-O “could not appropriately be leveraged to accept the risks associated with [TVT Secur]”: TJ [1692].

188 The documents relating to the dFMEA for TVT Secur did not fully comply with either Ethicon’s own procedural requirements or industry standards: TJ [1671].

189 The design validation for TVT Secur did not represent the simulated use conditions and led to false confidence in the performance of the device in the hands of inexperienced users without the benefit of one-on-one training by the design team: TJ [1678]-[1679].

190 The 2006 clinical evaluation report (**CER**)also declared that TVT Secur was a safe device, effective for treatment of stress urinary incontinence, and that additional clinical studies were unnecessary before the product was released to the market. These conclusions were unjustified and the report itself was insufficient to support CE marking. It was illogical to rely on safety and performance data from predicate devices when TVT Secur was designed to be different from, and an improvement on, those devices: TJ [1695].

191 In all likelihood the failure to recommend or conduct clinical studies, let alone a randomised controlled trial, before the device was launched, whether overseas or in Australia, was attributable to marketing considerations: TJ [1700].

3.9.1.4 TVT Exact

192 No studies or clinical trials of TVT Exact were undertaken before market launch in Australia in July 2010: TJ [1701].

193 Reliance on the TVT data was unjustified since the procedure used with TVT Exact was different in that it involved one less cystoscopy. A conclusion that review of safety and efficacy data for TVT was sufficient to assess TVT Exact would require a more critical assessment of the differences between the devices and the impact, both good and bad, on clinical use: TJ [1712].

3.9.1.5 TVT Abbrevo

194 The conclusion of the CER was unjustified by the clinical evidence presented and the report did not satisfy the European regulatory requirements for clinical evaluation: TJ [1731]. Ethicon should have conducted clinical investigations of TVT Abbrevo, with clearly defined acceptance criteria before CE marking or considered post-market clinical follow-up studies: TJ [1732].

195 By October 2010, when TVT Abbrevo was launched in Australia, no further clinical trials of the device had been conducted: TJ [1734].

3.9.2 POP devices

3.9.2.1 Gynemesh PS

196 In the technical file for Gynemesh PS no consideration was apparently given to the change in indication (from treatment for hernias in the abdominal wall to repair of POPs). At the very least, the new indication should have been addressed in the risk evaluation. In fact, the new indication was not “addressed as significant” in any of the submission files, despite the vast differences between Prolene sutures, hernia mesh, and Gynemesh PS: TJ [1751].

197 The 2002 Gynemesh PS CER and the material to which it referred did not represent a sufficient and adequate basis on which to come to a conclusion that the use of the mesh for the indication identified was safe and efficacious: TJ [1755]. Dr Weisberg signed this CER without independently reviewing the literature upon which it was based: TJ [1770]. The CER failed to advert to the essential requirements of the European Directive and it also failed to conform to them (the **Essential Requirements**): TJ [1776]. The conclusion that its use appeared to be safe and efficacious for pelvic floor repair was not justified and the CER was insufficient to justify CE marking of Gynemesh PS: TJ [1777].

198 A clinical study was begun before the CER was signed but the appellants did not wait for the results before applying for CE marking: TJ [1783].

3.9.2.2 Prolift

199 The conclusions of the CER for the Prolift were not justified as “[n]o clinical evidence was presented to demonstrate the safety and performance of the mesh under the normal conditions of use of the complete PROLIFT device”: TJ [1835].

200 The Prolift CER was “incoherent” and suffered from the same problems as the CER on Gynemesh PS: TJ [1848]. While Dr Hinoul conceded in cross-examination that the CER was inadequate to justify the product’s safety as a stand-alone document he steadfastly, and for no good reason, refused to concede that the statement about the absence of reports of tissue contraction in the Gynemesh clinical evaluation was misleading: TJ [1849]. Dr Hinoul contended that “[t]his risk assessment corresponds to the risk/benefit analyses I have performed”. In light of the numerous problems with the Prolift CER, if Dr Hinoul’s contention is an accurate representation of the nature of his risk/benefit analyses, it only serves to undermine those analyses: TJ [1852].

201 Prolift was first supplied in Europe in January 2005 and approved for sale in the United States in March 2005. Prolift was first supplied in Australia in June that year: TJ [1856]. As Ethicon frankly admitted in its “Prolift+M Clinical Strategy” finalised on 6 September 2007, Prolift was launched without clinical evidence. This is consistent with Dr Allman’s view that the information disclosed in the 2005 CER for Prolift was inadequate to justify CE marking: TJ [1857].

202 Special training of the intended user was necessaryfor implantation of the Prolift but he Prolift IFU merely stated that training on the use of the Prolift system was “recommended and available”: TJ [1869].

3.9.2.3 Prolift+M

203 No clinical studies of Prolift+M were carried out before the device was placed on the market. Prolift+M was cleared for supply on the basis of Ethicon’s claim, which proved to be false, that it was equivalent to other Ethicon devices that were already on the market TJ [1883].

204 The Prolift+M CER assumed that Prolift+M was an equivalent device to Prolift, which was made from Prolene Soft whilst at the same time asserting that Prolift+M, which used Gynemesh M, was designed to be an improvement on Prolift. They were not equivalent devices and there was no justification for using the literature route to certification: TJ [1904].

205 Given the design differences between Prolift and Prolift+M, a more rigorous argument, with clinical data, was needed to conclude that the risk/benefit ratio was acceptable. The CER did not meet the requirements of the European Directive or the European Commission guidelines on the evaluation of clinical data, April 2003 (**MEDDEV 2.7.1**). Its conclusions were not justified by the data presented, and it was insufficient to justify CE marking: TJ [1911].

3.9.2.4 Prosima

206 Ethicon’s clinical strategy for Prosima reflected a misunderstanding of European regulatory requirements. Clinical data were necessary to comply with the requirements for CE marking: TJ [1914].

207 The appellants were prepared to affix the CE Mark and release the Prosima device to the market before the additional clinical studies Carey et al said were necessary to establish the safety and efficacy of the device had been conducted (Carey M et al “Vaginal surgery for pelvic organ prolapse using mesh and a vaginal support device” (2008) 115(3) BJOG 391–397 (ETH.MESH.00154197)) and notwithstanding the conclusion of the Maher et al Cochrane review (Maher C et al, “Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse” *The Cochrane Collaboration* (John Wiley & Sons Ltd, 2016) (SHI.MESH.00005748)): TJ [1940].

###### 3.10 Post-market evaluation of the devices

3.10.1 General

208 The appellants were obliged to undertake post-market surveillance and evaluation of the safety and efficacy of the devices: TJ [1956].

209 Ethicon displayed a poor understanding of the European regulatory requirements for clinical evaluation and post-market surveillance: TJ [1960].

210 Ethicon’s post-market clinical evaluations were neither regular nor rigorous and, not until 2012 at the earliest, could they be described as detailed: TJ [1970].

211 The CERs were deficient in numerous respects, review of complaints and adverse events was unsatisfactory, and the conclusions drawn from them largely unjustified: TJ [1971].

3.10.2 Complaints

212 The appellants received numerous complaints about the devices: TJ [1973].

213 There was under-reporting of events in practice, and the incidence of events derived from the Manufacturer and User Facility Device Experience (**MAUDE**) database was unreliable: TJ [1979].

214 Ethicon had a practice of dismissing (and determining not to report) complaints on the basis that they were the subject of adequate warnings in the IFUs, even though that was not the case, and Ethicon would then proceed to feed back into its clinical evaluation process low adverse event rates as evidence of the safety of its products: TJ [1980].

215 Dr Pence provided 29 examples of complaints received by Ethicon in relation to its SUI devices which, in her opinion, were reportable but were not submitted to the FDA as medical device reports (note: the primary judge accepted Dr Pence’s evidence – see above). Many of Ethicon’s explanations were disingenuous and led to under-reporting of adverse events. A reasonably prudent manufacturer would have performed due diligence to follow-up some of these events to determine if there were any longer-term sequelae: TJ [1984]. Dr Pence undertook a similar exercise in respect of the complaints received for the POP devices. She reviewed 116 reports that were determined to be non-reportable, and provided a number of examples of events that she considered should have been reported: TJ [1990].

216 Similarly, on numerous occasions, Ethicon determined that adverse events were not reportable to the UK regulator, the UK Medicines and Healthcare products Regulatory Agency (**MHRA**): TJ [1996].

217 Ethicon’s approach to complaints reporting limited the capacity of the regulatory authorities to adequately determine the safety of the devices: TJ [2004].

218 The appellants’ internal documents showed that they recognised that inadequate reporting was an issue: TJ [2005].

3.10.3 BSI audits

219 The British Standards Institute (**BSI**) prepared 9 audit reports for the appellants: TJ [2008]. In June 2008, BSI found serious deficiencies in post-market surveillance with respect to Gynemesh PS, Prolift+M and Prosima: TJ [2009].

220 In June 2009, BSI’s findings were raised to major non-conformity status after Ethicon’s Corrective Action Plan (**CAP**) was rejected because it contained “insufficient information for Post Market surveillance feeding into Risk and Clinical, as well as insufficient details on implementation dates”: TJ [2010].

221 With respect to all files, BSI noted that the risk management report only appeared to have been completed on the basis of complaints, only addressed design/application risks, and did not consider process risks or other post-market surveillance activities: TJ [2011].

222 BSI also found that none of the CERs was consistent with the requirements of MEDDEV 2.7.1 for clear description of search methodology, clear exclusion data, citation of weighting methods, details of specific analysis of each cited paper, demonstration of equivalence, clear link to post-market surveillance, and because there was insufficient justification for the lack of post-market follow-up: TJ [2012].

223 In an audit in September 2012, BSI discovered that none of the risk management files had been finalised in accordance with the previous CAP, few of the CERs had been updated as required by another CAP, and the updated implementation plans indicated that completion may take three years, well-beyond the original or extended timelines: TJ [2013].

224 BSI’s assessments were based on sampling. Accordingly, it is reasonable to infer that the non-conformities were not confined to the audited files and were more likely than not equally applicable to Ethicon’s evaluations and risk assessments for the other devices: TJ [2018].

###### 3.11 Removal of some devices from the market

225 None of the POP devices is presently for sale in Australia, the United States or Europe. Neither is TVT Secur. These devices have been removed from the ARTG: TJ [2445].

226 The FDA issued an alert to doctors on 20 October 2008 entitled “FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence”: TJ [2448]-[2449].

227 On 13 July 2011, the FDA issued an “update” to its 2008 alert. Its stated purpose was to alert health care providers and patients alike, both actual and prospective, that the problem was more serious than the 2008 report might have suggested: TJ [2452].

228 On 3 January 2012, the FDA issued notices to Ethicon under § 522 of the Federal Food, Drug and Cosmetic Act 1938 (US): TJ [2469]. The FDA informed Ethicon that each of Gynemesh PS, Prolift, Prolift+M, Prosima and TVT Secur was subject to post-market surveillance under § 522 because they were class II devices the failure of which “would be reasonably likely to cause mesh erosion (i.e. organ perforation), severe pain, and fistula formation, which would meet the definition of ‘serious adverse health consequences’ at 21 C.F.R. § 822.3(j)”, and also because the devices were intended to be implanted in the body for more than one year: TJ [2470]. The FDA ordered Ethicon to submit a plan addressing a number of questions: TJ [2471]. Ethicon had no inclination to conduct either of the studies recommended in by the FDA: TJ [2472].

229 On 1 February 2012 Ethicon submitted “study plans” for Prolift and Prolift+M, Gynemesh PS, Prosima, and TVT Secur. In early April 2012, the FDA informed Ethicon that it did not accept its proposals: TJ [2474].

230 On 2 May 2012 Ethicon wrote to the FDA to inform it that Ethicon would “stop commercializing” (that is to say, stop selling) TVT Secur and had no intention of resuming sales in the future: TJ [2484]. Letters in like terms were sent on 9 May 2012 seeking a similar indulgence in relation to the § 522 orders for the POP devices, informing the FDA that Ethicon would stop the sale of Prosima, Prolift and Prolift+M within 120 days and had no intention of resuming sales in the future: TJ [2485]. On 9 July 2012, the FDA agreed to Ethicon’s request to conditionally suspend the § 522 orders: TJ [2488].

231 More likely than not, Ethicon realised it could not satisfy either the market or the FDA that, with respect to the transvaginal use of Gynemesh PS, the mesh kits, or TVT Secur, the benefits outweighed the risks: TJ [2491].

232 A hold was put on supply of the TVT Secur device in Australia in March 2008 and the ARTG registration for it was cancelled in June 2012: TJ [2493].

233 On 28 November 2017 the TGA decided to remove from the ARTG all transvaginal mesh products used in the treatment of POP. In its media release issued the same day the TGA explained that the decision was taken following its review of the most recent published international studies and an examination of the clinical evidence for each such product included in the ARTG and supplied in Australia. It concluded that “the benefits of using transvaginal mesh products in the treatment of POP do not outweigh the risks these products pose to patients”: TJ [2559].

###### 3.12 Information the appellants provided about the devices

234 In Australia, a medical device must be sold accompanied by an IFU document subject to some immaterial exceptions: TJ [2561].

235 IFUs for each of the devices were prepared by Ethicon Inc. and distributed across the world, including Australia, in the boxes in which the devices were sold, other than the original IFU for TVT where the IFU was prepared by Medscand Medical AB which Ethicon subsequently purchased: TJ [1559] and [2562].

236 The IFU is “an essential component of medical devices”, “the cornerstone of risk management”, and “the primary tool for communication between the manufacturer and the clinician about the particular device”: TJ [2563].

237 Twenty-five IFUs for the SUI devices were admitted into evidence. The IFUs were in use in Australia from 1999 to at least 2015: TJ [2586].

238 A reasonable manufacturer of medical devices in the position of Ethicon should have warned of risks which were not included in the IFUs for the SUI devices: TJ [2625]. Based on information Ethicon knew or should have known, the IFUs for all the SUI devices were, and remained, incomplete and certain warnings should have been given in the IFUs at the time those devices were available for sale. The IFUs for all the SUI devices were deficient: TJ [2627]-[2628].

239 Fourteen IFUs for the POP devices were tendered: TJ [2629].

240 Based on the information known by, or knowable to, Ethicon the warnings in the POP devices were incomplete. Failing to include them meant that surgeons were denied the full scope of the safety information necessary to weigh the potential risks and benefits of implanting the device and to fully inform patients of the potential risks to get their consent. A reasonable manufacturer would have warned surgeons (and hence, patients) of those risks: TJ [2645].

241 The warnings and precautions section of each of the IFUs for the POP devices were incomplete. Warnings in certain terms should have been included in all IFUs for the POP devices at all times: TJ [2654].

242 The appellants did not provide training to all surgeons who used the POP devices or take reasonable steps to ensure that the training they did provide adequately equipped those who received it with the skills and information to conduct the operations with minimal risk of injury: TJ [2705].

243 The appellants acknowledged that no surgeon brochures or presentations regarding Prolift contained relevant warnings and the IFU was the only material provided for surgeons that included relevant warnings: TJ [2779].

244 There were numerous deficiencies in the warnings and other information provided by the appellants about the safety and efficacy of the devices to patients and surgeons: TJ [2810] and [2811].

245 The obligation to inform users of the risks in the use of the devices was far more extensive than Dr Hinoul acknowledged and the appellants consistently failed to discharge it. Informing users of a risk requires informing users of the probability and severity of harm, and how that risk was established, not just informing users of a possible harm. None of the warnings or other information provided by the respondents satisfied this requirement. The appellants did provide warnings about some risks but the warnings they gave did not extend to all known risks or to all the pleaded complications. No information was provided about the probability of the risks and next to no information about their severity. Nor did the appellants disclose the manner in which the risks were established. Warnings and other information provided by the appellants about all the devices were deficient: TJ [3031]-[3034].

246 In summary, the primary judge found in respect of the SUI devices that the IFUs were inadequate because, amongst other things:

(1) the first IFU for TVT (the Medscand IFU) omitted any mention of the risk of erosion, exposure or contraction of the mesh: TJ [3276];

(2) the first reference to “implant contraction” in an IFU for a device, which included the SUI devices, did not appear until the 11 January 2005 Prolift IFU: TJ [3276];

(3) the IFUs for the SUI devices warned against using the devices in women with urinary tract infections and advised that “as with all foreign bodies Prolene mesh may potentiate an existing infection”. But until 2015 none of them warned that the mesh could actually cause infection: TJ [3277];

(4) the first reference to potential difficulties with mesh removal did not appear in any IFU until 3 April 2015 when they were mentioned for the first time in the Gynemesh PS IFU: TJ [3278];

(5) a number of other complications associated with the implantation of the devices and known to the appellants at all relevant times, were not included in the IFUs until 2013, some not until 2015; some were never included: TJ [3279];

(6) in respect of permanent foreign body responses following the surgical implantation of mesh, the representations contained in all IFUs for the SUI devices until September or October 2015 which claimed that such responses were “transitory” were misleading, because it was liable to lead the reader to believe that there is no possibility of a permanent or long-lasting abnormal foreign body response, which was consistent with the appellants’ internal position that the foreign body responses were not transitory at all: TJ [3282]-[3286];

(7) inaccurately and in a manner which was apt to mislead the reader, the IFUs represented that the inflammatory reaction elicited in the tissues is transient. Although immediate or acute post-operative inflammation due to implantation may resolve within days or weeks, the inflammatory foreign body reaction around the implants can persist for years; having been told that a minimal and transient inflammatory response to the mesh could occur, persons generally are entitled to expect no more severe or enduring a reaction: TJ [3293] and [3295];

(8) though the clinical significance of degradation and weakening of mesh was controversial, the IFUs all contained an incorrect representation that mesh is not subject to degradation or weakening by the action of tissue enzymes: TJ [3298];

(9) the description in the IFUs for, among others, all the SUI devices includes the sentence: “[t]his material, when used as a suture, has been reported to be non-reactive …”. The primary judge found this was unjustified because the tissue reactions between mesh and sutures were not comparable and that the statement could lull readers into a false sense of security: TJ [3299];

(10) the description of the devices in the IFUs for TVT, TVT-O, TVT Secur, included the representation that the mesh has “elasticity in both directions” or a “bi-directional elastic property [which] allows adaptation to various stresses encountered in the body”. The primary judge accepted that there was no scientific data to justify these statements. Moreover, her Honour found that whatever elastic properties the devices possessed, they were not adapted to the stresses of the female pelvis: TJ [3300]-[3301]; and

(11) some of the IFUs for TVT, TVT Secur, TVT Exact, contained a statement to the effect that if the implant is used in contaminated areas it must only be with the understanding that subsequent infection may require its removal. The primary judge found that the statement was misleading in that it indicated that removal would only be required in the case of infection and it was deficient in that it did not advert to the difficulties of removal or to the fact that removal might not alleviate pain. Moreover, none of the IFUs provided any instruction on the method of removal: TJ [3307].

247 The primary judge made the following findings about the marketing of the SUI devices:

(1) the marketing strategy targeted surgeons which it divided and classified as “Community Practitioner”; “Practice Driven”; “Technical Innovator” and “Clinical Innovator”: TJ [2708];

(2) the appellants particularly targeted the “Practice Driven Physician” who was focussed on profitability and efficiency;

(3) the appellants’ group sales representatives visited surgeons to convince them to use its mesh for (at least) prolapse surgery: TJ [2717];

(4) the appellants produced two kinds of product brochures: brochures directed to patients and brochures targeted at surgeons. Both kinds were integral to the appellants’ marketing strategy: TJ [3261];

(5) a brochure was produced for “the TVT family of products” which represented that the products had benefits including “no late onset adverse events”; “no tape erosion” and “no tissue reactions”; this was “not a true reflection of the information in Ethicon’s possession.”: TJ [2719] and [2721];

(6) the patient brochures for the SUI devices contained representations that told “a story of simple fixes for [stress urinary incontinence] that would restore the patient to a life free from social embarrassment and inhibition.” They tended to minimise the significance of any accompanying warning: TJ [2730];

(7) a 2004 patient brochure for the TVT family of products made no suggestion that long term complications could arise, and created the impression that with the exception of lower urinary tract obstruction, any complications would be short lived: TJ [2741];

(8) the 2010 TVT family of products patient brochure in response to the question “What are the risks?” said (see: TJ [2743]):

All medical procedures present risks. Although rare, complications include difficulty urinating, injury to blood vessels of the pelvic sidewall and abdominal wall, and bladder and bowel injury. For a complete description of risks, see the adverse events section of the attached product information.

(9) the adverse events section of the attached product information said (see TJ [2744]):

Punctures or lacerations or injury to vessels, nerves, bladder, urethra, or bowel may occur during instrument passage and may require surgical repair.

Improper placement of the TVT device may result in incomplete or no relief from urinary incontinence or may cause urinary tract obstruction.

The primary judge found that this was misleading because it represented that adverse reactions only occur because of intraoperative surgical error, and it omitted mention of mesh erosion, exposure, contraction and the potential consequences. There was no acknowledgment of the possibility of long-term complications: TJ [2745];

(10) the 2013 brochure was updated to include (see TJ [2746):

Transitory local irritation at the wound site and a transitory foreign body response may occur. The response could result in extrusion, erosion, fistula formation and inflammation.

(11) the brochures directed at surgeons emphasised the benefits of the SUI devices over those manufactured by the appellants’ competitors, though they were more muted in tone than the patient brochures they paid little attention to the potential risks: TJ [2748]; and

(12) in respect of a brochure for the TVT Secur, the respondents represented that the product had (see: TJ [2751]):

* Low incidence of serious reported complications (<0.03%)
* Low retention rate (<3%)
* No reported urethral erosions in multiple clinical studies of 50+ patients.

248 In summary, the primary judge found in respect of the POP devices that the IFUs were inadequate because, amongst other things:

(1) the first reference to the “implant contraction” in an IFU for any device did not appear until the 11 January 2005 Prolift IFU: TJ [3276];

(2) the first reference to potential difficulties with mesh removal did not appear in any IFU until 3 April 2015 when they were mentioned for the first time in the Gynemesh PS IFU. By then, however, all the other POP devices were no longer sold or manufactured: TJ [3278];

(3) a number of other complications associated with the implantation of the devices and known to the appellants at all relevant times, were not included in the IFUs until 2013, some not until 2015. Some were never included: TJ [3279];

(4) inaccurately and in a manner which was apt to mislead the reader, the IFUs represented that the inflammatory reaction elicited in the tissues is transient. Although immediate or acute post-operative inflammation due to implantation may resolve within days or weeks, the inflammatory foreign body reaction around the implants can persist for years; having been told that a minimal and transient inflammatory response to the mesh could occur, persons generally are entitled to expect no more severe or enduring a reaction: TJ [3293] and [3295];

(5) the representation in the IFUs for the POP devices that “[t]he mesh remains soft and pliable” is misleading, given the evidence about contraction and the development of a solid mass in the area of the implanted mesh: TJ [3296];

(6) the unqualified statement [in the IFUs for the POP devices] that “normal wound healing is not noticeably impaired” was also misleading: TJ [3297];

(7) though the clinical significance of degradation and weakening of mesh was controversial, the IFUs all contained an incorrect representation that mesh is not subject to degradation or weakening by the action of tissue enzymes: TJ [3298];

(8) the description in the IFUs for all the devices except for Prolift+M includes the sentence: “[t]his material, when used as a suture, has been reported to be non-reactive …”. The primary judge found this was unjustified because the tissue reactions between mesh and sutures were not comparable and that the statement could lull readers into a false sense of security: TJ [3299];

(9) the description of the devices in the IFUs for Gynemesh PS, Prolift, and Prosima also includes the representation that the mesh has “elasticity in both directions” or a “bi-directional elastic property [which] allows adaptation to various stresses encountered in the body”. The primary judge accepted that there was no scientific data to justify these statements. Moreover, her Honour found that whatever elastic properties the devices possessed, they were not adapted to the stresses of the female pelvis: TJ [3300]-[3301];

(10) the IFUs for Gynemesh PS, Prolift and Prosima stated that “[t]he mesh affords excellent strength, durability, and surgical adaptability …” when the evidence was to the contrary: TJ [3302];

(11) the Gynemesh PS IFU also represented that Gynemesh PS has “sufficient porosity for necessary tissue ingrowth”. This representation was misleading because the type of tissue ingrowth was not a type of tissue ingrowth that avoided complications: TJ [3303];

(12) it was misleading to describe Gynemesh PS as a mesh “…knitted into a unique design that results in a mesh that is approximately 50% more flexible than standard PROLENE mesh” because it is capable of causing the reader to erroneously think that Gynemesh PS was designed for the specific purpose of prolapse repair in women when it is in fact a mesh designed for use in the abdominal wall rebadged for pelvic use as Gynemesh PS: TJ [3304]; and

(13) some of the IFUs for Gynemesh PS, Prosima and Prolift+M contained a statement to the effect that if the implant is used in contaminated areas it must only be with the understanding that subsequent infection may require its removal. The primary judge found that the statement was misleading in that it indicated that removal would only be required in the case of infection and it was deficient in that it did not advert to the difficulties of removal or to the fact that removal might not alleviate pain. Moreover, none of the IFUs provided any instruction on the method of removal: TJ [3307].

249 The primary judge made the following findings about the marketing of the POP devices:

(1) a surgeon brochure for Gynemesh PS contained misleading representations including that the product was “[a]n inert synthetic mesh” and that it “conforms to the anatomy and lies flat” when it was likely that the appellants knew from the work of Professors Klinge and Klosterhalfen that meshes were not inert: TJ [2759]-[2760];

(2) as Gynemesh PS was Prolene Soft Mesh and manufactured for abdominal hernia repairs, there was no sound foundation for the representations that Gynemesh PS conformed to the anatomy of the pelvic floor, that it lies flat, and that it did not harbour bacteria: TJ [2761];

(3) a 2005 patient brochure for Prolift informed patients that mesh was “a soft synthetic material specially designed for placement through the vagina to support pelvic organs that have ‘dropped out’ of their normal position (prolapsed)”, yet this was not correct as the mesh was “not ‘specifically designed’” for the Prolift application and “[t]his statement is unsupportable from … a design history standpoint.”” This brochure also contained the following representations regarding what the product could do:

It allows for the restoration of sexual function by restoring normal vaginal anatomy.

Using this new surgical procedure there is often no need to perform a hysterectomy if the uterus itself is not diseased.

The 2005 brochure did not warn patients that they might experience a great deal more pain than with traditional surgery or that the pain could be chronic and resistant to treatment: TJ [2764]-[2766];

(4) the same patient brochure included a section on risks that said:

All surgical procedures present some risks. Although rare, complications associated with the procedure include injury to blood vessels of the pelvis, nerve damage, difficulty urinating, bladder and bowel injury. There is also a small risk of the mesh material becoming exposed into the vaginal canal.

The primary judge found that the warning created the impression that the nominated risks, with the exception of the risk of mesh exposure, were risks which could occur with traditional pelvic surgery. It also understated the risks: TJ [2767]-[2769];

(5) the respondents acknowledged that no surgeon brochures or presentations regarding Prolift contained relevant warnings and the IFU was the only material provided that contained relevant warnings: TJ [2779];

(6) the Prolift +M brochure from 2010 was promoted as being a device suitable for all surgeons of varying skill levels: TJ [2780];

(7) brochures for Prosima omitted reference to the randomised trial conducted by its inventor, Dr Marcus Carey, which demonstrated that the product produced no better results that native tissue colporrhaphy: TJ [2783]; and

(8) the Prosima brochures all directed the reader to the IFUs “for complete contraindications, warnings, precautions, and adverse reactions”. The primary judge found that this was a clear message from the manufacturer that surgeons need look no further than the IFUs for information on those matters: TJ [2797].

###### 3.13 Statutory claims

3.13.1 Defect

250 At all relevant times Ethicon Sàrl and Ethicon Inc. were “manufacturers” under the TPA and ACL, at least because they manufactured the devices and used their brand name in relation to them, and JJM was a deemed “manufacturer” because it imported the devices into Australia: TJ [3121].

251 The statutory causes of action apply to Ethicon Sàrl and Ethicon Inc. even though they are incorporated overseas and neither has a place of business in Australia: TJ [3124] and [3125].

252 The relevant conduct of Ethicon Sàrl and Ethicon Inc. was in trade or commerce: TJ [3131].

253 In any event, at all relevant times both Ethicon Sàrl and Ethicon Inc. were carrying on business in Australia: TJ [3132].

254 The mere fact that the CE marking was affixed to the devices did not prove that the devices met the regulatory requirements and standards. All the CE marking proved was that the manufacturer asserted and represented that a device met those requirements and that the steps taken to meet the requirements of the European Directive had occurred: TJ [3270].

255 It is reasonable for the public to expect that a medical device which carries CE marking has been cleared for sale and meets the regulatory requirements and standards of the European Directive and, relatedly, the requirements of the TGA. If it does not, it is unlikely to have the safety persons generally are entitled to expect. An isolated episode of non-compliance or an insignificant infraction may not matter. Repeated and systematic non-compliance, however, certainly does: TJ [3272].

256 At all relevant times none of the SUI devices met the level of safety persons generally were entitled to expect: TJ [3413].

257 Many of the representations the appellants made about the SUI devices were misleading: TJ [3418].

258 Having regard to the nature and extent of the risks associated with all the devices, the deficiencies of the appellants’ warnings and the other information they provided, the repeated failure to comply with the requirements for CE marking, and the way in which the devices were marketed, at no relevant time was the safety of any of the SUI devices such as persons generally were entitled to expect. Accordingly, each SUI device had a “defect” or “a safety defect” within the meaning of the TPA and the ACL respectively: TJ [3458].

259 The information provided in the IFUs for all the POP devices was deficient in numerous respects from the first iteration to the last: TJ [3464].

260 While amendments were made to the IFUs from time to time, they did not adequately capture either the true nature or extent of the adverse events that could arise from implantation with the devices or the categories of patients for whom surgery using those devices was contraindicated: TJ [3465].

261 There was a wealth of evidence to indicate that the POP devices were never safe for general use in the wide range of patients for whom they were indicated and promoted: TJ [3470].

262 Despite Ethicon’s repeated unqualified representations to the regulators that all the devices were safe and efficacious and despite the indications in the IFUs, not even Dr Hinoul could justify the unrestricted use of the POP devices: TJ [3494].

263 None of the POP devices satisfied all the requirements for CE marking at any relevant time: TJ [3495].

264 The weight of evidence leads inexorably to the conclusion that at all relevant times the safety of all the POP devices was below the level that persons generally were entitled to expect. Notwithstanding the differences in the various devices, each of them exposed women to significant risks of injury against which inadequate warnings were given and in respect of which misleading representations were made. The appellants were not candid with the public about the risks of, and contraindications for, use of the devices or the limitations of the available data. The appellants represented that the benefits of using the POP devices outweighed the risks for women with any level of prolapse when the evidence did not support that. None of the POP devices was the subject of an adequately powered clinical trial, before it was released to market. The appellants represented that the devices met the Essential Requirements for CE marking when the material upon which they relied to affix and maintain the CE Mark was insufficient to satisfy those requirements: TJ [3496].

265 The POP devices 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 POP or where native tissue repair 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: TJ [3498].

266 At all relevant times, Gynemesh PS was also defective within the meaning of s 75AD of the TPA and s 138 of the ACL because its implantation exposed women to the risk of significant injury, the warnings given by the appellants were insufficient to protect users from those risks, and the information supplied with and about the device was liable to lull users into a false sense of security. The limitation made to the indication for use, which only came into effect on 16 March 2013, might have lessened the complication rate but it did not raise the level of safety to that which persons generally were entitled to expect, because the information accompanying the sale of the device was still insufficient to put users on notice of the true nature and extent of the risks: TJ [3499].

267 At all material times each of the POP devices had a “defect” within the meaning of the TPA and a “safety defect” within the meaning of the ACL: TJ [3500].

268 The defence under s 75AK(1)(c) of the TPA (the state of scientific or technical knowledge at the time when [the goods in question] were supplied by their actual manufacturer was not such as to enable that defect to be discovered) is not available as the appellants were admittedly aware of all the risks before any of the devices were supplied: TJ [3501]-[3504].

269 At all material times Ethicon Sàrl manufactured and supplied all the SUI devices, Prolift, Prolift+M, and Prosima when those devices had a defect within the meaning of s 75AC of the TPA. Consequently, if any applicant and/or group member suffered injury because of the defect in the device she received, Ethicon Sàrl is liable to compensate her for the amount of the loss and damage she sustained as a result of that injury, unless the action is statute-barred and the limitation period is not extended: TJ [3515].

270 At all material times Ethicon Inc. manufactured and supplied Gynemesh PS when it had a defect within the meaning of s 75AC of the TPA. Accordingly, Ethicon Inc. is 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: TJ [3516].

271 JJM was the deemed manufacturer and supplier of all the devices and is jointly and severally liable with Ethicon Sàrl and Ethicon Inc.: TJ [3517].

272 Since the use of Prolift Total as intended carried risks of significant and serious injury, including infection, erosion and chronic pain, about which insufficient and misleading warnings were given, and Mrs Gill sustained injury of that kind, she suffered damage caused by the defect: TJ [4428].

273 Since the transvaginal implantation of Gynemesh PS carried risks of significant and serious injury, including infection, erosion and chronic refractory pain about which the respondents gave no, or no sufficient, warning, and Mrs Dawson sustained injury of that kind, she suffered injury caused by the defect: TJ [4498].

274 Since TVT carried a number of risks about which the respondents provided no, or no adequate, warning, it was defective and, since a number of those risks came home, Mrs Sanders has established that she suffered injury as a result of the defect: TJ [4517].

3.13.2 Misleading and deceptive conduct

275 At all relevant times, the information in the IFUs and the brochures the appellants provided to patients and surgeons about the devices omitted warnings of the pleaded complications and the limits to the evaluation of the devices. The appellants also failed to provide information about the gravity of the risks and, with few exceptions, about how they could be mitigated. What is more, that same information made inaccurate and, at times, false representations about the devices. This conduct considered as a whole was misleading or likely to mislead: TJ [3581].

276 Having regard to all the relevant circumstances, at all material times the devices were or have been on the market, the appellants engaged in a course of conduct which was misleading or deceptive or likely to mislead or deceive a not insignificant number of patients and surgeons as to both their safety and efficacy: TJ [3607].

277 The two potentially operative IFUs (relevant to Mrs Sanders) misrepresented and minimised the nature and extent of the risks. It is more likely than not that those representations materially contributed to Mrs Sanders’ damage. Consequently, Mrs Sanders suffered damage by some of the appellants’ misleading conduct: TJ [4560].

###### 3.14 Negligence

3.14.1 Duty and breach

278 The appellants accepted that they owed a duty to exercise reasonable care to avoid injury to consumers: TJ [3624].

279 The manufacturers had a duty to take reasonable care in the design, testing, evaluation, supply, and marketing of the devices. That duty extended to providing accurate information about the performance and safety of the devices, including warnings about potential complications and contraindications. The duty was not confined to the period before the devices were made or placed on the market, it was a continuing obligation to evaluate their safety and keep abreast of information about the nature and extent of potential complications and to convey that information to users of the devices: TJ [3627].

280 JJM is deemed to be a manufacturer for the purposes of the statutory claims but at common law it is a supplier: TJ [3628].

281 JJM was not a mere vendor or distributor of Ethicon’s products. It was a member of the same corporate group as Ethicon Sàrl and Ethicon Inc., with ready access to all their expertise and information. It published material promoting the devices. It was also the sponsor of the devices within the meaning of the TG Act. Because of its close relationship with the manufacturers and especially because of its role as sponsor of their products, JJM had reason to know of the various risks. If it did not know, it ought to have known of the risks of which Ethicon was aware, including the pleaded complications, as well as the limitations in the clinical evaluations conducted by Ethicon: TJ [3636].

282 With one qualification, JJM’s duty of care was co-extensive with the duty of care owed by the manufacturers. All three appellants were obliged to exercise reasonable care in the supply and marketing of the devices: TJ [3643]. The exception relates to the allegation that JJM had a duty to undertake clinical evaluations of the devices. Either as a matter of law or fact, the scope of JJM’s duty did not extend that far: TJ [3644].

283 I do not accept the appellants’ contention that the standard of care expected of the manufacturer, or the supplier for that matter, is affected by the fact that the devices are supplied through surgeons or following consultation with surgeons: TJ [3652].

284 The pre-market evaluations of the devices evinced a want of reasonable care for the safety of the women for whose benefit they were intended and promoted: TJ [3680]-[3681].

285 The pre-market evaluation of all of the devices was insufficient to discharge Ethicon’s duty of care. All evinced a want of reasonable care: TJ [3762].

286 Ethicon failed to undertake post-market evaluation of the devices adequately and, in certain respects, at all: TJ [3776]-[3778].

287 The post-market evaluation of all of the devices was deficient. It fell well below the level of care required of a reasonably prudent manufacturer: TJ [3784].

288 Ethicon supplied and marketed the devices without conducting sufficient post-market evaluations. The evaluations that were undertaken were haphazard, often perfunctory, and passive. For all the reasons canvassed above, they did not conform to the standard of care expected of a reasonable person in the position of Ethicon in response to the foreseeable risks of injury and having regard to the gravity of the potential consequences: TJ [3827].

289 Reasonable care required warnings about the pleaded complications: TJ [3836]. A reasonably prudent manufacturer and supplier in the position of the appellants would have warned prospective users of all but one of the pleaded complications. The exception concerns the risk of psychiatric injury. There is no evidence to indicate that there was a risk of psychiatric injury independently of an antecedent physical injury. On the available material, I am not satisfied that a reasonably prudent manufacturer and supplier in the position of the appellants would have warned of the risk of psychiatric injury: TJ [3850]. As with all the other pleaded complications except for psychiatric injury, the warnings should have been provided from the time each of the devices was first supplied: TJ [3862].

290 The information about the potential risks in the IFUs and promotional material for all devices was below the standard required of a reasonably prudent manufacturer or supplier in the position of the appellants. It fell well short of capturing all known, let alone reasonably foreseeable risks, and was liable to mislead the reader about the safety and efficacy of the various devices. From the first of the IFUs to the last, the warnings they contained and the information they conveyed were insufficient to discharge the appellants’ duty of care: TJ [3878].

291 Each of the appellants was negligent. The risks were known, not insignificant, and on Ethicon’s own admission, serious harm could ensue if they eventuated. A far more cautious approach was warranted than the appellants took: TJ [3879].

3.14.2 Causation – negligence

3.14.2.1 General

292 The primary judge recognised that the respondents had to prove that the first and second appellants’ negligence (in pre-market and post-market evaluations of the devices and/or in failing to warn about the pleaded complications which the devices could cause) caused the injuries of Mrs Gill, Mrs Dawson and Mrs Sanders, each of whom had a unique medical history and had been implanted with a different device (Prolift Total for Mrs Gill, Gynemesh for Mrs Dawson, and TVT for Mrs Sanders): TJ [4359].

293 The primary judge recognised that the test for causation for negligence at common law did not require that the negligent conduct be the sole cause of the harm. Causation would be proved if the negligent conduct materially contributed to the harm in the sense that but for the negligence the injury would not have occurred: *March v E & MH Stramare Pty Ltd* [1991] HCA 12; (1991) 171 CLR 506 (at 508 and 514 per Mason CJ) (***March v Stramare***): TJ [4362] and [4363].

294 The primary judge rejected the appellants’ arguments that, as the respondents had not called evidence from the treating surgeons that they would have passed any warnings of the pleaded complications on to the respondents, it necessarily followed that the respondents must fail in their negligence claims; and/or that if the first and second appellants had provided warnings about the pleaded complications to the relevant treating surgeons, they would not have communicated that information to their patients. The primary judge reasoned instead that:

(1) if the appellants were right that the respondents had to prove their treating doctors would have passed on to them a warning about the pleaded complications, then it is not the case that the only way in which those facts could be proved was by direct evidence from the treating surgeons. Circumstantial evidence could support inferences about these facts: TJ [4426];

(2) contrary to the circumstances in *Black v Lipovac (by his next friend Lipovac)* [1998] FCA 699; (1998) 217 ALR 365, in the present case, there was no evidence from which it could be inferred that if the treating surgeons of the respondents had received a warning from the first and second appellants about the pleaded complications they each would nevertheless have treated their respective patients in the same way as they in fact treated them: TJ [4418]-[4421];

(3) in the present case it should be inferred that the treating surgeons would have passed on warnings about the pleaded complications consistently with their professional obligations: TJ [4421]; and

(4) in any event, consistently with the reasoning in ***Hollis*** *v Dow Corning Ltd* [1995] 4 SCR 634, having placed the devices with their associated material risk of clinically significant complications on the market without warning of those complications, the first and second appellants could not escape liability by any failure of the respondents to have proved the hypothetical fact that their treating surgeon, if warned of the pleaded complications, would have communicated the warning to them: TJ [4422]-[4425].

3.14.2.2 Mrs Gill

295 Section 5C of the CLA applies to Mrs Gill’s claim. Section 5C provides that:

(1) A determination that the fault of a person (the tortfeasor) caused particular harm comprises the following elements—

(a) that the fault was a necessary condition of the occurrence of the harm (***factual causation***); and

(b) that it is appropriate for the scope for the tortfeasor’s liability to extend to the harm so caused (***scope of liability***).

(2) In determining in an appropriate case, in accordance with established principles, whether a fault that cannot be established as a necessary condition of the occurrence of harm should be taken to establish factual causation, the court is to consider (amongst other relevant things) —

(a) whether and why responsibility for the harm should, or should not, be imposed on the tortfeasor; and

(b) whether and why the harm should be left to lie where it fell.

(3) If it is relevant to the determination of factual causation to determine what the person who suffered harm (the injured person) would have done if the tortfeasor had not been at fault —

(a) subject to paragraph (b), the matter is to be determined by considering what the injured person would have done if the tortfeasor had not been at fault; and

(b) evidence of the injured person as to what he or she would have done if the tortfeasor had not been at fault is inadmissible.

(4) For the purpose of determining the scope of liability, the court is to consider (amongst other relevant things) whether and why responsibility for the harm should, or should not, be imposed on the tortfeasor.

296 By s 5D of the CLA Mrs Gill had to prove any fact relevant to causation.

297 Factual causation in s 5C(1)(a) requires satisfaction of the “but for” test: *Wallace v Kam* [2013] HCA 19; (2013) 250 CLR 375 at [16], referred to by the primary judge at TJ [4435], and *Hunt & Hunt Lawyers v Mitchell Morgan Nominees Pty Limited* [2013] HCA 10; (2013) 247 CLR 613 at [43]-[45], referred to by the primary judge at TJ [4437]. The provision does not require that the negligence be the sole cause of the harm. It is enough that the negligence is a necessary, even if not a sufficient, condition of the harm: *Strong v Woolworths Ltd* [2012] HCA 5; (2012) 246 CLR 182 at [20], referred to by the primary judge at TJ [4436].

298 *Negligent pre-market and post-market evaluation of the devices*: the primary judge confirmed at TJ [4445] that she had concluded as follows:

Ethicon was negligent in its evaluations and that they did not justify CE marking either before Prolift was taken to market or afterwards. In other words, they were not entitled to apply the CE mark. Further, at no time before Mrs Gill’s implant surgery was Prolift Total proven to be safe enough to go to market. Thus, even if clinical evaluations had been conducted with reasonable care and in accordance with the requirements of the European Directive, a reasonably prudent manufacturer would not have affixed the mark or taken the device to market until or unless its safety had been demonstrated in adequately powered randomised controlled trials.

299 The primary judge also said:

(1) there is no evidence to indicate, and the respondents did not submit that, without CE marking, Prolift would have been sold in Australia: TJ [4446];

(2) Ethicon’s conduct did not satisfy the requirements of the Australian law: TJ [4446]; and

(3) if Prolift was not sold in Australia, more probably than not it would not have been available to Mrs Gill’s surgeon and it would not have been implanted in Mrs Gill: TJ [4446].

300 The causation requirement was thus satisfied with respect to Mrs Gill’s claims for negligent pre-market and post-market evaluation of the devices: TJ [4447].

301 *Negligent failure to warn*: the primary judge said that:

(1) Mrs Gill must prove that, but for the first and second appellants’ failure to warn of the pleaded complications (other than the risk of psychiatric injury) and the inadequate evaluations, she would not have consented to implantation with the device: TJ [4448];

(2) the standard of proof is the balance of probabilities: TJ [4449];

(3) s 5C(3) of the CLA is not picked up by s 79 of the *Judiciary Act 1903* (Cth) so Mrs Gill’s counter-factual evidence is relevant: TJ [4458] and [4459];

(4) the information provided to Mrs Gill by Dr Chapple before her implant surgery in January 2007 was consistent with the information contained in the 11 January 2005 Prolift IFU (in use until 13 December 2007) which I have determined had significant deficiencies: TJ [4463];

(5) while it is theoretically possible that Dr Chapple knew about all the pleaded complications despite the appellants’ negligence, there is no evidence that he did and the evidence of Professor Korda and others suggests that that is highly unlikely. Moreover, it is extremely unlikely, if not inconceivable, that Dr Chapple would have been aware of the deficiencies in the clinical evaluations of Prolift in general or Prolift Total in particular: TJ [4464];

(6) Mrs Gill said she would not have had the surgery if she had known about certain matters as described at TJ [4465];

(7) consistent with the IFU, what she was told was that the use of mesh would prevent a recurrence and that any complications were easy to fix and short-lived: TJ [4476];

(8) she was not advised that the use of mesh in prolapse repair surgery could result in permanent complications, such as chronic and severe pain, or that multiple revision operations could be required. Nor was she told that it could result in chronic pain during intercourse or that the procedure was best reserved for elderly women who are not sexually active. Since she was then only 36, if she had been given such advice, I have no doubt that she would have attached significance to it: TJ [4485];

(9) nor was she told that the use of mesh might be unsuitable for her because of her psoriasis, which is an autoimmune disorder. She was not informed of the risks of vaginal narrowing or shortening or the percentage of cases in which they develop. Neither was she informed of the risk of contraction or its consequences: TJ [4486];

(10) the inference is open on the evidence that a proper warning from the manufacturer would have been passed on by Dr Chapple to Mrs Gill: TJ [4488]. A reasonably prudent doctor in Dr Chapple’s position would have been obliged to pass on information of this kind to his patient and, noting senior counsel’s characterisation of Dr Chapple and the evidentiary support for it (Dr Chapple was “a very competent and diligent doctor” who engaged in “a careful consult process”: TJ [4489]), I consider that Dr Chapple would have done so. Having regard to his professional, legal and ethical obligations, the contrary inference is highly improbable. Indeed, there is no evidentiary foundation for it: TJ [4491]. Thus, it is more probable than not that, if the respondents had warned of the pleaded complications, Dr Chapple would have communicated that information to Mrs Gill: TJ [4492];

(11) Mrs Gill is an intelligent and thoughtful person with scientific training. She gave the option of surgery careful consideration. She was agonising over her decision and she was worried about the cons. At her young age and in her circumstances, the prospect of chronic pain, dyspareunia and repeat surgery with no promise of recovery would have been repugnant: TJ [4493]. It was not put to her that even if she had been warned of the pleaded complications or the inadequate evaluations, she would still have opted for Prolift: TJ [4495]; and

(12) it is more likely than not that, but for the deficiencies in the information provided by the first and second appellants, Mrs Gill would not have agreed to mesh surgery in general and Prolift in particular. Rather, she would have opted for native tissue repair or perhaps consented to the loss of her uterus: TJ [4496].

302 The causation requirement was thus satisfied with respect to Mrs Gill’s claims for negligent failure to warn: TJ [4497].

303 The primary judge otherwise dealt with issues of causation of Mrs Gill’s injuries in Pt XVIII concerning damages and compensation (see below).

3.14.2.3 Mrs Dawson

304 Sections 51 and 52 of the Wrongs Act apply to Mrs Dawson’s claim. Those provisions are in substance the same as ss 5C and 5D of the CLA: TJ [4500].

305 *Negligent pre-market and post-market evaluation of the devices*: the primary judge said that pre and post-market evaluations of Gynemesh PS were insufficient to justify CE marking. Gynemesh PS should not have been on the market. If it had not been on the market, Mrs Dawson would not have been offered the device. Inadequate evaluation of Gynemesh PS thus caused Mrs Dawson’s injuries: TJ [4502].

306 *Negligent failure to warn*: the primary judge said:

(1) the question is whether, but for the first and second appellants’ failure to warn of the pleaded complications and/or the deficiencies in the evaluations, Mrs Dawson would have undergone surgery with Gynemesh PS: TJ [4503];

(2) it is unlikely that Mrs Dawson was informed of the risk of chronic pain, the possibility of multiple operations to deal with erosions, and the difficulties associated with removal of the mesh, risks about which the appellants should have, but did not, warn: TJ [4507];

(3) there is no reason to think that Dr Lim would have overlooked her legal and ethical obligations. The risk of chronic pain, the possibility of multiple operations to deal with erosions, and the difficulties associated with removal of the mesh were all material risks of which she would have been bound to warn her patient: TJ [4508];

(4) Mrs Dawson said she would not have had the surgery had she been warned of the pleaded complications. This evidence was untouched by cross-examination and her honesty was not impugned: TJ [4511] and [4512];

(5) her evidence was consistent with the contemporaneous evidence except to the extent that she said she was not warned about the risk of dyspareunia or pain during sexual intercourse: TJ [4513]; and

(6) I accept her evidence and find that but for the first and second appellants’ negligent failure to warn Mrs Dawson would not have had the surgery but would have had native tissue repair if that was an option or, if not, would have pursued conservative treatment: TJ [4514] and [4515].

307 The primary judge otherwise dealt with issues of causation of Mrs Dawson’s injuries in Pt XVIII concerning damages and compensation (see below).

3.14.2.4 Mrs Sanders

308 Sections 5C and 5D of the CLA apply to Mrs Sanders’ claim.

309 *Negligent pre-market and post-market evaluation of the devices*: the primary judge said that no clinical investigations were conducted by the appellants before CE marking was applied to the TVT device and no post-market clinical follow-up studies were undertaken until well after Mrs Sanders’ operation. CE marking was not justified at the time the mark was applied or at any time before Mrs Sanders’ surgery: TJ [4518]. The CE Mark should not have been applied to TVT before Mrs Sanders’ implant surgery in March 2001. More likely than not, had it not been for those negligent evaluations the mark would not have been applied in 1998 and TVT would not have been on the Australian market in March 2001, in which case Mrs Sanders would not have received the device and would not have suffered the damage that ensued from its implantation. It follows that the negligent evaluations caused the damage Mrs Sanders suffered as a result of its implantation: TJ [4521].

310 *Negligent failure to warn*: the primary judge said:

(1) Mrs Sanders’ evidence was that she would not have agreed to the procedure had she been warned about certain matters as set out at TJ [4554];

(2) she was not cross-examined about this evidence and her honesty was not in doubt: TJ [4555]; and

(3) there was no evidence to suggest that, if informed of those matters, she would have agreed to TVT when there were alternative forms of treatment: TJ [4555]; and

(4) it was more likely than not that Mrs Sanders would not have agreed to TVT surgery if she had been informed of the pleaded complications and the above listed matters in particular. But for the absence of a suitable warning, it is more likely than not that she would have undergone some other form of incontinence surgery which did not involve the use of polypropylene mesh: TJ [4556].

311 The primary judge otherwise dealt with issues of causation of Mrs Sanders’ injuries in Pt XVIII concerning damages and compensation (see below).

###### 3.15 Limitation issues

3.15.1 Mrs Gill

312 Mrs Gill received Prolift Total on 12 January 2007: TJ [4605].

313 Regardless of when injury first occurred, by June 2007, Mrs Gill knew that the mesh had eroded: TJ [4621].

314 It is more probable than not that injury to Mrs Gill occurred soon after Prolift was implanted, within a matter of weeks, perhaps a month at most: TJ [4627].

315 At that stage, however, Mrs Gill did not know that she had sustained an injury. She only knew that she had sustained an injury when she could feel the mesh tear her, causing sharp pain. That was in about May or June 2007, in all likelihood before 11 June 2007 when she presented to Dr Chapple and told him that about three weeks earlier she could feel mesh in her vagina: TJ [4628].

316 I do not think that when she was first told she had a mesh erosion Mrs Gill knew that she had an injury significant enough to justify bringing an action: TJ [4632].

317 Mrs Gill first knew or should have known that she had an injury significant enough to justify bringing an action in about late October 2007 by which time it was apparent to her that the revision surgery had been unsuccessful: TJ [4634].

318 Mrs Gill knew that she had received a mesh implant in January 2007: TJ [4645].

319 The contemporaneous evidence indicates that Mrs Gill knew by July 2007, if not before, that she was in fact implanted with a Prolift implant: TJ [4648].

320 By 26 July 2007 Mrs Gill was aware that the mesh with which she had been implanted was called Prolift, although she may have forgotten the name: TJ [4650].

321 Mrs Gill’s evidence was that, until she learned from Dr Dowling in 2013 that other women were having problems and that Prolift had been withdrawn from sale, she did not know that there was anything wrong with Prolift. I accept that evidence: TJ [4659]. I conclude that Mrs Gill did not know that Prolift was defective until about June or July 2013. By that time, this proceeding had already commenced: TJ [4660].

322 I am not satisfied that before this proceeding commenced Mrs Gill knew or ought to have known that she had been injured because of a contravention of the TPA: TJ [4666].

323 It follows that the limitation defence for the statutory claims is not made out. The proceedings were not commenced more than three years after the date of discoverability, that is more than three years from the time Mrs Gill knew or ought to have known that she had been injured, that the injury was significant enough to justify bringing an action, and that the injury was attributable to a contravention of the TPA: TJ [4667].

324 As to the limitation period for the negligence claims, the appellants have discharged their burden of proof. The period of limitation expired by 11 June 2007 or, at the very latest, by October 2007, five years before these proceedings were commenced. Mrs Gill’s action is therefore statute-barred: TJ [4806].

325 The last date that a claimant becomes aware or ought reasonably to have become aware of the relevant fact will determine the starting time for the three-year period during which the time to sue for negligence may be extended. In the circumstances of this case, on the facts as proved, that three-year period did not commence until after Dr Dowling informed Mrs Gill in 2013 that Prolift had been removed from the market. It follows that the Court has the power to extend time to enable Mrs Gill to sue. It may exercise that power in its discretion: TJ [4827]-[4829].

326 The limitation period should be extended to enable Mrs Gill to sue for damages for negligence: TJ [4832].

3.15.2 Mrs Sanders

327 Mrs Sanders was implanted with TVT before the commencement of the *Trade Practices Amendment (Personal Injuries and Death) Act 2004 (No 2)* (Cth), being 13 July 2004: TJ [4567] and [4668].

328 In Mrs Sanders’ case, the date the proceeding relevantly commenced is the date on which women who had been implanted with TVT were added as group members. That was 29 January 2013, when the amended statement of claim was filed: TJ [4675].

329 By late January 2011, although she did not know, Mrs Sanders ought reasonably to have known that she had a mesh erosion and that the erosion was the cause of her pain. That was the earliest time these causes of action could have accrued. Since her claim commenced within three years of that time, Mrs Sanders’ action is not barred by either s 74J(1) or s 75AO(1) of the TPA: TJ [4760].

330 Mrs Sanders’ claim under s 52 of the TPA for misleading and deceptive conduct, however, is statute-barred: TJ [4773].

331 The first symptom or other manifestation of personal injury consistent with Mrs Sanders having sustained a not insignificant personal injury occurred either in 2007 when she began experiencing discomfort urinating and recurrent urinary frequency or in 2008 when she first experienced dyspareunia and groin pain. I therefore find that Mrs Sanders’ cause of action in negligence accrued no earlier than January 2007. This means that her common law claim is caught by the 2005 Limitation Act, not the 1935 Limitation Act. Two consequences flow from this. One is that the action is statute-barred since, whether 2007 or 2008 is correct, the three-year limitation period under the 2005 Limitation Act expired well before the SUI subgroup was included in the pleading. The other is that Mrs Sanders is entitled to apply for an extension of time: TJ [4853] and [4854].

332 The physical cause of Mrs Sanders’ personal injury was the erosion of the TVT tape. Mrs Sanders was not aware that the tape had eroded until she was told by a doctor. The first doctor to refer to an erosion was Dr Gilbert in May 2011. The first time she became aware that the tape had moved was during or soon after the conversation with Dr Tan on 28 January 2011. There is no reason why she ought reasonably to have become aware of these matters at an earlier time. In these circumstances, the Court has power to extend the time in which Mrs Sanders could bring her action. The three year period set by s 37(4) of the 2005 Limitation Act only expired after the SUI subgroup were added to the proceeding: TJ [4859].

333 The limitation period should be extended to enable Mrs Sanders to prosecute her case in negligence: TJ [4863].

###### 3.16 Damages and compensation

3.16.1 General

334 The law of Western Australia applies to the assessment of damages for the causes of action in negligence brought by Mrs Gill and Mrs Sanders and the law of Victoria applies to the claim for damages brought by Mrs Dawson: TJ [4864].

3.16.2 Mrs Gill

335 The appellants conceded that Mrs Gill proved that the following items of damage are caused by the Prolift implant: items 2-10 of the identified injuries (the various exposures and the surgery to address them) and “certain” of her ongoing pelvic pain: TJ [4916]-[4918].

336 Mrs Gill is entitled to damages for the recurrent prolapses. That is because I am persuaded that the multiple excision procedures necessitated by the painful erosions caused a reduction in the support the device was designed to provide and increased the risk that eventuated: TJ [4931].

337 On the balance of probabilities the pain Mrs Gill experienced after her Prolift surgery in her pelvis, coccyx, her groin, her lower back, her vagina and her rectum was caused by the implantation of Prolift Total, as were the mesh infection, mesh erosions or exposure, and the surgery undertaken to treat the exposures: TJ [4981].

338 The Prolift surgery caused a multitude of other colorectal problems, including chronic pain, pain on large bowel movements, pain when straining to defecate, pain with orgasms, and faecal and flatal incontinence: TJ [5002].

339 In addition to an aggravation of her underlying depression, Mrs Gill developed a generalised anxiety disorder in response to the complications of Prolift and the revision surgery: TJ [5027].

340 Mrs Gill has not proved a connection between her urinary symptoms and the implantation of Prolift: TJ [5032].

341 In summary, I am not satisfied that the anteverted bulky uterus and intramural posterior fibroid were caused, either directly or indirectly, by the Prolift implant. Nor am I satisfied that the vaginal bleeding and spotting or the urinary symptoms are related to the implant. On the other hand, I am satisfied that the implant caused chronic inflammation, chronic pelvic pain (including coccygeal, groin, vaginal, and low back pain), severe pain on defecation and the need to take Movicol to avoid large bowel movements and the consequential faecal urgency and flatal and faecal incontinence. I am also satisfied that the complications of the Prolift implant aggravated an underlying depressive disorder and caused a generalised anxiety disorder. The recurrent prolapses were caused by the excision of pieces of mesh, including the supportive arms, which were undertaken to treat the painful erosions: TJ [5048]-[5049].

3.16.3 Mrs Dawson

342 The appellants accepted that the Court could accept that the following identified injuries were caused by the Gynemesh PS implant – items 2 and 3 (the exposure requiring surgery on 14 October 2009 and the surgery itself), items 5, 6, 7, and 9 (the exposure requiring surgery on 31 January 2014 and the surgery itself), items 10, 11, and 12 (the exposure requiring surgery on 30 October 2015 and the surgery itself), and items 16 and 22 (the scarring on the left side of the vagina and the operation on 17 May 2017 to remove it): TJ [5336]-[5337].

343 It is more likely than not that pudendal neuropathy is at least making a contribution to Mrs Dawson’s chronic pelvic pain and that more likely than not it was caused by the installation of the mesh: TJ [5354].

344 Mrs Dawson’s detrusor instability or overactivity and lower urinary tract dysfunction were not caused by the appellants’ device and I am not satisfied that they were exacerbated by it: TJ [5364].

345 Mrs Dawson is entitled to damages for her chronic pain syndrome: TJ [5371].

346 I am not persuaded that Mrs Dawson suffered a psychiatric disorder as a result of damage caused by the appellants’ wrongdoing: TJ [5403].

347 Mrs Dawson’s coccygeal pain was caused by the mesh implant: TJ [5420] and [5422].

348 Mrs Dawson’s apareunia was caused by the worsening of her dyspareunia following the first mesh revision surgery and was more likely than not related to the surgery: TJ [5431].

349 The insertion of the mesh and the repeated surgical interventions to deal with its complications aggravated to some degree Mrs Dawson’s pre-existing defecation disorder, most likely by damaging the pararectal tissues: TJ [5442].

350 The weight of the evidence supports the conclusion that, independent of the coccygeal pain, Mrs Dawson developed chronic and severe pelvic pain caused by the complications of the Gynemesh implant: TJ [5456].

351 Mrs Dawson has suffered all the injuries particularised in her Statement of Particulars with the exception of the rigid vagina. While I accept that Mrs Dawson has a psychiatric disorder, except for a few months in late 2009, it was not caused or significantly aggravated by the implantation of Gynemesh PS or its sequelae: TJ [5459].

352 The Gynemesh PS implant caused or materially contributed, directly or indirectly, to the disabilities listed in the Statement of Particulars with the exception of – detrusor instability, detrusor overactivity, and lower urinary tract dysfunction including stress urinary incontinence, urinary urge incontinence and difficulty urinating, coccydynia, dyspareunia, and bowel problems: TJ [5460].

353 The implant directly or indirectly aggravated Mrs Dawson’s pre-existing dyspareunia and defecation problems. The implantation of the mesh caused Mrs Dawson to suffer much more severe pain in the region of her coccyx than she had previously experienced: TJ [5461].

3.16.4 Mrs Sanders

354 The appellants accepted that the mesh exposure requiring surgery on 8 August 2011 and the adjustment disorder with mixed anxiety and depressed mood should be attributed to the TVT implant and the latter only to the extent that the reduction in Mrs Sanders’ mobility is found to be causally related to the implant rather than to her co-morbidities: TJ [5606].

355 Mrs Sanders’ TVT caused the formation of scar tissue. But the evidence does not permit me to say how extensive it was or precisely where it occurred: TJ [5616].

356 I am not satisfied that the TVT eroded into either the bladder or the urethra: TJ [5617].

357 There is no evidence that squamous metaplasia of the trigone was caused by the TVT device or the mesh excision surgery: TJ [5623]-[5624].

358 The erosion and subsequent urinary symptoms were all caused by the TVT and subsequent corrective surgery: TJ [5626]-[5627].

359 Mrs Sanders’ overactive bladder symptoms of urgency and frequency are attributable to urethral instability either caused or aggravated by the erosion of the tape and its sequelae. In view of her pre-existing symptoms, however, some allowance must be made for the chance that they would have persisted or recurred even if she had not undergone TVT surgery: TJ [5652].

360 Mrs Sanders’ claim for flatal incontinence and constipation is not made out: TJ [5653].

361 Some of Mrs Sanders’ pain was attributable to TVT: TJ [5657]. On the balance of probabilities Mrs Sanders’ dyspareunia, apareunia, and chronic pelvic pain, with the exception of the hip pain which was cured by the hip replacement, were caused by the erosion of the TVT and its sequelae: TJ [5669].

362 Mrs Sanders suffered an adjustment order with mixed anxiety and depression caused by the complications of the TVT: TJ [5674].

363 Mrs Sanders underwent chronic inflammation and scarring of her perivaginal tissues as a result of the implantation of the TVT device. TVT is responsible for her urethral instability, recurrent stress incontinence, urge incontinence, and urinary frequency. Her dyspareunia, apareunia, and chronic pelvic pain in the groin and pubic area, which sometimes radiates into her legs, were caused by the erosion of the TVT: TJ [5676].

364 I am not satisfied that the TVT eroded into either her bladder or her urethra, that she has squamous metaplasia of the trigone, or that if she does it has anything to do with the TVT. Nor am I satisfied that there is any connection between her bowel problems and the TVT or the repair surgery: TJ [5677].

###### 3.17 Other observations

365 It is not necessary to summarise the primary judge’s findings about other issues. The grounds of appeal may now be considered.

##### 4. OVERARCHING OBSERVATIONS

###### 4.1 Appellants’ submissions

366 The appellants made a number of written submissions in support of the appeal which should be considered immediately as they relate to many of the grounds of appeal. The appellants also made oral submissions which, variously, reworked the effect of their written submissions, made explicit propositions which were merely implicit in their written submissions, or were simply new. As noted below, some of these new submissions went beyond the grounds of appeal.

367 References to AS below means the appellants’ written submissions. RS means the respondents’ written submissions.

368 The appellants’ key overarching propositions in writing were that:

(1) the primary judge’s approach to the key role of pelvic surgeons (and the treating pelvic surgeons of the representative respondents) was wrong. Given the informed consent process, their role was critical. In contrast, the evidence of other experts (including epidemiologists, biostatisticians, biomaterials experts and pathologists, who the appellants sought to characterise as “non-clinical experts”) must be recognised as evidence of a person who has a limited understanding of the range and significance of the clinical issues, does not treat patients with POP or SUI, and who is not involved in the informed consent process: AS [18];

(2) inherent in the nature of the informed consent process is the fact that each discussion will be tailored to that patient. That tailoring is done by the individual treating surgeon, applying specialist medical knowledge (including knowledge of their surgical experience and preferences) to the patient’s circumstances. Consequently, the warnings to be given (and in what form) to a particular patient and the evaluation of the adequacy of such a warning, including whether any asserted inadequacy caused the injury to the patient must take that specialist knowledge into account, consistent with common law requirements: AS [22];

(3) the primary judge was wrong to attempt to assess the relative safety and efficacy of the devices compared to alternative treatments, as the inquiry as to safety and efficacy is necessarily individual: AS [20];

(4) contrary to the primary judge’s finding, a drug’s safety and efficacy (and therefore its suitability) does not depend on the individual experience, surgical expertise and preferences of treating surgeons and thus the analysis in ***Merck*** *Sharp & Dohme (Australia) Pty Ltd v Peterson* [2011] FCAFC 128; (2011) 196 FCR 145 is distinguishable and the primary judge’s finding at TJ [4410] (that *Merck* should not be distinguished) is wrong: AS [21]; and

(5) the primary judge’s approach to causation involved error in various respects, in particular because the treating surgeons of the representative respondents were not called to give evidence and it had not been proved that the did not know about the pleaded complications or, if they had been informed of them by the appellants, that they would have passed them on to their patients. It also could not be inferred that the devices would not have been supplied in Australia irrespective of the fact that they were registered on the ARTG by reason of the appellants’ application of a CE Mark to each of the devices: AS [110]-[114].

369 The appellants’ key overarching oral submissions were to the effect that:

(1) it is critical to recognise that all surgery involves risks and the existence of the pleaded complications does not of itself make good the respondents’ causes of action under statute or in negligence;

(2) the primary judge erred in failing to find that pelvic surgeons knew about the pleaded complications or erred in finding (explicitly or implicitly) that pelvic surgeons did not know about the pleaded complications, as the respondents had not discharged their onus of proving that fact;

(3) the primary judge erred in failing to recognise that there was a clinical consensus about the value of the devices in treating POP and SUI, which consensus is inconsistent with the primary judge’s conclusion to the effect that the devices should never have been on the market;

(4) the primary judge erred in failing to recognise that the fact that some of the devices (that is, the SUI devices excluding TVT Secur) were still on the market and in use necessarily defeated the respondents’ claims about those devices; and

(5) to the extent that her reasons for judgment consider the issue of direct communication by the appellants to patients, the primary judge erred as there was no evidence that any patient had seen any such communication and the issue was thus hypothetical.

370 These overarching submissions are discussed below. We note immediately, however, three matters.

371 First, given the detailed consideration which the primary judge gave to the facts, care must be taken before latching on to some or other apparent statement of principle in her Honour’s reasons. As we explain below, there are some such statements in her Honour’s reasons with which we disagree. On analysis, however, it is also clear that these apparent statements of principle are immaterial because the primary judge made findings of fact which supported her conclusions even assuming the apparent statements of principle to be wrong. Further, on analysis, these findings are unassailable given the weight of the evidence which the primary judge comprehensively considered.

372 Second, care must also be taken when examining any factual finding or piece of evidence in isolation. The context of the factual finding or piece of evidence must be considered. So too must the other evidence, potentially competing, which was before her Honour. The appellants repeatedly focussed on some piece of evidence or some finding of fact without regard to the context or other relevant findings and evidence. This approach to the appeal is impermissible.

373 Third, the proceeding before us is an appeal by way of rehearing. It involves correction of error: ***Branir*** *Pty Ltd v Owston Nominees Pty Ltd (No 2)* [2001] FCA 1833; (2001) 117 FCR 424 at [20]-[22]. Error is demonstrated when it is shown that some aspect of the trial judge’s reasoning is wrong. How the trial judge’s reasoning may be shown to be wrong depends on what the reasoning is about: *Branir* at [24]); *Aldi Foods Pty Ltd v Moroccanoil Israel Ltd* [2018] FCAFC 93; (2018) 261 FCR 301 at [45].

374 The primary judge in the present case enjoyed a significant advantage compared to the Court on appeal. In *Fox v Percy* [2003] HCA 22; (2003) 214 CLR 118 [23] Gleeson CJ, Gummow and Kirby JJ explained that one of the relative advantages of a trial judge is that:

…the appellate court does not typically get taken to, or read, all of the evidence taken at the trial. Commonly, the trial judge therefore has advantages that derive from the obligation at trial to receive and consider the entirety of the evidence and the opportunity, normally over a longer interval, to reflect upon that evidence and to draw conclusions from it, viewed as a whole.

375 Their Honours approved the observations of Kirby J in *State Rail Authority of New South Wales v Earthline Constructions Pty Ltd* [1999] HCA 3; (1999) 160 ALR 588 at [89]-[91]. In that case his Honour said (at [90]):

The true advantages in fact-finding which the trial judge enjoys include the fact that the judge hears the evidence in its entirety whereas the appellate court is typically taken to selected passages, chosen by the parties so as to advance their respective arguments. The trial judge hears and sees all of the evidence. The evidence is generally presented in a reasonably logical context. It unfolds, usually with a measure of chronological order, as it is given in testimony or tendered in documentary or electronic form. During the trial and adjournments, the judge has the opportunity to reflect on the evidence and to weigh particular elements against the rest of the evidence whilst the latter is still fresh in mind. A busy appellate court may not have the time or opportunity to read the entire transcript and all of the exhibits. **As it seems to me, these are the real reasons for caution on the part of an appellate court where it inclines to conclusions on factual matters different from those reached by the trial judge.** These considerations acquire added force where, as in the present case, the trial was a very long one, the exhibits are most numerous, the issues are multiple and the oral and written submissions were detailed and protracted.

(Citations omitted, emphasis added).

376 Those remarks apply in the present case. The trial before the primary judge started in July 2017 and ended in February 2018. As noted above, evidence was adduced from 48 witnesses, 35 of whom gave oral evidence. The experts who gave evidence, 37 in all, came from nine different disciplines. More than 5,500 documents were tendered in the trial, running to over 164,000 pages. The primary judge had the advantage of seeing all of this evidence unfold. The significance of that advantage should not be underestimated.

377 We turn to the appellants’ overarching submissions.

###### 4.2 All surgery involves risks

378 In oral submissions the appellants stressed that: (a) all surgery carries risks, (b) the surgical implantation on a permanent basis of a foreign body such as the SUI and POP devices necessarily carries risks of the kind associated with foreign body reactions, and (c) the mere fact of complications in some cases does not prove either that the devices had a defect (for the purposes of the TPA and ACL) or that the appellants were negligent in supplying those devices in Australia.

379 These propositions may be accepted. They do not inform the resolution of the appeal, however. Nothing in the primary judge’s reasons suggests that she assumed or inferred that the devices needed to be free from all risk in order for the devices not to have a defect or for the appellants to have acted with reasonable care in relation to the women who were implanted with the devices.

380 The primary judge was well aware that all surgical treatments carry risks: for example, see TJ [60] and [130]. There is nothing in her Honour’s reasons to suggest that she proceeded on the basis that the devices would be defective if their implantation involved any potential complication or that she conflated the risks ordinarily associated with any surgery or any pelvic surgery and the risk of the pleaded complications. There are many parts of the primary judge’s reasons which indicate to the contrary and that the primary judge, when dealing with the concept of the pleaded complications, understood that the issue was the specific risks to which the devices themselves gave rise and was not the general risk associated with any surgical procedure or any pelvic surgery. These observations include (as examples only), the primary judge’s reasons as follows:

(1) all surgical treatment options are associated with risks, although the evidence indicates that complications from native tissue repair are generally short-lived and treatable. Professor Korda listed them as failure; injury to adjacent and contiguous organs, such as the bladder, urethra, ureters, bowel, major blood vessels, and nerves; the development of lower urinary tract symptoms such as urinary incontinence, narrowing of the vagina, and dyspareunia: TJ [130];

(2) the [appellants] emphasised that several of the complications could occur regardless of the use of mesh. But the weight of the evidence indicates that the use of mesh causes complications of a kind, degree or rate different from or greater than those associated with traditional methods of pelvic floor repair. These complications cannot wholly be explained by insufficient surgical training or experience. Other factors, including product design, mesh porosity, the quantity of mesh used, the route and methods of implantation and patient-specific factors cause or contribute to the development of adverse reactions following the implantation of synthetic mesh, including the various devices: TJ [199];

(3) mesh exposure can occur immediately or soon after surgery. But it can also occur much later, including years after surgery, and away from the incision line: TJ [216];

(4) the evidence indicates that pain can be both more severe and more enduring after repair with procedures involving the use of mesh than after procedures which do not: TJ [228];

(5) in contrast with native tissue repair, pain after mesh repair can arise well after surgery, sometimes years later: TJ [232];

(6) Professor Korda (whose evidence the primary judge accepted) said that in his long period of clinical practice in urogynaecology (around 30 years) during which he had performed thousands of native tissue repairs, the severe, chronic and intractable pain that can occur after mesh surgery was “virtually non-existent” after native tissue repair: TJ [233];

(7) according to Professor Korda, mesh surgery carried “new and unique” risks likely to be permanently incapacitating, such as chronic and severe pain, mesh contracture, and mesh erosion. He said that complications such as mesh erosion, mesh contraction and bunching, severe chronic pelvic pain, severe dyspareunia and pain on movement, sitting, and standing were not encountered in pelvic floor surgery before the introduction of synthetic mesh: TJ [236];

(8) Professor Korda expressed the view that the complications of mesh surgery for prolapse are generally long-term and sometimes incurable: TJ [240];

(9) the evidence on both sides was that the mesh is difficult, if not impossible, to remove entirely as it is or becomes integrated in the connective tissue, and that removal surgery may not relieve pain: TJ [246];

(10) all meshes used in the devices must be inserted without tension. Yet achieving the requisite amount of tension is not easy: TJ [263]-[264];

(11) the respondents proved that the foreign body reaction is clinically significant and can cause many, if not all, of the pleaded complications: TJ [354];

(12) the evidence establishes that all women implanted with one of the devices could suffer from all of the pleaded complications: TJ [405];

(13) bridging fibrosis can occur following implantation of all the devices and is clinically significant: TJ [533]-[537];

(14) contraction can occur with all the devices and has clinical significance: TJ [564] and [610];

(15) mesh cannot expand or contract and, in order to function properly, several organs in the pelvis need to expand and contract: TJ [637];

(16) all the devices may cause pain, including chronic pain: TJ [684];

(17) it was common ground that mesh-related adverse events may occur years after vaginal mesh surgery: TJ [839];

(18) mesh exposure/extrusion/erosion, recurrent urinary tract infections, chronic pain, dyspareunia, difficulty voiding, *de novo* urinary incontinence, recurrence of stress urinary incontinence, bladder perforations (with retropubic slings) (uncommon but not rare with transobturator slings), reoperation or revision surgery associated with complications are common complications of implantation of the devices (that is, occurring in 1% to 10% of patients): TJ [1139]-[1140];

(19) this warning (in the Gynemesh PS IFU) remained deficient. It was also misleading. It implied that the risk of infection could only arise intra-operatively or post-operatively. It did not advert to the risk that infection could occur long after surgery: TJ [2964];

(20) Professor Korda, another very experienced urogynaecologist, gave evidence that polypropylene mesh implants carried a risk of certain complications that were unknown to pelvic surgeons versed in native tissue repair. He said that “complications such as mesh erosion, mesh contracture, bunching, severe chronic pelvic pain, severe dyspareunia and pain on movement, sitting, standing were not seen before the introduction of mesh surgery”: TJ [3235];

(21) in the October 2015 version of the IFUs for the SUI devices then on the market, which remains current, the respondents inserted the statement that “as with all surgical procedures, there is a risk of infection”. This statement minimised the significance of the risk since the risk was not one merely associated with surgical procedures; there was a superadded risk because the mesh was a foreign body implanted in a clean contaminated area and there was a risk of bacterial colonisation: TJ [3322]; and

(22) it is true, as the appellants argued, that pain is a complication of any surgery. Yet, the evidence indicates that chronic pain of the kind reported in connection with the devices is almost unheard of in traditional forms of surgery for the treatment of stress urinary incontinence: TJ [3426].

381 The fact that the primary judge was analysing the evidence on the basis that it was the risks caused by the devices themselves which were relevant and not the risks of all surgery or all pelvic surgery, is also clear from the answer the primary judge gave to common question 18 which asked in what respects was the information, advice or warnings provided by the appellants about the complications inadequate. The primary judge answered this question in the RJ in these terms:

A: Save as indicated below, the respondents failed to disclose or make adequate disclosure of the following matters:

(a) that the mesh used in the Ethicon devices was designed to, and would invariably elicit in patients, an acute inflammatory reaction followed by a chronic inflammatory response;

(b) that in some patients the chronic inflammatory response will have adverse effects;

(c) that it is not possible to predict which patients will be adversely affected but they include healthy patients;

(d) that the severity of a patient’s chronic inflammatory response can be affected by conditions which affect the immune response and healing, such as autoimmune and connective tissue disorders;

(e) that the severity of a patient’s chronic inflammatory response can be affected by physical activity and mechanical loading of the pelvic floor;

(f) that the mechanical forces in the pelvic floor may influence the compatibility and function of the implant;

(g) that the adverse effects of the chronic inflammatory response in some patients include:

(i) infection, rather than merely the potentiation of infection;

(ii) that erosion of the mesh into the vaginal canal could cause infection which might be difficult to treat and cause offensive vaginal discharge and pain;

(iii) that erosion of the mesh into surrounding organs, such as the bladder, urethra or rectum, could cause pain and damage those organs;

(iv) damage to nerves in the scar tissue surrounding the implant or elsewhere (except for Gynemesh PS from 16 March 2013, Prolift from 1 October 2009, and Prolift+M from 12 December 2008);

(v) chronic pain, which may be severe;

(vi) dyspareunia, which may be severe and become chronic;

(vii) apareunia;

(viii) leg weakness;

(ix) *de novo* or recurrent incontinence (except TVT from 7 October 2015, TVT-O from 22 September 2015, TVT Abbrevo from 24 September 2015, TVT Exact from 18 September 2015, Gynemesh PS from 16 March 2013, Prolift from 1 October 2009, Prolift+M from 12 December 2008);

(x) difficulty voiding (except for TVT from 7 October 2015, TVT-O from 22 September 2015, TVT Abbrevo from 24 September 2015, TVT Exact from 18 September 2015, Gynemesh PS from 16 March 2013, Prolift from 1 October 2009, Prolift+M from 12 December 2008);

(xii) vaginal discharge (except TVT from 7 October 2015, TVT-O from 22 September 2015, TVT Abbrevo from 24 September 2015, TVT Exact from 18 September 2015, Gynemesh PS from 3 April 2015); and

(xiii) (in the case of the POP devices only) recurrent prolapse (except for Gynemesh PS from 16 March 2013, Prolift from 1 October 2009, and Prolift+M from 12 December 2008) and pain on defaecation;

(h) that the adverse events may occur years after implantation and the risk will endure for as long as the implant remains in the body;

(i) that the adverse events may occur regardless of the skill of the surgeon;

(j) that the true incidence of the adverse events is unknown but they are not rare;

(k) that removal of the implant in whole or in part will not necessarily alleviate the patient’s symptoms;

(l) that removal of part of an implant can be difficult and removal of the whole may be practically impossible;

(m) that mesh removal surgery can result in further scarring and tissue damage which, in turn, may have adverse outcomes, including severe chronic pain which may not be able to be satisfactorily treated;

(n) that surgery to remove the whole or part of an implanted SUI device can result in recurrence of stress urinary incontinence;

(o) that surgery to remove the whole or part of an implanted POP device can result in recurrence of pelvic organ prolapse; and

(p) that removal of eroded mesh will not necessarily prevent further erosions or other adverse events.

382 These matters are also reflected in the terms of the Injunction that the primary judge made in respect of the warnings that must be given for the SUI devices which remain on the market other than TVT Secur which was only available in Australia between April 2007 and March 2008 (noting also that all of the POP devices have been removed from the market): see Schedule B below.

383 It is apparent from these matters that the primary judge, when considering the pleaded complications, was focused on the risks associated with the devices themselves, not the ordinary risks associated with any surgery, any pelvic surgery, or implantation of any device within the body. Thus, care must be taken in relation to references in materials such as “pain”, “infection”, and “foreign body reaction” (an inflammatory response of the body to any foreign object involving scarring, varying in intensity: TJ [341]-[362]). It is easy to assume or infer that pelvic surgeons in general must be taken to have known that the surgical implantation of any device within the body will involve surgical pain and the risk of infection, as well as a foreign body reaction. But this is not the relevant area of discourse. As the primary judge’s reasons repeatedly make clear, it is the acute nature of the foreign body reaction caused by the devices and the resulting chronic inflammatory response (a pleaded complication), and the potentially serious sequelae which may arise at any time unconnected to the event of surgery (the other pleaded complications), with which the primary judge was concerned. This reality, moreover, was in stark contrast to the appellants’ public insistence (until forced by regulators to disclose otherwise) that the devices generated a transient or transitory foreign body reaction: see, for example, TJ [353], [2595], [2812], [2818], [2819], [2824]-[2834], [2946]-[2948], [3289], [3291]-[3295], [3424], and [3586]-[3590]. The acute and chronic inflammatory reaction, which continues for so long as the device is in the body, is responsible for the chronic and severe pain which the devices may cause at any time, including years after surgery. Again, this reality is in stark contrast to the appellants’ public insistence (until forced by regulators to disclose otherwise) that the devices may cause transient pain: see, for example, TJ [2605]-[2607], [2652], [2769], [2865]-[2875], [2968]-[2972], [3325], [3591], and [3734]-[3735].

384 This is why, when it comes to the question of what pelvic surgeons as a cohort knew or must be taken to have known (discussed below), it is not legitimate to seize upon references in materials to “pain”, “infection”, and “foreign body reaction” as if they mean the pleaded complications with which this case is concerned.

385 The same evidence as set out above (in addition to other evidence discussed below) also puts paid to the appellants’ oral submission to the effect that the mere fact of the existence of one or more of the pleaded complications in a given patient does not prove that the devices were defective or that the appellants were negligent in bringing them to the market. Again, so much may be accepted. But it would be wrong to assume that the primary judge proceeded on the basis of this misconception. The primary judge was not dealing with a body of evidence the effect of which was that one or another patient suffered from one or more of the pleaded complications. As her reasons disclose, she was dealing with a body of evidence to the effect that all of the devices, irrespective of surgical proficiency, involved the risk of causing each and every one of the pleaded complications in any woman who was implanted with one of the devices, at any time, and that every one of the pleaded complications, if it manifested itself, was clinically significant. The evidence of the epidemiologists, biostatisticians, biomaterials experts and pathologists, although decried by the appellants (as to which see below), also proved that many of the pleaded complications were at least common in that they occurred in 1 to 10% of patients: for example, TJ [1139] and [1140].

386 In other words, it is clear that the primary judge did not assume that the mere existence of the pleaded complications in one or more women proved the statutory and common law causes of action against the appellants.

###### 4.3 Knowledge of pelvic surgeons

4.3.1 Preliminary observations

387 In oral submissions the appellants confronted an issue which had remained implicit in their written submissions in respect of the appeal – that pelvic surgeons in general knew about all of the pleaded complications in any event or that, at the least, the respondents had not proved that pelvic surgeons generally did not know about the pleaded complications, it being the respondents’ onus to do so.

388 Although it was not the focus of written submissions made by either party, at the outset it is important to identify where within the class action the issue of the state of knowledge of pelvic surgeons generally was relevant. In this regard it is critical that the appellants radically changed their case after Dr Hinoul’s evidence from a contention that the pleaded complications did not exist and they could not know about them given the state of scientific knowledge to a contention, put in different ways, that they could not be liable for failing to warn pelvic surgeons about the pleaded complications because pelvic surgeons in general knew or should or could have known about them.

389 The initial trial dealt with the individual cases of each representative respondent and in doing so dealt with common issues. As to both the representative respondents and all group members, the issue as to the state of knowledge of pelvic surgeons generally, following the appellants’ radical shift in position, was relevant to:

(1) the *negligence cases*, as to the content of the duty to take reasonable care in the circumstances;

(2) the *misleading and deceptive conduct cases*, as to the objective characterisation exercise concerning whether the impugned conduct was misleading or deceptive, being a question of fact to be determined in the context of all relevant surrounding facts and circumstances including the likely relationship between the impugned conduct and the class of persons to whom the conduct was directed; and

(3) the *defect cases,* asto whether in fact the devices have a defect. In this regard, as we later explain, in circumstances where the devices and the accompanying IFUs are supplied to treating pelvic surgeons rather than directly to patients, and the surgeons provide their patients with medical advice and a recommendation, which can be expected to include an appropriate warning as to any risk associated with the device of which the surgeon is aware, the knowledge of pelvic surgeons generally as to risks associated with the devices may be relevant to the objective assessment of whether the safety of the devices is not such as persons generally are entitled to expect.

390 Additionally, focussing only on the individual claims determined, given the forensic decisions made below by the representative respondents, the knowledge of pelvic surgeons generally was also relevant to the way in which her Honour, through a process of inferential reasoning, made findings as to the likely knowledge of the relevant treating surgeons whose individual knowledge was relevant to the individual causation case of each of the three representative respondents as to their claim for common law damages (in negligence) and statutory compensation (in relation to the statutory claims).

391 As we also explain below, to the extent the primary judge made statements of principle apparently indicating that the knowledge of pelvic surgeons in general was not material to these issues, we disagree. But on the facts as found by the primary judge, this disagreement is immaterial both because it must be inferred that her Honour found that pelvic surgeons in general did not know about the pleaded complications and because this finding (express in part and admittedly implicit in part) was amply supported by the evidence.

392 The relevance of the knowledge of pelvic surgeons generally to the claims of group members, which were not determined at the initial trial, is another reason why the failure of the parties to identify common questions in advance of that trial was both regrettable and important. As can be seen from the above, the state of knowledge of pelvic surgeons generally is material to these future claims which, absent settlement, will be the subject of future determination.

393 Needless to say, findings as to the state of knowledge of pelvic surgeons generally should have been the subject of an express answer to common question and formalised by a s 33ZB order, but this omission is likely to have little practical significance and, in any event, is not the subject of a ground of appeal. It has little ongoing significance because the primary judge’s finding as to the state of knowledge of pelvic surgeons generally was implicitly part of the process of reasoning by which her Honour concluded, for example, that the devices have a defect. That is a finding that applies to all the devices, which could not be re-agitated by the appellants, as parties, in any subsequent determination of group member’s individual claims. But this is happenstance; if the issue as to the state of knowledge of pelvic surgeons generally had been determined favourably to the appellants, unless a s 33ZB order was made the group members (as non-parties) would not have been bound by a statutory estoppel on the issue. As the Full Court said in *Dyczynski v Gibson* [2020] FCAFC 120; (2020) 381 ALR 1 at [249] per Murphy and Colvin JJ and [391] per Lee J, the way that the statutory scheme works to bind non-parties to an order made by the Court is by operation of s 33ZB. Group members are only bound by the determination of the claims giving rise to the common questions: *Timbercorp* *Finance* at [53] per French CJ, Kiefel, Keane and Nettle JJ.

394 According to the appellants, it cannot be the case that they contravened any statutory or common law duty in failing to inform pelvic surgeons about risks of which the pelvic surgeons were already aware. In a related submission the appellants said that it could never have been the case that pelvic surgeons assumed that the appellants’ IFUs carried a complete statement of all of the risks associated with the implantation of the devices. In a further related submission the appellants said that the representative respondents should never have succeeded in their individual claims because they had not called their treating surgeons and thus could not prove that their treating surgeon was unaware of the pleaded complications.

395 According to the appellants, the primary judge’s reasons involve internal inconsistency and error in relation to these issues. For example, at TJ [3215] the primary judge said this:

Furthermore, it may be accepted that treating surgeons would be aware of the risks of pelvic surgery and that it is unlikely that the IFU would be the sole source of information for most, if not all, surgeons. And I am prepared to assume that some pelvic surgeons would have been aware of many, if not most, of the risks associated with the implantation of the various Ethicon devices as a result of their own experience or research.

396 Yet, the appellants said, the primary judge at TJ [3252] rejected their argument that the representative respondents’ individual claims must fail because they had not called their treating surgeons (that is, the surgeons who had implanted the devices) and said whether the “safety of goods is not such that persons generally are entitled to expect does not depend on the knowledge of individual surgeons”. Further, the primary judge said this, which the appellants contended exposes error:

(1) the [appellants’] promotional material was designed to encourage surgeons to recommend the devices to patients and patients to accept those recommendations. The devices were marketed as safe and effective to treat either stress urinary incontinence or pelvic organ prolapse. As I noted previously, risks were minimised and some not mentioned at all. Notwithstanding the way the [appellants] put their case, a number of their product brochures told surgeons, in effect, that they could and should rely on the IFUs for “complete” contraindications, warnings, precautions, and adverse reactions: TJ [3260]; and

(2) I accept that the IFUs will not be the only source of information for surgeons. I also recognise that the IFUs were drafted for pelvic surgeons familiar with pelvic floor surgery. Moreover, I accept that none of the relevant witnesses gave evidence that he or she relied solely on the IFUs for information as to the risks associated with the devices. But that does not mean that surgeons are not entitled to rely on the IFUs or to depend on the manufacturer for accurate information about the risks posed by the devices and the precautions that should be taken to guard against or minimise them. Indeed, unless they had reason to know that an IFU was deficient in these respects, they might well consider that there was no need to look beyond it: TJ [3311].

397 Given the length of the primary judge’s reasons, there are other statements to the same effect as those noted above on which the appellants relied to demonstrate alleged error and internal inconsistency on the part of the primary judge.

398 Again, the appellants’ submissions require caution. For example, it is one thing to accept that pelvic surgeons, as a cohort, may be aware of the general risks associated with pelvic surgery. It is another to assume that they (or, as matter of inference, the relevant surgeons whose knowledge was material to the determination of the cases of the representative respondents) would have been aware of the specific risks associated with the implantation of the devices. It is also one thing to accept that the IFUs were not the sole source of information for pelvic surgeons about the general risks associated with pelvic surgery. It is another to assume that pelvic surgeons had other information sources about the specific risks associated with the implantation of these devices. Similarly, it is one thing to assume that *some* pelvic surgeons would have been aware of many, if not most, of the risks associated with the implantation of the various devices as a result of their own experience or research. It is another to assume that the relevant cohort of pelvic surgeons generally would have been aware of all of the pleaded complications. In making these observations it should not be thought we are reversing the onus of proof, as the appellants contend the primary judge has done. The respondents bore the onus of proof and in accordance with s 140(1) of the Evidence Actthey were not to succeed in their cases unless the whole of the evidence established a reasonable satisfaction on the preponderance of probabilities such as to sustain their case as to the state of knowledge of pelvic surgeons generally. Our observations are intended only to expose the critical differences, of which the primary judge was aware, between:

(1) the risks of pelvic surgery generally and the risks presented by the devices;

(2) the availability of other information about the risks of pelvic surgery generally and the important role of the IFUs in informing pelvic surgeons of the risks of the devices; and

(3) the kinds of complications which were associated with pelvic surgery generally and the pleaded complications caused by the devices.

399 The appellants’ submissions consistently glossed over these critical differences.

400 Nor, when the primary judge’s reasons are analysed, may it be said that the primary judge reversed the onus of proof in this regard. As explained below, there cannot be any serious doubt that the primary judge was satisfied on the evidence that the necessary inference was that pelvic surgeons generally (and the particular surgeons relevant to the cases of the representative respondents) did not know about the pleaded complications. The fact that this issue was not directly addressed in these terms in the primary judge’s reason may be accepted. But the appellants’ submissions to the effect that the primary judge should have found that pelvic surgeons were so aware or that the respondents had not proved they were not so aware must be rejected. In explaining why this is so, it is necessary to deal with a number of disparate oral submissions of the appellants, as well as the effect of the evidence as a whole.

401 First, the fact that a number of the pelvic surgeons who gave evidence continued to use devices the equivalent of the SUI devices (an issue discussed below), despite now knowing of the pleaded complications, is not inconsistent with the primary judge’s findings to the effect that pelvic surgeons did not know of the pleaded complications until many years after the devices were on the market (and after they were implanted in the three representative respondents). Nor does it prove that the primary judge was wrong in holding the appellants liable under statute and at common law.

402 Second, the appellants cannot have it all ways in respect of Professor Korda’s evidence. The appellants wished to rely on him as representative of pelvic surgeons as a cohort in respect of his evidence that he continued to use a device equivalent to the SUI devices for SUI (TJ [2153], [3388]-[3393]) and that he considered abdominal sacrocolpopexy as the “gold standard” for POP (TJ [1279]). Yet they contended he could not be taken as representative of the relevant cohort in respect of his lack of knowledge of the pleaded complications for many years whilst the devices were on the market: for example only, TJ [2871], [2984], [3232], [3235]-[3237], [3244]-[3247]. The primary judge had good reason to infer that Professor Korda’s evidence about what he did *not* know was representative of the state of knowledge of pelvic surgeons generally. Professor Korda is a very experienced Australian urogynaecologist: TJ [22] and [203]. He had been in practice for around 30 years: TJ [233]. The appellants used him as a preceptor to train other surgeons in respect of the implantation of the devices: TJ [2691], [2695]-[2698] and [3603]. The obvious inference is that, if a pelvic surgeon such as Professor Korda did not know of some or all of the pleaded complications until many years after the devices had been on the market, then the cohort of pelvic surgeons generally may be taken not to have known of those complications. The unavoidable inference is that Professor Korda, given his experience and role as a preceptor, must have known more, and probably materially more, than pelvic surgeons generally about the risks of the devices.

403 Third, the evidence of the other pelvic surgeons, properly analysed, in fact supports the inference the primary judge drew that pelvic surgeons did not know of the pleaded complications. Accordingly, it may be accepted that the evidence of the pelvic surgeons was to the effect that their role was to apply their medical expertise in determining suitable treatment options for their patients and that in so doing, they took steps to inform themselves about the risks of the options. It thus may be accepted that, as the appellants submitted:

(a) Professor Chughtai opined that pelvic floor surgeons should be able to discuss all treatment options (including their risks and alternatives), that a surgeon who focuses on mesh implant surgery should be aware of the mesh specific adverse events, and that surgeons ought know when not to operate and have a detailed understanding of conservative measures as well (Chughtai 2, p.8 [EXP.010.112.0001\_3 at .0009\_3]);

(b) Professor Lam had regard to his reading and textbooks as well as product information pamphlets in preparing his presentation used to discuss risks and warnings with patients (T3745.01-09 [TRA.500.047.0001\_3 at .0037\_3]);

(c) Professor Rosamilia informed herself of risks and techniques involved in a procedure (eg. native tissue repair) by way of her initial training, sub-speciality training, optimising surgical techniques, following up patients and reading the literature (T4172.19-21 [TRA.500.052.0001\_2 at .0012\_2]);

(d) Professor Blaivas agreed that there are a number of ways a surgeon will learn and inform themselves of the risks and benefits of a procedure, including their medical training, literature review, continuing education, in-hospital seminars, and statements from professional regulatory bodies (T627.05-628.18 [TRA.500.008.0001\_2 at .0016\_2-.0017\_2]);

(e) Professor Korda agreed his knowledge of techniques and complications come from a number of sources including colleagues, personal experience, and anecdotal evidence (T1263.42-1264.06 [TRA.500.015.0001\_2 at .0046\_2-.0047\_2]);

(f) Professor Agur indicated he relied on guidance from NICE (the National Institute for Health and Care Excellence), meetings in national and international conferences, annual scientific updates from the Royal College, and scientific opinions and guidelines from the Royal College (T1030.13-25 [TRA.500.012.0001\_2 at .0040\_2]);

(g) Professor Deprest was trained in the specifics of each individual product by proctorship with an expert for each novel product and learnt about complications with experience (Deprest 1, [197] [EXP.020.006.0001\_4 at .0044\_4]); and

(h) Professor Collinet received training in urogynaecology, including in treatment of POP and SUI as part of his fellowship qualifications in gynaecology and obstetrics and, in turn, took part and led training sessions in surgical technique (particularly in relation to the technique of implanting Prolift) and gave presentations on urogynaecology and on the evaluation of vaginal meshes for pelvic floor repair (Collinet 1, pp.3-5 [EXP.020.005.0001\_4 at .0003\_4-.0005\_4]; T4329.25-4339.10 [TRA.500.054.0001\_2 at .0034\_2-0044\_2]).

404 This is only part of the evidence before the primary judge, however. It is evidence expressed at a high level of generality. It does not directly confront the issue of pelvic surgeons’ knowledge of the pleaded complications, nor how that knowledge emerged many years after the devices were supplied to the market and, indeed, in large part after the commencement of this litigation in 2012. Moreover, the primary judge also had evidence that:

(1) the evidence indicated that at least some of the effects on the human body of polypropylene mesh, including the devices, were not well-known to the medical or surgical community during the relevant period and that some of the information was not available in the journals commonly read by the cohort: TJ [3228];

(2) Assistant Professor Chughtai said that it would be unlikely that a reasonably competent gynaecologist or urologist would be aware of the scientific literature on the inflammatory response to mesh: TJ [3228];

(3) Collinet et al (2006) (Collinet P et al, “Transvaginal mesh technique for pelvic organ prolapse repair: mesh exposure management and risk factors” (2006) 17(4) Int Urogynecol J Pelvic Floor Dysfunct 315–320 (ETH.MESH.00034322)) observed that the published data about the management of mesh exposure was sparse. Based on the material before the Court, little changed in the following decade: TJ [3229];

(4) Moalli et al (2008) (Moalli P et al, “Tensile properties of five commonly used mid-urethral slings relative to the TVT™” (2008) 19 Int Urogynecol J 655–663 (SHI.MESH.00033759)) recognised that there were “knowledge deficits”, the greatest of which, they said, was in the area of material properties, and surgeons are “completely dependent on the mesh information supplied by a representative of the vendor”: TJ [3230];

(5) an inquiry made of JJM by an Australian surgeon as recently as 2013 underscores the gap in the knowledge of the user community and the importance of providing information in the IFU: TJ [3231];

(6) Professor Korda said that the literature does not reflect the devastation caused by some of the Mesh Complications: TJ [3232]. Specifically:

The literature merely states for example that the mesh erosion rate is for instance 10 per cent after mesh implant surgery. It does not state that those who suffer erosion are often sexually active young women who are unable to have intercourse because of a repulsive vaginal discharge, bleeding and chronic pain on sitting, standing or movement and that this may not be easily corrected.

It is my view that the published literature does not adequately convey the pain and suffering of the patients who have had mesh complications.

The published literature does not mention the fact that the placement of mesh is permanent and the patient has to live with the mesh for the rest of her life. Nor does the literature allude to the fact that when patients are counselled for the mesh placement they should be advised that if they have mesh surgery and complications develop there may not be a cure for their problem;

(7) no matter how learned the intermediary may be, it is highly unlikely, if not inconceivable, that the intermediary would know as much about the product as the manufacturer itself. In this regard, Dr Hinoul conceded that Ethicon had spent hundreds of thousands of dollars on reports, studies and consultancies relating to the foreign body reaction and had access to a body of knowledge on the subject which far surpasses the knowledge of gynaecological surgeons, regardless of their experience. He also conceded that surgeons are entitled to think that the manufacturer is likely to have more knowledge about its own product than members of the medical community: TJ [3233];

(8) Professor Blaivas, a very experienced urologist, observed that the mesh manufacturers provided no guidance as to exactly where within the thickness of the vaginal wall the mesh should be placed and experimental studies do not address the issue. This was a matter of concern since placing the mesh too close to the vaginal epithelium or the lower urinary tract or in the vaginal wall can cause the mesh to erode: TJ [3234];

(9) Professor Korda, another very experienced urogynaecologist, gave evidence that polypropylene mesh implants carried a risk of certain complications that were unknown to pelvic surgeons versed in native tissue repair. He said that “complications such as mesh erosion, mesh contracture, bunching, severe chronic pelvic pain, severe dyspareunia and pain on movement, sitting, standing were not seen before the introduction of mesh surgery”: TJ [3235];

(10) Professor Korda’s evidence alone is an answer to the appellants’ submission that “there is no suggestion that there was a relevant knowledge gap between the [appellants] and the general surgical community”: TJ [3236];

(11) Professor Korda’s evidence was that he did not appreciate the extent of the potential harm from the use of transvaginal mesh in prolapse repair until around the time of the publication of the Altman article in 2011 (Altman D et al, “Anterior colporrhaphy versus transvaginal mesh for pelvic-organ prolapse” (2011) 364 N Engl J Med 1826–1836 (ETH.MESH.07971133)), which was more than four years after Mrs Gill’s implant surgery and about two years after Mrs Dawson’s. It was at that time, he wrote in his first report, that he began seeing patients who had been implanted with mesh by other gynaecologists and were seeking treatment for the complications. Not all implanting surgeons would see a similar cohort of patients. Professor Korda said that the patients he was seeing at that time had such “alarming problems and poor quality of life” that he considered that implantation of mesh caused too much harm in exchange for very little benefit: TJ [3237];

(12) Professor Deprest reported that, for each novel product, he and other consultants were typically trained by an expert in the specifics of individual polypropylene kits for transvaginal anterior, posterior and combined repairs. Nevertheless, it seems, this proctorship did not prepare him for all potential complications, which he became aware of only through experience: TJ [3238]. Specifically, he said:

As the experience grew we, like others, came across a number of complications, in essence mainly graft exposures, and to a lesser extent chronic pain, either associated with mesh folding yet at times without a direct anatomical substrate;

(13) Dr Agur included in an appendix to his first report a narrative explaining the warnings he provided patients over the years. At no time did he refer in that narrative to the risk of chronic pain. Nor did he refer to the potential for additional surgery to remove the mesh, the difficulties that could present, and the complications that might ensue: TJ [3239];

(14) notwithstanding his own practice of warning of an increased risk of complications in patients with certain conditions, Dr Agur considered that the failure of mesh manufacturers to identify whether mesh would be indicated or contraindicated in certain patients “directly resulted in the blanket use of mesh in a one-size-fits-all approach”: TJ [3240];

(15) Dr Lam’s presentation to patients does not distinguish between the pain, inflammation, dyspareunia, or painful scars that might arise with prolapse surgery in general and mesh surgery in particular and does not mention the risk of chronic pain after mesh surgery, the potential for multiple operations to treat erosions, or difficulties associated with removal of the mesh: TJ [3242];

(16) Professor Korda was taken to slides from 2004 which represented his then understanding of all complications for TVT but the slides do not refer to a number of admitted or otherwise established complications: TJ [3244];

(17) the evidence established that at all material times the respondents knew that there was a risk of chronic pain following implantation with all of their devices. It appears from Professor Korda’s slides and his evidence in this case that for a good deal of that time he did not share that knowledge including of dyspareunia, complications associated with the removal of the tape, tape erosion due to mechanical movements of the body, complications due to irritation of the urethra by the tape, fibrotic tissue surrounding the tape, contraction of the tape by fibrotic tissue, fibrosis due to chronic inflammation, voiding dysfunction or other complications due to subsequent tensioning of the tape by reason of contraction of the tape by scar tissue, or chronic pain. Nor did they refer to the particular risks polypropylene mesh posed for a woman with a compromised immune system: TJ [3244], [3246];

(18) Professor Korda also testified that, since he was both a user of the devices and a preceptor, teaching surgeons and registrars in training how to perform the operations to implant them, he expected that JJM would have informed him of any complications of which it was or became aware: TJ [3247];

(19) it is absurd to think that average gynaecologists and urologists, acting reasonably, would attend every conference at which the POP and SUI devices were discussed or read every article in every journal in which their complications were canvassed: TJ [3248];

(20) the evidence of Assistant Professor Chughtai was that an average, reasonably competent gynaecologist would expect the manufacturer to provide her or him with information about the use, surgical technique, risks of adverse events, and studies supporting safety and efficacy is accepted: TJ [3249]; and

(21) the notion that the medical literature was sufficient to alert the medical profession of the true nature and extent of the risks associated with implantation of mesh was rebuffed by a number of witnesses: TJ [3843].

405 This evidence alone is sufficient to undermine the appellants’ oral submissions to the effect that the primary judge failed to explain why her conclusion at TJ [3215] did not mean that the appellants could not be liable under statute and at common law. In short, a preparedness to assume that pelvic surgeons had access to information other than the IFUs and that “some” pelvic surgeons may be taken to have known of “most” of the pleaded complications is a long way from defeating the claims under statute and at common law.

406 As the respondents also put it, the evidence of the pelvic surgeons before the primary judge involved highly credentialed, trained, experienced, clinical professors with research interests in mesh surgery. As a group, it must be expected that they would know more than the cohort of pelvic surgeons generally. Even for these highly qualified pelvic surgeons engaged in research, as the respondents submitted, the evidence was that:

(1) it was only through experience, research and engagement with injured patients that [the pelvic surgeons] ultimately came to understand that the use of mesh for POP repair outside of a randomised clinical trial was unsupportable and the use of mesh in transvaginal surgery was premature: see TJ [2984], [3237]-[3250]; and

(2) the understanding of the pelvic surgeons about the risks of the SUI devices evolved over time whereas the appellants were aware of the risk of the pleaded complications at all times: TJ [3244]-[3246].

407 The appellants contended that the fact that the primary judge did not directly confront the issue of the knowledge of pelvic surgeons of each pleaded complication in a systematic way indicates error on her part. We do not accept this contention. The fact that the primary judge addresses this issue of the knowledge of treating surgeons obliquely, as explained below, is at least in part an artefact of the way in which the forensic contest developed below. While the nature of the forensic contest below does not mean that the respondents were relieved of their burden of proof, it is relevant to the nature of the primary judge’s reasons. The nature of that forensic contest also explains why the expert evidence called by the respondents did not itself directly confront, in any apparently systematic way, the knowledge of the pelvic surgeons of each of the pleaded complications. Recognising this fact does not mean that either the primary judge or we are engaged in a failure to apply the onus of proof or a reversal of the onus of proof. It merely explains why the evidence and the primary judge’s reasons take the form that they do.

408 It should also not be overlooked that, rightly or wrongly, the appellants’ senior counsel at trial accepted in oral closing submissions that the appellants bore an evidentiary onus in respect of the issue of the state of knowledge of pelvic surgeons generally about the pleaded complications and also said that the knowledge of pelvic surgeons in general was relevant only to the extent that such information was “so common and well known that it is legitimate to expect” that the information formed part of the instructions for use or warnings which accompany a product: TRA.500.076.0011 at 6046. No doubt this was a result of the way in which the forensic contest about that issue developed. As noted, until Dr Hinoul was cross-examined, the appellants denied the existence of the pleaded complications and denied that they could have known about them given the state of scientific knowledge at the time. The appellants only changed position after his evidence, which was given after the evidence of respondents’ relevant experts. In these circumstances it would not be appropriate for any inference of the kind referred to in *Jones v Dunkel* or *Commercial Union Assurance Co of Australia Ltd v* ***Ferrcom*** *Pty Ltd* (1991) 22 NSWLR 389 at 418-419 to be drawn to the effect that the evidence of the respondents’ experts about their state of knowledge would not have assisted the respondents merely because they did not directly and systematically deal with that state of knowledge about each pleaded complication at various times.

409 We also acknowledge that another partial explanation for the form of the primary judge’s reasons is her conclusion that the fact that pelvic surgeons may be taken to have known of a risk does not mean that the appellants were immune from statutory or common law liability for failing to warn of that risk: see, for example, TJ [3216], [3252], [3313], [3317], [3652], [3838] and [3844]. These paragraphs need to be understood in the context that the primary judge also accepted, correctly, that it was relevant that the devices were supplied to doctors and hospitals and not to patients directly: TJ [3213].

410 At TJ [3216], in the context of the statutory claims, the primary judge said:

Nevertheless, to the extent that the respondents argue that manufacturers are excused from liability with respect to risks or complications that should be known to doctors or which they are able to discover for themselves, that argument should be rejected.

411 At TJ [3252], in the context of the statutory claims, the primary judge said this:

The respondents also submitted that the applicants’ failure to call surgeons with whom the applicants or any other patient decided to have “the index surgery” was “particularly significant”. They contended that, without evidence from them, the Court could not be satisfied that the information provided by the respondents or the warnings they gave were inadequate. This argument must be rejected, too. Whether the safety of goods is not such that persons generally are entitled to expect does not depend on the knowledge of individual surgeons.

(Citations omitted).

412 At TJ [3313], in the context of the statutory claims, the primary judge said this:

I reject the proposition that it is unreasonable to expect manufacturers to include in an IFU warnings about matters of which they were aware because the surgeons should also have been aware of them or could have discovered them by other means or from other sources. Dr Pence pointed out the fallacy of this argument. A manufacturer who fails to draw attention in an IFU to risks associated with the use or implantation of its medical devices endangers the safety of patients because it leaves to chance the prospect that a particular risk or contraindication of which the manufacturer is aware but the doctor is unaware (either as to its incidence or extent) will be made known to the patient. Such an approach does not serve the statutory purpose.

413 At TJ [3317], in the context of the statutory claims, the primary judge said this:

The fact that some doctors were or may have been aware of risks not mentioned in the IFUs and may or may not have warned some patients of those risks would not mean that the devices were not defective. Whether or not a device has a defect is determined by reference to the reasonable expectations of persons generally. In my opinion, persons generally are entitled to expect that, if the manufacturer of a medical device is aware, or ought reasonably to be aware, of a risk to patient safety arising from the implantation of its device, then it would disclose that risk in the instructions for use supplied with the device and in brochures, leaflets, and other material it produces about the device.

414 At TJ [3652], in the context of the negligence claims, the primary judge said this:

…But I do not accept the respondents’ contention that the standard of care expected of the manufacturer, or the supplier for that matter, is affected by the fact that the devices are supplied through surgeons or following consultation with surgeons.

415 At TJ [3838], in the context of the negligence claims, the primary judge said this:

The respondents submitted that the users of the devices were trained medical professionals who should be familiar with surgical procedures and techniques involving pelvic floor repair and non-absorbable or synthetic meshes and pointed to the instructions to this effect in the IFUs for all the devices. Such a person, they argued, would appreciate the risks of using the devices. Besides, they added, JJM offered a professional education program and surgeons who required training and guidance on the relevant procedures for implanting the devices could enrol in that program if necessary. They also argued that, in any event, to the extent that the IFUs were said to be deficient or confusing, it was reasonable for the respondents to expect that medical practitioners, acting reasonably, would seek guidance or clarification should they not understand a statement in the IFU. In other words, the respondents’ argument was that they were not obliged to mention risks of which they were aware because the users of the devices (the physicians or surgeons) either knew of them already or had at their disposal other sources from which they could have acquired the information. I have already rejected that argument in the context of the defective goods case. For the following reasons, it must be rejected here, too.

416 At TJ [3844], in the context of the negligence claims, the primary judge said this:

It is no answer to the applicants’ claim to point to the fact that professional education was offered and surgeons who elected to undergo it could have asked questions. As I have already stated, the respondents had an obligation to warn of all reasonably foreseeable risks regardless of what they might presume to think surgeons already knew or could learn from their own research or upon inquiry or after further education. As the applicants argued, the existence of the duty of a medical practitioner to warn or provide information does not obviate the duty of care owed by a manufacturer; the duties are at least co-extensive. One reason for this is the likelihood that the manufacturer would “overvalue a product and underemphasise its risk”: *Hollis* at [46].

417 It may be the case that the primary judge made these observations because senior counsel for the appellants accepted the matters set out above. Whatever the explanation, these statements involve a range of concepts, including what pelvic surgeons (generally and individually) knew, what they should have known, and what they could have known if they had made further inquiry. The problem with the statements is that they are expressed at a level of generality which is inapt for the resolution of the common issues or the representative respondents’ individual claims.

418 For example, it seems to us that, in the factual context of the present case, liability could not attach itself to the appellants, either under statute or at common law, for a mere failure to warn pelvic surgeons that all pelvic surgery involves certain risks (such as the risk of bleeding during pelvic surgery, surgical pain, and infection from surgery). It might be said that these risks are so obvious to pelvic surgeons that they go without saying. It is difficult to accept that a product may be defective, not of merchantable or acceptable quality or not reasonably fit for purpose, or that a manufacturer/supplier may have failed to take reasonable care, merely because the manufacturer/supplier did not inform a learned intermediary or the ultimate user about a risk that is so obvious that it goes without saying. This concept, for example, finds expression in the civil liability legislation which provides that there is no duty of care to warn of an obvious risk: for example, ss 5F and 5O of the CLA.

419 The appellants never suggested that the concept of obvious risk, and the statutory provisions relevant to such a risk, were relevant to the resolution of the respondents’ claims. Their case, at least after Dr Hinoul’s concessions, was different. It was that the respondents had not proved that pelvic surgeons (either generally or the treating surgeons relevant to the representative respondents’ claims) did not know about the pleaded complications or that it should be inferred that pelvic surgeons did know about the pleaded complications. Their case was not, however, that the pleaded complications involved obvious risks as provided for in either the CLA or the Wrongs Act.

420 Beyond this class of case of an obvious risk, there are questions of fact relevant to each cause of action which must be answered on the facts and not at the level of principle. To the extent that the primary judge gave an in principle answer to these issues as set out above, we would disagree. Equally, we do not agree with the primary judge that the applicable standard of care is unaffected by the fact that the devices were supplied to women via their pelvic surgeon. This fact must be relevant to the meaning of reasonable care (which is the relevant standard of care) in the circumstances and whether or not that standard has been breached. Thus, the independent duty of care the appellants owed to patients is necessarily affected by the fact that patients receive the devices from a pelvic surgeon who has professional training, experience and knowledge and owes their patients a duty of care to exercise the skill and competence that an ordinary person having those special skills would exercise: ***Rogers v Whitaker*** [1992] HCA 58; (1992) 175 CLR 479 at 487. Accepting this, however, is very different from the appellants’ proposition, which is to the effect that the independent duty of care owed by pelvic surgeons to their patients effectively abrogates their own duty of care in respect of the safety of their devices.

421 That said, we do not accept that the mere fact that pelvic surgeons *could* have obtained information about all of the pleaded complications the devices could cause from medical literature (if it were the fact, which it is not) means that the appellants cannot be liable for such a risk which is not disclosed by it to a learned intermediary or the ultimate user. Still less can the liability of a manufacturer/supplier either under statute or at common law depend on the potentially idiosyncratic belief of a manufacturer/supplier about what the learned intermediary knew about the product, should have known about the product, or could have known had they made further inquiry. We too would have rejected the appellants’ submissions about the medical literature recorded at TJ [3210]. It is not that the medical literature is irrelevant. It is that the mere reference to a risk in medical literature does not necessarily mean that it may be inferred that pelvic surgeons generally may be taken to have known of that risk or that the treating pelvic surgeon may be taken to have known of that risk. Or, at the least, it did not mean that in the present case, where there was evidence which strongly weighed in favour of the inference that pelvic surgeons did not know about the pleaded complications, and that the individual treating surgeons were in no different position.

422 As noted, our disagreement with aspects of the primary judge’s apparent statements of principle is not material. As discussed below, the weight of the evidence amply supported the inference that pelvic surgeons in general did not know of the pleaded complications (nor even that they could have known of them until many years after the devices were on the market and the problems with the devices became manifest). The fact that the primary judge accepted that some pelvic surgeons may be taken to have known of many, if not most, of the pleaded complications (at TJ [3215]) is not inconsistent with the conclusion which the primary judge must be taken to have reached that it should be inferred that pelvic surgeons generally did not in fact know of the pleaded complications: for example, TJ [3233], [3235]-[3246]. Insofar as the claims of the representative respondents are concerned, the primary judge inferred that their treating surgeons did not in fact know about the pleaded complications and, if they had been warned of the pleaded complications, they would have communicated that information to their patients including the representative respondents: TJ [4421], [4426], [4464], [4488], [4492], [4508], [4551]-[4552].

423 In their oral submissions in reply the appellants referred to the Medical Devices Regulations. The essential principles about the design and construction of medical devices include those contained in Pt 2 of Sch 1, including cl 13.1 – Information to be provided with medical devices – general, which provides that certain information must be provided with a medical device including information explaining how to use the device safely “having regard to the training and knowledge of potential users of the device”. This reference is not determinative of the relevance of the knowledge of pelvic surgeons in the present case. It may also be noted that this reference concerns the general requirements for a medical device. There are particular requirements in cl 13.3, which requires other information to be provided with a medical device, including item 5 “any warnings, restrictions, or precautions that should be taken, in relation to the use of the device”. See also items 5 and 19 in cl 13.4 – Instructions for use. Item 5 is the same as item 5 in cl 13.3, save that it also requires information on contraindications to be provided. Item 19 requires the information to be provided with an implantable medical device to include “information about *any* risks associated with its implantation” (emphasis added). These requirements are not qualified by any reference to the training and knowledge of potential users of the device.

4.3.2 The relevant state of knowledge

424 We return now to the allegation of error by the primary judge in the appellants’ oral submissions to the effect that the primary judge should not have inferred (explicitly or implicitly) that pelvic surgeons did not know about the pleaded complications. Rather, the primary judge should have inferred that pelvic surgeons in fact knew of each of the pleaded complications or that the appellants had failed to prove to the contrary.

425 In considering this evidence, some facts need to be kept in mind.

426 One, as explained above, the pleaded complications are not concerned with the general risks of surgery or pelvic surgery.

427 Two, it should not be assumed or inferred that a mere reference to “pain”, “infection” or “foreign body reaction” (and other risks) means the same thing as the pleaded complications.

428 As to these first two matters, the primary judge’s answer to common question 18 discloses the true nature and extent of the pleaded complication as things different in nature and extent from the general risks of surgery.

429 Three, the litigation was commenced in 2012 by which time it might be expected that knowledge of the pleaded complications was at least beginning to be disseminated, but the devices had been supplied in Australia from 1999 (the first SUI device) and 2005 (the first POP device). Further, Mrs Gill was implanted with Prolift Total in January 2007. Mrs Dawson was implanted with Gynemesh PS in May 2009. Mrs Sanders was implanted with TVT in March 2001.

430 Four, there was evidence before the primary judge which was relevant to the question of the extent to which pelvic surgeons were aware of the medical literature.

431 Five, there was evidence before the primary judge of the importance to pelvic surgeons of the information contained in the IFUs, not about the general risks of surgery, but about the specific risks to which the devices gave rise.

432 With this in mind, the appellants’ collation of what they identified as evidence demonstrating error by the primary judge in concluding that pelvic surgeons were unaware of the pleaded complications may be considered.

4.3.2.1 Chronic inflammation

433 The appellants sought to dismiss this as immaterial as the primary judge did not regard chronic inflammation to be an injury in and of itself: TJ [4925]. But the answer to common question 18 exposes that chronic inflammation caused by the devices is responsible for most of the other pleaded complications. It necessarily follows that it was critical that pelvic surgeon understood this fact, as summarised at TJ [3419]. But not only did pelvic surgeons plainly not know this fact, the appellants repeatedly insisted to them in the IFUs that the foreign body reaction caused by the devices was transitory or transient: TJ [353], [2595]-[2598], [2812], [2814]-[2827], [2830]-[2835], [2946]-[2948], [3293]-[3295], [3424], [3577]-[3578], [3586], and [3588]. The question may be asked – if the appellants believed that pelvic surgeons knew that the devices precipitated acute and chronic inflammation, then why would they have repeatedly insisted that the devices engendered a slight inflammatory reaction which was transient? The answer is inescapable. In common with the evidence of pelvic surgeons before the primary judge, the appellants did not believe that pelvic surgeons knew that the devices precipitated acute and chronic inflammation. They wished to convince pelvic surgeons that the devices elicited a mere transient foreign body reaction involving slight inflammation.

434 Accordingly, the appellants’ contention that the primary judge erred in inferring that pelvic surgeons were unaware that the devices caused chronic inflammation cannot be accepted.

4.3.2.2 Extrusion or erosion of the mesh into surrounding organs, including the vaginal wall, bladder or urethra

435 The appellants pointed to the following evidence:

(1) Professor Agur said his training in SUI and POP surgery included the risk of erosion. See TJ [3211] which discloses this training was in around 2003 to 2005;

(2) the 2007 Ward Hilton study (Ward K and Hilton P “Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow up” (2008) 115 BJOG 226–233 at 232 (ETH.MESH.04045078)) refers to a TVT complication of erosion into the vagina;

(3) the 2000 TVT IFU refers to “erosion” (in fact it says “[t]ransitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation”);

(4) the 2003 Gynemesh PS IFU states that “potential adverse reactions are those typically associated with surgically implantable materials including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, and extrusion”; and

(5) the 2008 NICE (UK National Institute for Health and Care Excellence) guidance for surgical repair of vaginal wall prolapse using mesh referred to mesh erosion and exposure.

436 However, there was other evidence before the primary judge. That evidence included that:

(1) the appellants knew the devices involved a lifelong risk of erosion (that is, erosion could occur at any time and not merely immediately after surgery): TJ [189], [216];

(2) erosion was a new and unique risk of mesh surgery: TJ [236], [238], [3235];

(3) erosion can occur despite great surgical skill: TJ [270]-[271], [837];

(4) mesh erosions are common for both the SUI and POP devices (that is, occurring in 1 to 10% of patients): TJ [1139]-[1140];

(5) mesh erosions are not easy to manage: TJ [2717];

(6) erosion can be caused by the fact that the mesh is rigid whereas the vagina is flexible. It can also be caused by infection generated by transvaginal implantation of the mesh, as well as by the contraction of the mesh: TJ [218], [610]-[671];

(7) erosion may cause intractable pain, and offensive continuous blood stained vaginal discharge, dyspareunia, difficulty sitting or moving and in such patients removing the exposed part of the mesh and closing the epithelium does not resolve their problem: TJ [248], [3232];

(8) erosions can cause infection including late onset infections: TJ [3594];

(9) the mesh can migrate or move in the body: TJ [217];

(10) erosion may have nothing to do with the foreign body response but may occur as late onset erosion including erosion not merely into the vagina but into surrounding organs including the urethra, bladder and bowel: TJ [2065], [3421]-[3422], [3435], [3464], [3466], [3592];

(11) erosion may require removal of the mesh on multiple occasions: TJ [247], [2627], [2654], [3242]; and

(12) removing the mesh is technically difficult and fraught with danger: TJ [249]. In any event, chronic pain may continue: TJ [2627], [2654], [2952], [3242].

437 The passing references in the IFUs to “erosion” as a potential adverse reaction associated with the devices would not have put pelvic surgeons on notice of the fact that erosion was a common complication of the devices, that erosion could occur at any time years after implantation as the mesh migrated, that erosion was not easily managed and could involve not merely erosion of the mesh into the vagina but also into the surrounding organs, that erosion could involve chronic pain and infection, dyspareunia, difficulty moving and sitting, and vaginal discharge, that multiple mesh removal surgeries which were difficult and fraught with danger may be required and that, even with multiple revision surgeries, the consequences of mesh erosion may continue. This evidence supported the inference which the primary judge drew (see TJ [3232]-[3237], [3244]) that the knowledge gap between pelvic surgeons and the appellants included pelvic surgeons’ lack of knowledge of the incidence and complications of erosion. Contrary to the appellants’ submissions, Professor Korda’s evidence was not idiosyncratic in this regard. It was supported by evidence of Professor Deprest (TJ [3238]), Dr Agur [3239]-[3240]), and Associate Professor Lam (TJ [3241]-[3242]).

438 Accordingly, the appellants’ contention that the primary judge erred in inferring that pelvic surgeons were unaware that the devices may cause extrusion or erosion of the mesh into surrounding organs, including the vaginal wall, bladder or urethra cannot be accepted.

4.3.2.3 Infection

439 The appellants referred to the fact that the implantation of the devices involved surgery and the implantation was permanent. They also referred to the following evidence:

(1) the 2000 TVT IFU refers to “infection” (in fact, it says “as with all foreign bodies PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimise the risk of contamination”); and

(2) the 2003 Gynemesh PS IFU states that potential adverse reactions are those typically associated with surgically implantable materials including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, and extrusion.

440 It may be accepted that infection is a general risk of all surgery. But that is not the risk which it is relevant. The evidence before the primary judge disclosed that the risk was of a different kind and, contrary to the IFUs, was not confined to the potentiation of an existing infection. In fact, the devices carried a lifelong risk of chronic infection which might occur at any time due to the chronic inflammatory reaction the devices engendered and the associated risks of erosion. This risk was also exacerbated by transvaginal implantation of the devices because it is a contaminated field: see TJ [651], [1812], [2855], [2856], [2964], [3277], [3593].

441 Given this evidence, the primary judge did not err in inferring that pelvic surgeons were not aware that the devices involved a risk of chronic infection which may occur at any time for so long as the devices remained implanted.

4.3.2.4 Chronic pain

442 The appellants referred to the evidence of Dr Agur that in his training in pelvic surgery in about 2003-2005 he had been taught that pain was a risk. Again, it may be accepted that all surgery carries the risk of pain. It is evident from the context of Dr Agur’s evidence that in fact the risk of pain with non-mesh surgery was rare and, if it occurred, it was not long-term. This was consistent with the information the appellants provided to pelvic surgeons about the risk of pain associated with surgery using the devices. Some of the IFUs with respect to some of the devices referred to a risk of “transient leg pain” but that is all: TJ [2863]-[2867], [2966]-[2972], [3591]. Before 2015 none of them referred to the risk of chronic, intractable, severe pain which the devices could cause in any woman at any time and which was not caused by pre-existing surgical methods (that is, it was unique to mesh surgery): TJ [233], [236], [3235], [3236], [3238], [3239], [3242]. But, for example, the appellants knew from early on about the issue of non-surgical pain after implantation of TVT: TJ [1158]-[1159], [2582].

443 The same question may be posed – if the appellants believed that pelvic surgeons knew that the implantation of the devices could cause chronic pain, at any time, even years after implantation, then why would they have informed pelvic surgeons of the risk of transient leg pain? The notion that pelvic surgeons were aware that the devices could result at any time in a woman suffering severe, intractable, chronic pain is inconsistent with the evidence. The primary judge did not err in inferring that pelvic surgeons were unaware of this risk of the devices.

4.3.2.5 Dyspareunia and/or apareunia (avoidance of sexual intercourse)

444 The appellants referred to the following evidence:

(1) the 2007 Ward Hilton study referred to pain with intercourse as a potential complication of mesh surgery; and

(2) the 2008 NICE guidance for surgical repair of vaginal wall prolapse using mesh referred to dyspareunia as a potential complication of mesh repair surgery.

445 The evidence before the primary judge included that dyspareunia and/or apareunia were common complications of the devices: TJ [1174] and [1234]. The appellants, however, gave no warning of a risk of dyspareunia and/or apareunia for the SUI devices until 2015: TJ [2876]. They gave no warning of the risk for the POP devices until 2007: TJ [2973]. The warnings, when given, referred to “pain with intercourse which in some patients may not resolve” and potential adverse reactions are those typically associated with “pelvic organ prolapse repair procedures, including pain with intercourse and pelvic pain. These may be self-resolving over time”. It will be recalled that Professor Korda, whose evidence the primary judge accepted, identified that the complications of the devices meant that sexually active young women were “unable to have intercourse because of a repulsive vaginal discharge, bleeding and chronic pain on sitting, standing or movement and that this may not be easily corrected”. If the true position was that pelvic surgeons generally were aware of the fact that the devices involved the risk in any woman that she would be unable to have intercourse again after implantation because of, amongst other things, severe, chronic pain, then it is difficult to understand why the appellants considered that warnings of pain with intercourse should be given in 2007 and 2015. The obvious inference which had to be drawn was that the appellants considered that pelvic surgeons were not aware that implantation of the devices in any woman involved the risk that she would be unable to have intercourse either at all or without pain due to the complications caused by the devices. Even then, there was no disclosure of the risk of inability to have intercourse at all or the kinds of severe, chronic pain which the devices could cause. The primary judge did not err in inferring that pelvic surgeons were not aware of these risks of the devices.

4.3.2.6 Difficulty voiding

446 The appellants referred to the following evidence:

(1) the 2007 Ward Hilton study referred to *de novo* urgency and urge incontinence as a result of mesh surgery; and

(2) the 2008 NICE guidance for surgical repair of vaginal wall prolapse using mesh referred to *de novo* defecation difficulties.

447 The primary judge found that difficult voiding was a common complication of the SUI devices but there was insufficient evidence to determine the rate of this complication for the POP devices: TJ [1183] and [1241]-[1242]. The appellants warned surgeons only that too much tension applied to the device (ie overcorrection) may cause temporary or permanent lower urinary tract obstruction. In fact, contraction of the device unconnected to surgical technique could cause, at any time, urinary tract obstruction, retention, irritation of the urethra and *de novo* urge incontinence. A warning of the risk of voiding dysfunction and urinary retention did not appear in the IFUs for the SUI devices until 2015: TJ [2906]-[2911]. Such a warning was not given in the IFUs for a POP device until 2007: TJ [2995]-[2998]. Given that pelvic surgeons were not aware of the risk that the devices may contract over time and the consequential complications, it cannot be the case that they were aware that the devices themselves may cause difficulty voiding at any time. The primary judge did not err in inferring that pelvic surgeons were not aware that the devices could contract over time causing, amongst other things, difficulty voiding.

4.3.2.7 Offensive vaginal discharge

448 The appellants contended that this was an obvious consequence of the risk of erosion. The primary judge could not make any finding about the prevalence of this complication: TJ [1203], [1247]. However, as discussed above, it is evident that pelvic surgeons were not aware of the true nature of the risk of erosion, nor its incidence. Nor were they aware that this may result in a repulsive vaginal discharge: TJ [3232]. The appellants gave no warning about this risk until 2015: TJ [2920]-[2921], [3003]-[3004]. Even when a warning was given it referred only to atypical vaginal discharge and not the fact that the discharge may be offensive. The primary judge did not err in inferring that pelvic surgeons were not aware of this risk of the devices.

4.3.2.8 De novo or recurrent urinary incontinence

449 The appellants referred to the following evidence:

(1) the 2007 Ward Hilton study referred to *de novo* urgency and urge incontinence as a result of mesh surgery; and

(2) the 2008 NICE guidance for surgical repair of vaginal wall prolapse using mesh referred to *de novo* urinary incontinence.

450 The primary judge found that *de novo* or recurrent urinary incontinence is a common outcome of surgery using the devices: TJ [1192] and [1245]. The IFUs did not warn of *de novo* urinary incontinence or recurrent urinary incontinence outside of pregnancy until 2003, for one device (TVT) (but limited to a context of surgical technique): TJ [2913]. It was not until 2015 that a general warning of the risk of *de novo* or recurrent urinary incontinence was disclosed in the SUI IFUs: TJ [2912]-[2918]. A warning about a POP device, Prolift+M, was not given until 2008. The primary judge did not err in inferring that pelvic surgeons were not aware that *de novo* or recurrent urinary incontinence was a common complication of the devices, unconnected to surgical technique.

4.3.2.9 Damage to surrounding organs, nerves, ligaments, tissue and/or blood vessels

451 The appellants referred to the fact that the devices are surgically implanted. Further:

(1) the 2000 TVT IFU referred to the procedure needing to be performed with care to avoid large vessels, nerves, bladder and bowel, and that punctures or lacerations of vessels, nerves, bladder and bowel may occur during needle passage and may require surgical repair;

(2) the 2008 NICE guidance for surgical repair of vaginal wall prolapse using mesh referred to damage to organs during surgery.

452 The primary judge found that bladder and vaginal perforations are common after implantation with the retropubic SUI devices and uncommon after implantation with the transobturator SUI devices, and the evidence did not allow a finding of prevalence about the incidence of damage to other surrounding organs or vessels or to nerves, ligaments, tissue and blood vessels: TJ [1199]. She found that injury to the bladder after POP surgery appeared to be more common that after native tissue repair: TJ [1253]. The primary judge noted that the warnings in the IFUs were confined to injury during surgery and did not include the injury to vessels, nerves, organs and tissues which could be caused by the devices at any time due to mesh migration, exposure, extrusion and erosion: TJ [2924]-[2925] and [3008]-[3014]. The primary judge did not err in inferring that pelvic surgeons were not aware that the devices could cause injury to vessels, nerves, organs and tissues, at any time and unconnected to the surgery, by reason of mesh migration and erosion.

4.3.2.10 Haemorrhage

453 The appellants submitted that haemorrhage is an obvious risk of any surgery. The IFUs did not refer to the risk of haemorrhage until 2015: TJ [2930] and [3015]. This complication is rare but serious: TJ [1204], [1257]. We consider that it may be accepted that pelvic surgeons would have been aware of the fact that pelvic surgery involves the risk of haemorrhage by reason of puncturing a major vessel. If it were necessary to so conclude we would say that this is a risk obvious to pelvic surgeons. On the evidence, they would not have been aware, however, that the mesh might migrate or erode into a vessel at any time after surgery, which we infer carries with it a post-surgical risk of bleeding and haemorrhage. For this reason, if the primary judge erred by implicitly inferring that pelvic surgeons were unaware of the intra-surgical risk of haemorrhage, the error is immaterial.

4.3.2.11 Leg weakness

454 The appellants noted that at TJ [1200] the primary judge found that there was not a great deal of evidence about leg weakness as a complication of any of the SUI devices and thus the issue was moot. However, the evidence was the appellants knew of this risk in respect of all of the devices from the time of first supply: TJ [189]. The evidence was also to the effect that it was a risk with the POP devices but its prevalence was unknown: TJ [1260]-[1262]. The IFUs did not warn of any such risk: TJ [2931], [3016]. The primary judge noted that Dr Hinoul considered this a risk of any pelvic surgery but that it appeared to be a higher risk for some of the devices than others: TJ [3440]. The primary judge did not err in inferring that pelvic surgeons were not aware of the risk of leg weakness caused by implantation of the devices.

4.3.2.12 Reoperation or revision surgery associated with complications

455 The appellants contended that this risk must have been obvious to pelvic surgeons.

456 The primary judge found this risk was common for the SUI devices: TJ [1177]. It also was common on the evidence for the POP devices although the primary judge did not make that finding expressly: TJ [1235]-[1238]. Where an IFU referred to this risk, it was only in the context of infection and surgery. It was not until 2015 that the IFUs identified this risk as a result of adverse reactions to the devices generally: TJ [2890]-[2899], [2987]-[2990]. Contrary to the appellants’ submissions, it would not have been obvious to pelvic surgeons that the pleaded complications could include revision surgery as a result not of any surgical technique or device failure issue but as a result of the devices themselves functioning as they were designed to function. As discussed, pelvic surgeons must be inferred not to have known of the real nature of the risks of chronic infection, chronic, severe, intractable pain, or mesh erosions caused by the devices or their migration. As such, they could not have known of the real nature of the risk of reoperation or revision surgery. It is far more likely that they believed that reoperation or revision surgery would only be required to deal with surgical error or some unforeseeable problem with the particular implantation. They would not have known that reoperation or revision surgery could be required because of the inherent characteristics of the devices that they could cause any pleaded complication in any woman at any time irrespective of any issue of surgical skill. The primary judge did not err in inferring that pelvic surgeons were not aware of this risk of the devices.

4.3.2.13 Psychiatric injury

457 It may be accepted that the primary judge concluded that there was no requirement to warn of the risk of psychiatric injury: TJ [3850].

4.3.2.14 Recurrence of prolapse

458 The appellants submitted that it must have been obvious to pelvic surgeon that implantation with a POP device may not succeed so that recurrence of prolapse was an obvious risk. The primary judge found that this was a common risk of implantation of a POP device: TJ [1248]. This risk was not mentioned in any IFU for a POP device until 2008: TJ [3005]. It is one thing to accept that a surgical procedure may not succeed so that the original condition (relevantly, POP) may remain or recur. It is another to assume or infer that pelvic surgeons were aware that because of the inherent characteristic of the devices that they could cause any pleaded complication in any woman at any time, partial removal or excision of the devices may be required, as a consequence of which the original condition may recur. That is, insofar as recurrence of POP is a result of that characteristic of the devices, we do not accept that the primary judge erred in inferring that pelvic surgeons were not aware of this risk of the devices.

4.3.2.15 Difficulty of removing devices

459 The appellants pointed to the fact that the devices were permanent implants and said that it must have been obvious to pelvic surgeons that removal of them would be difficult, if not impossible. No warning about this risk was given until 2015 and when given the warning did not disclose that removal may be impossible and may not alleviate the woman’s symptoms: TJ [2900]-[2905] and [2992]-[2994]. Given that pelvic surgeons must be taken not to have known of the acute ongoing foreign body reaction caused by the devices, the associated chronic inflammation, or the true nature of the risk of erosion including caused by mesh migration, it should be inferred (consistent with Professor Korda’s evidence at TJ [3232], also at TJ [3235]) that pelvic surgeons did not know that the devices, in effect, could not be removed from women or that partial removal would not resolve the complications.

460 The appellants also pointed to the 2002 version of the Ward Hilton study (Ward K and Hilton P, “Prospective multicentre randomised trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence” (2002) 325 BMJ 1-7 at 4 (ETH.MESH.13649139 at 9142)) as relevant. This version refers to the potential complications of bladder injury, vaginal perforation, wound infection, vascular injury, tape erosion and urinary tract infection in six weeks after surgery (table 2), as well as urge incontinence and pain with intercourse (table 4). As discussed, to the extent that the references are to risks of the surgery itself, they do not encompass the true nature of the risks of the devices which have nothing to do with the fact of surgery. Otherwise, they also do not encompass the true nature or extent of the complication. Thus, for example, urge incontinence does not disclose that the device may migrate and contract at any time, even years after the implantation surgery, and thereby cause incontinence and impossibility of intercourse or painful intercourse. The primary judge did not err in inferring that pelvic surgeons were not aware of this risk of the devices.

461 Accordingly, we do not accept the appellants’ oral submissions to the effect that the primary judge erred in inferring that at all material times pelvic surgeons in general did not know of the pleaded complications, nor their submission that she should have found that pelvic surgeons knew of the pleaded complications. We consider that the evidence amply supported the primary judge’s express and implicit inferences that pelvic surgeons in general did not know of the pleaded complications (excluding the risk of psychiatric injury which the primary judge found not to be relevant).

4.3.3 The forensic contest

462 The relevance of the forensic contest below should be emphasised. As we have explained, the appellants did not plead that pelvic surgeons in general knew about all of the pleaded complications so that the appellants expected those surgeons would warn their patients to this effect. Their defence said that they expected the treating surgeon to perform certain tasks with respect to the patient ([18]), that the mesh was designed to allow for an inflammatory response that is necessary for tissue ingrowth, and that all surgical procedures carry risks, but otherwise denies the allegations including the existence of the pleaded complications: [23] and [23A]. Further, the appellants pleaded in [86] of their defence in answer to [26] and [61] of the fifth further amended statement of claim or **5FASOC** (which identify the pleaded complications) that if those matters are found to exist the state of scientific knowledge was not such as to enable the appellants to discover those matters, thereby affording them various defences. The appellants maintained this position in opening. This position did not, of course, change until Dr Hinoul gave the oral evidence recorded at TJ [189]-[191].

463 None of this relieved the respondents of their onus of proof. But it exposes the fact that until Dr Hinoul gave evidence it had never been suggested by the appellants that pelvic surgeons generally or the representative respondents’ pelvic surgeons knew about the pleaded complications. To the contrary, and at the risk of repetition, the appellants’ case was that the pleaded complications either did not exist or, if they did exist, they could not have been known to the appellants at all given the state of scientific knowledge at the time. It goes without saying that the shift from that position to the contention that pelvic surgeons were aware of all the pleaded complications is radical. This radical shift, so late in the course of the hearing, seems a likely explanation for the fact that the respondents’ experts did not systematically address the state of their knowledge in respect of each pleaded complication and the primary judge did not make express findings about the state of knowledge of pelvic surgeons in general in respect of each and every one of the pleaded complications.

4.3.4 RANZCOG position statements

464 The differences between the 2014 and 2017 RANZCOG (Royal Australian and New Zealand College of Obstetricians and Gynaecologists) position statements on midurethral slings (relevant to the SUI devices but not the POP devices) discloses the development of knowledge of pelvic surgeons in general over time (and many years after the devices were on the market). Thus, the 2014 version of the RANZCOG statement says nothing about chronic intractable pain or the fact that complications may arise years after the implantation. The 2017 version of the RANZCOG statement, however (and in stark contrast), says that:

Complications must be discussed with women considering surgery including the different complications associated with each MUS route. Discussion must include bleeding, damage to the bladder and urethra, bowel and major vessel perforation. Voiding difficulties which may require catheterisation, loosening or even division of the sling at a later stage which may result in recurrent SUI. Denovo urge incontinence or worsening of pre existing over active bladder symptoms can occur. **Sling insertion can cause pain and dyspareunia and with the TOR, groin pain can occur. This is usually short lived but may become intractable. In some women these long term adverse outcomes have had severe effects on everyday activities and their quality of life. The mesh is a permanent material that can result in mesh exposure and infection which may occur soon after surgery or many years later. This can result in the need for mesh removal which may be difficult, may have complications and may not completely resolve chronic pain or other adverse symptoms.**

(Citations omitted, emphasis added).

465 The stark differences between the two documents disclose that knowledge of a number of the pleaded complications emerged over time (and very late in the life of the devices). Further, as the respondents submitted, it may be inferred to be unlikely that RANZCOG would expressly inform pelvic surgeons about risks which pelvic surgeons in general must be taken to have known.

4.3.5 The IFUs

466 Although the appellants produced many kinds of documents, only the IFUs contained information comprising the appellants’ warnings about the risks of the devices: TJ [2584], [2690]. There was evidence that the IFUs were important to pelvic surgeons as a statement of the manufacturer’s knowledge of the risks of the devices which correspondingly meant that it was important that all risks associated with the implantation of the devices (in contrast to the ordinary risks of all surgery) must be included in the IFUs: TJ [3315], [3371]-[3373]. Accordingly, contrary to the appellants’ oral submissions, there is no meaningful analogy between the present case and the circumstances considered in *AstraZeneca Pty Ltd v GlaxoSmithKline Australia Pty Ltd* [2005] FCA 1645 at [112]-[114] where there was no evidence that general practitioners would rely on representations by the manufacturer/supplier.

467 Further, the IFUs were all premised on the devices causing a transient foreign body reaction when, in fact, they caused a chronic and acute foreign body reaction causing chronic inflammation which itself created the risk of the majority of the pleaded complications. The profound inadequacies of the IFUs to communicate these risks, specific to the devices themselves, is explained by the primary judge at TJ [2812]-[2840] for the SUI devices and TJ [2940]-[3028] for the POP devices. If the appellants believed that pelvic surgeons were aware that the devices generated a chronic and acute foreign body reaction causing chronic inflammation which itself created the risk of the majority of the pleaded complications it makes little sense that they represented in the IFUs that the devices generated only a transient foreign body reaction.

468 The appellants’ contention that no pelvic surgeon could have believed that the IFUs for the devices identified all risks of the devices of which the manufacturer was aware is inconsistent with the regulatory schemes which required the manufacturer to inform users of “residual risks” of the devices (that is, risks which cannot be eliminated or protected against) and to provide information about “any undesirable side-effects of the device”, “any contra-indications, warnings, restrictions or precautions that may apply” and, importantly, “any risks associated with its implantation”: see TJ [1380] at (2)(d), [1387] at 4 and 19, and [1409] at (3)(c). Since the commencement of the Medical Device Regulations on 4 October 2002 the appellants had an unqualified statutory obligation to provide such information with the devices: TJ [3840], [3841]. The regulatory scheme does not assume that a surgeon or surgeons in general will know about any risk mentioned in any medical publication.

469 It is also evident that the TGA considered that the IFUs were inadequate in failing to disclose complications caused by the devices: TJ [2676]-[2681]. This suggests that the TGA did not consider these complications to be known to pelvic surgeons generally. Either that or the TGA took the view that even obvious risks should be disclosed. As the primary judge also noted at TJ [3442], the appellants did not suggest to the TGA that the amendments to the IFUs were unnecessary because those risks were known to pelvic surgeons generally.

4.3.6 Patient brochures

470 The appellants contended that the primary judge erred in referring to patient brochures at all because there was no evidence that a representative respondent had seen any such brochure. The latter proposition is correct. But it does not follow from this that the primary judge’s statements at, for example, TJ [3651], [3764], [3845] and [3849], about the direct marketing of the devices to patients, was in error. The primary judge was not merely assuming, speculating or hypothesising that the issue of the direct marketing of the devices to patients might have occurred, even if that did not occur in respect of the representative respondents.

471 The fact is the primary judge inferred that the appellants produced patient brochures intending that they should be given to surgeons and seen by patients: TJ [3267]. This inference was consistent with the appellants’ own written submissions in opening to the primary judge at [37]. To this extent, at least, they are relevant to the appellants’ views about the state of knowledge of pelvic surgeons generally. Nor can it fairly be said, as the appellants submitted, that the primary judge was mistaken about the effect of Associate Professor Lam’s evidence. The primary judge did not suggest that he distributed the appellants’ brochures to patients, merely that he gave information brochures to patients: see TJ [3262]. In any event, the fact that the appellants accepted that they produced brochures for surgeons to give to patients justified the primary judge in making findings about those brochures whether or not they were seen by the representative respondents. The primary judge was not merely speculating or proceeding on a hypothetical basis in doing so.

472 For these reasons we do not accept the appellants’ oral submissions to the effect that there was no basis upon which the primary judge could properly make any findings relating to the requirement of any direct communication by the appellants to patients.

473 Otherwise, the relevant fact is the content of the brochures and what that content says about what the appellants considered pelvic surgeons knew. For example:

(1) a 2001 TVT brochure asserted that the TVT procedure “avoids the pain and long hospital stay of the more major operations” as it is “a minimally invasive procedure that has little post-operative pain associated with it so the patient leaves the hospital on the same day or the following day after the operation”. It said in answer to a question about pain after the operation that there may be some mild pain over twenty four to forty eight hours after surgery. It said the tape is inert: TJ [2732]-[2736];

(2) a 2004 TVT brochure contained statements to the same effect and other statements consistent with only short-term or surgical complications: TJ [2739]-[2741];

(3) a 2010 TVT brochure contained statements to the same effect and other statements which indicate that adverse reactions were confined to surgical issues: TJ [2742]-[2745]; and

(4) a 2013 TVT brochure made one change but again it is confined to transient issues: TJ [2746].

474 If the appellants believed that pelvic surgeons knew about the pleaded complications then this content makes no sense. Why warn of the risk of mild post-operative pain if pelvic surgeons generally knew of the risk that the device could cause long-term chronic pain?

4.3.7 Medical publications

475 As the respondents submitted, there are a number of problems with the use of medical publications. Whatever else might be said in respect of them, it cannot be that the mere mention of one or more of the pleaded complications in any medical publication necessarily undermines an inference which should otherwise be drawn on the evidence that pelvic surgeons did not know about the pleaded complications. In particular, leaving aside the knowledge of an individual treating surgeon (which may be relevant or determinative of the issue of causation), it is the knowledge which a manufacturer/supplier may properly assume is known by pelvic surgeons generally which is relevant. In that regard, as the respondents submitted:

(1) the mere mention of a matter in a medical publication does not necessarily mean that the matter is known to and accepted by pelvic surgeons generally. At the least, the nature of the publication and the other evidence relating to their knowledge will be relevant to the use that can be made of the publication. In this regard, there was no basis, for example, to infer that the publications on which the appellants relied to support their proposition that pelvic surgeons in general knew about the pleaded complications (see above) were in fact generally read by pelvic surgeons and, indeed, the evidence about publications was to the contrary (see below);

(2) there was evidence from which it could be inferred that a publication which did identify a pleaded complication did not necessarily come to the notice of pelvic surgeons: for example, see TJ [2582];

(3) there was evidence that surgeons only read the abstract of medical publications which may be incomplete: TJ [1069];

(4) the primary judge was rightly sceptical of the quality and reliability of some of the medical publications, some of which were influenced by the appellants: for example, see TJ [910]-[911], [2510]-[2515], [1071];

(5) some publications were inconsistent with the existence of the pleaded complications so that if a pelvic surgeon had relied on that publication it is unlikely that it could be said that they knew or even should have known of the pleaded complications: for example, see TJ [907]. Similarly, published complication rates varied wildly in respect of the devices: TJ [851]. Pelvic surgeons could not necessarily know which studies were reliable and which were not: TJ [805];

(6) most of the publications involved a short-term review of the safety and efficacy of the devices whereas, on the evidence, the pleaded complications could first emerge years after the implantation of the device, again making it unlikely that the publications could put pelvic surgeons on notice of the pleaded complications: for example, see TJ [839]-[840], [874];

(7) because the pleaded complications could arise years after the implantation surgery, it could be difficult for pelvic surgeons to associate the complication with the device: for example, see TJ [840]-[841];

(8) all of these matters meant that the under-reporting of complications associated with the devices was common: for example, see TJ [843]-[849], [1471];

(9) some of the pleaded complications might have been considered uncommon and thus not widely reported, but nevertheless are significant: for example, see TJ [3427];

(10) because the devices were approved by regulators based on clinical literature reviews and not clinical evaluations, over the time of their use, the rate of complications caused by the devices increased and thus so did the knowledge of pelvic surgeons: for example, see TJ [2126];

(11) the appellants’ approach to the analysis and reporting of complaints effectively suppressed widespread knowledge of the complications caused by the devices, as exposed by TJ [1980]-[1981], [1996], [2004]; and

(12) the evidence was to the effect that some important matters about the devices were not generally available and were not well-known: for example, see TJ [3228]-[3250], [3843], [3859]-[3860].

476 For these reasons, we agree with the primary judge that to the extent that the appellants submitted that pelvic surgeons in general should be taken to have known about any pleaded complication mentioned in the medical literature so that any failure by the appellants to warn surgeons about that pleaded complication could not be relevant to determining the appellants’ liability under statute and at common law, the submission must be rejected. To the contrary, the medical literature supported the inference that pelvic surgeons in general were not aware of the pleaded complications.

4.3.8 The appellants’ conduct

477 As discussed above, the appellants’ conduct is inconsistent with any inference that they believed pelvic surgeons knew about the pleaded complications. If this had been their belief their conduct would not have been so influenced by marketing considerations as the primary judge found at TJ [3318]-[3345]. That is to say, had the appellants believed that pelvic surgeons knew about the pleaded complications then there would have been no concern from their marketers that disclosing these matters in the IFUs was undesirable. The fact that the marketers considered disclosure undesirable indicates that the appellants themselves did not believe that pelvic surgeons knew about the pleaded complications.

4.3.9 Conclusions

478 The primary judge did not err in inferring that at all material times pelvic surgeons in general did not know about the pleaded complications, nor in failing to conclude that the pelvic surgeons knew about the pleaded complications at all material times. On the evidence, the inference that she drew, that pelvic surgeons in general did not know about the pleaded complications, was correct.

###### 4.4 Clinical consensus?

479 The appellants contended that the evidence disclosed a consensus among clinicians that the devices were appropriate to be on the market with the consequence that any conclusion that the devices were defective under the statutory provisions or that it was negligent for the appellants to have brought the devices to the market must be wrong.

480 However, the evidence does not support the existence of any such clinical consensus about the devices generally. Nor does it support the notion that it was proper for the appellants to have brought the devices to the market as they did. Nor can it be said that the fact that the SUI devices (apart from TVT Secur) remain on the market and are still in use, with what must now be presumed to be knowledge of pelvic surgeons of the pleaded complications, necessarily defeats the respondents’ claims.

481 As to the evidence, it may be accepted that the RANZCOG 2014 position statement on midurethral slings (that is, the SUI devices but not the POP devices) said that there was robust evidence to support the use of midurethral slings. As noted, however, the 2017 RANZCOG position statement, while continuing to support use of the slings, required surgeons to disclose far more about the risks of adverse consequences to the patients than had been disclosed by the appellants before 2015: TJ [3399]-[3401]. The primary judge also identified evidence that indicated that the RANZCOG 2014 position statement by no means reflected any form of clinical consensus: TJ [911], [2508]-[2515]. To the extent it can be inferred that the 2017 position statement reflected a clinical consensus about the SUI devices, the consensus provided for a far more confined use of the devices than the appellants had marketed as being appropriate and a requirement for far more extensive warnings than the appellants had provided. In other words, the publication does not reflect a consensus that supports the way in which the appellants supplied the SUI devices to the market.

482 The same may be said of the IUGA position statement on mid-urethral slings for SUI which was also published in much the same terms in 2014: TJ [2509]. Even then there was evidence which undermined the notion of the existence of a consensus about the safety and efficacy of the SUI devices: TJ [3412].

483 It goes without saying that none of this concerns the POP devices which were withdrawn from the market in 2012, a fact which of itself at least supports the inference that those devices were not the subject of any clinical consensus as to the appropriateness of their availability.

484 The appellants also referred to an American Urogynecologic Society (**AUGS**) 2013 position statement on restriction of surgical options for pelvic floor disorders. The statement concerns the transvaginal placement of mesh for POP or SUI. The idea that it reflects a clinical consensus about this issue is difficult to accept given the other evidence before the primary judge. The statement says that AUGS opposed any restriction on surgical options. The very fact that AUGS considered it necessary to release such a statement is indicative of clinical dispute about the safety and efficacy of the transvaginal placement of mesh for POP or SUI. The subsequent position statement of AUGS and the Society of Urodynamics, Female Pelvic Medicine and Urogenetial Reconstruction on midurethral slings for SUI in 2014 is in no different category than the RANZCOG 2014 position statement.

485 The appellants identified evidence of pelvic surgeons said to support the existence of a clinical consensus about the value of the devices. This general statement is unsupportable. Annexure D is selective. In the words of the respondents, it ignores “all of Dr Hinoul’s admissions as to Ethicon’s understanding of the role of the IFU, the disparity in resources between Ethicon and treating surgeons, the approach of treating surgeons to medical literature and the nature of medical practice”. It ignores the primary judge’s credit findings. It ignores the evidence of the pelvic surgeons which supported the respondents’ claims. It sidelines the evidence of Professors Klosterhalfen and Klinge whose expertise was recognised by the appellants at all times: TJ [363]-[389]. It ignores the primary judge’s reasoning about the utility of the evidence of the evidence of the epidemiologists and biostatisticians (see below).

486 Accordingly, it cannot be said that the evidence supported an inference that there was a clinical consensus about the value of the devices. Nor does the fact that the SUI devices remain on the market (apart from TVT Secur) undermine the primary judge’s conclusion of liability on the part of the appellants under statute and at common law. The warnings which the regulatory authorities ultimately required to be provided about the SUI devices and the evidence before the primary judge about the proper limitations on their use involve a context markedly different from the appellants’ supply of these devices from 1999 onwards. As the respondents also noted, the appellants do not suggest that the primary judge erred in concluding that the warnings identified at the answer to common question 18 should be given to patients considering implantation with one of the SUI devices remaining on the market. This is the basis for the Injunction which the primary judge made in relation to the SUI devices which remain on the market. The relevant point for present purposes is that the nature of the information which now must be provided to a patient before implantation of an SUI device bears no resemblance to the circumstances in which the appellants supplied the devices for implantation over many years.

487 Contrary to the appellants’ submissions, the evidence of Professor Blaivas that “it’s not my position that sling should be taken off the market … they’re not the enemy of people” does not support the appellants’ case of a clinical consensus. First, the evidence relates only to slings, that is, the SUI devices, not the POP devices. Second, Professor Blaivas went on to say that the problem was that information had to be provided about the risks of the devices or doctors would never have known about those risks: see TRA.500.008.0001\_2 or 723. Third, the appellants are incorrect to submit that the primary judge did not consider this evidence. The primary judge referred to this evidence at TJ [3386] and otherwise dealt with the evidence about the SUI devices at TJ [3387]-[3404].

488 Nor can it be said, as the appellants orally submitted, that the primary judge’s analysis of the evidence at TJ [3387]-[3404] amounts to nothing more than a preference for the evidence of Professors Klosterhalfen and Klinge who were not clinicians and whose evidence, accordingly, could not be relevant to clinical preferences. First, the evidence of Professors Klosterhalfen and Klinge was but one reason for the primary judge’s rejection of the decisive role of this aspect of some of the clinical evidence: TJ [3391]. Second, it may be accepted that Professors Klosterhalfen and Klinge are not pelvic surgeons. Professor Klinge is a general surgeon with expertise in abdominal surgery and a biomaterials researcher. Professor Klosterhalfen is a pathologist: TJ [24]. But this does not mean that their evidence about the safety of the devices is irrelevant. The primary judge said that “their knowledge of, and experience with, the use of polypropylene implants, in general, and the POP devices, in particular, was far superior to that of any other witness”, and their evidence was informed by “their extensive and profound experience”: TJ [302]. The appellants did not quarrel with Professor Klosterhalfen’s self-description as “a world leader in understanding the mechanical properties of polypropylene mesh and the response of human tissue to it” ([TJ 368]) and the appellants engaged him as a consultant to undertake studies and provide advice in relation to their devices from 2001 to 2011: TJ [383]-[389].

489 The appellants referred to certain entries in their Annexure D to which we now turn.

*Item 51: Professor Korda accepted the proposition that mesh can be used in circumstances where the natural tissues are sufficiently compromised that natural tissues cannot be relied upon to effect the repair. It will be up to the individual surgeon to decide for him or herself whether the tissues of a particular patient are so sufficiently compromised.*

490 From the rest of his evidence it is apparent that Professor Korda was not referring to the POP devices: TJ [3237]. Accordingly, this observation cannot apply to the POP devices. Further, the limitation of the use of mesh to cases where native tissue repair was impossible bears no resemblance to the indications for which the devices were approved and supplied by the appellants. And as the respondents pointed out, there was other evidence that was relevant as set out in items 51A to 51C of the respondents’ Annexure D as follows:

(1) Dr Agur: stricter control is required for the use of mesh implants in prolapse surgery and this is best achieved by restricting these procedures for use only within research context. Efficacy is yet unproven for either primary or secondary procedures and the adverse event rates are higher than expected. This is consistent with the recommendation of the latest Cochrane review (published March 2016);

(2) Associate Professor Lam: as at 2004, the evidence was insufficient to support the use of permanent meshes in vaginal prolapse repair surgery except in the context of randomised controlled clinical trials and Ethicon ought to have informed potential users of its devices that this was the state of the evidence concerning the mesh implants. By 2016 the risk/benefit profile was such that transvaginal mesh had limited utility in primary surgery and that there was no evidence that the benefits of mesh surgery outweigh the risks: TJ [2942]; and

(3) Associate Professor Rosamilia: as at 2004, there was insufficient evidence to support the use of permanent meshes or grafts for vaginal repair surgery, except in the context of adequately powered randomised controlled clinical trials: TJ [1791].

*Item 53: abdominal sacrocolpopexy remains the gold standard for the management of vault prolapse, according to Professor Korda: TJ [1279].*

*Item 54: The surgical concept and comprehensive defect repair of sacrocolpopexy is the “gold standard” in France. The procedure has a long learning curve, particularly during laparoscopy: Professor Collinet.*

491 However, the primary judge also had evidence that:

(1) mesh erosion is a common outcome of sacrocolpopexy but in the short to medium term the rates are lower than they are after transvaginal implantation: TJ [1269];

(2) a 2009 study (Diwadkar G et al, “Complication and reoperation rates after apical vaginal prolapse surgical repair: a systematic review” (2009) 113(2 Pt 1) Obstet Gynecol 367–373 (ETH.MESH.00020695)) said that “our results suggest that, despite the lowest reoperation rate for prolapse recurrence, vaginal mesh kits have the highest rate of complications that require surgical intervention, which, on balance, results in the highest rate of total reoperation after apical suspension for pelvic organ prolapse. This raises the concern that the risks of these newer procedures may be greater than their benefits. One can speculate that more recurrences and complications may be diagnosed with time, given the relatively shorter mean follow-up period in the mesh kit group”: TJ [2242];

(3) before the publication of the long-term outcomes of the CARE study by Nygaard et al (2013) (Nygaard I et al, “Long-term outcomes following abdominal sacrocolpopexy for pelvic organ prolapse” (2013) 309(19) JAMA 2016–2024 (ETH.MESH.09466922)), the evidence is that little was known about long-term durability, complications, and pelvic floor symptoms after abdominal sacrocolpopexy: TJ [2255]; and

(4) Nygaard et al (2013) extracted key points from the data including that abdominal sacrocolpopexy is less effective than desired and complications related to synthetic mesh continue to occur over time: TJ [2281]-[2284].

*Item 81: MUS as a treatment option for SUI: Professor Blaivas agreed is the most studied treatment for female SUI and, other than bulking agents, it is the least invasive surgical option to treat SUI. The effectiveness of MUS is well documented in the short and medium term, with increasing evidence supporting its effectiveness in the long term as well.*

*The MUS is effective in terms of symptoms; symptomatic improvement is sustained but drops off in time, as with all the operations.*

*The volume of literature and length of follow-up in relation to MUS is not available for pubovaginal sling or colposuspension: TJ [3412].*

492 These are references to the evidence of Professor Blaivas. As the primary judge made clear at TJ [3412] Professor Blaivas did not endorse any of the SUI devices. Further, “[h]e did not say, for example, that TVT had a good safety profile. To the contrary, his opinion was that TVT carried significant long-term safety risks and that insufficient warnings had been given about those risks. His position, he explained, was that information about potential complications or safety risks associated with a device, whether rare or not, needed to be passed on to doctors and patients. Professor Blaivas said that, had it not been for the worldwide litigation about pelvic mesh, even he would not have known about all the risks. He considered, in effect, that the endorsements of TVT by RANZCOG and others were ill-informed” (citations omitted). As pointed out at item 81A of the respondents’ Annexure D, moreover, Professor Blaivas was concerned that all of the peer reviewed studies underestimated the incidence of complications.

*Item 82: Minimally invasive sub-urethral sling procedures: are the gold standard surgical treatment for urodynamic stress incontinence: Professor Korda.*

493 The primary judge referred to this and similar evidence at TJ [3388]. She explained why she did not consider that evidence decisive at TJ [3389]-[3404]. Leaving aside the evidence of Professors Klosterhalfen and Klinge (as they are not pelvic surgeons and the appellants raise a separate issue about the primary judge’s use of their evidence), as the primary judge noted at TJ [3392], the evidence did not relate to the SUI devices specifically and was not all to the same effect. The primary judge identified that other evidence at TJ [3393]-[3404]. The evidence as a whole did not support an inference of a clinical consensus about the value of the SUI devices. There was also other evidence which the respondents identified in their version of Annexure D at items 82A and 82B. In summary:

(1) there is no agreement amongst pelvic surgeons about what constitutes the gold standard for the treatment of SUI: Professor Blaivas; and

(2) the warnings considered necessary for devices such as the SUI devices bear no resemblance to the appellants’ approach to that issue.

*Item 84: Personal preference: At the time of giving evidence, Professor Korda was using a Boston product called Advantage Fit, which is a retropubic mid-urethral tape (“But it’s the same product essentially” as the TVT retropubic). Professor Korda would use the retropubic tape for people who have intrinsic sphincter deficiency. In all other cases, he uses a trans-obturator TVT or TVT-O: TVT [2153], [3393].*

494 Professor Korda’s evidence of the limits to his use of retropubic midurethral tape does not reflect the basis upon which the appellants supplied TVT to the market: TJ [3393]. The same may be said of the other evidence of continued use of mid-urethral slings: see TJ [3394]-[3404].

*Item 89: MUS: “Given my experience and work in the area, there is no doubt in my mind that mid-urethral slings are the surgical treatment of first choice for SUI”.*

*Prof Roovers uses different products in his clinical practice:*

*“The reason to use different types of surgery is based on indication…whereas the reason to use different brands of a certain type of mid-urethral sling, was mostly based on the collaboration with an industry in research. So when we for example conducted the Miniarc vs Monarc RCT, patients not participating in this study were also surgically treated with products of AMS, who manufactured Miniarc and Monarc.*

*When the RCT comparing TVT-secur and TVT-O was finished, we did not offer single-incision mid-urethral slings to our patients in daily clinical practice.”*

495 Professor Roovers’ evidence, as noted, was not the only evidence about SUI treatment (see above).

###### 4.5 The evidence of the pelvic surgeons and other “non-clinical” experts

496 The appellants contended that the primary judge misapplied the evidence of “non-clinical” experts (that is, any expert who was not a pelvic surgeon) instead of assessing that evidence through the lens of the pelvic surgeons and applying that assessment to the pleaded causes of action. It is said that the primary judge did so in circumstances where:

(1) the non-clinical experts did not have any experience in pelvic surgery, in using the relevant surgically implanted devices, or the clinical issues in treating patients with SUI and POP;

(2) the pelvic surgeons were specialist medical practitioners with the requisite specialised training and clinical expertise to appreciate the range of clinical issues that are synthesised and brought to bear when considering available treatment options for individual patients and in discussing the risks and benefits associated with each treatment option with individual patients; and

(3) it is the pelvic surgeons who have the role of assessing the appropriate treatments and their relative safety and efficacy for their individual patients.

497 The first problem for the appellants is that propositions (2) and (3) above assume that treating pelvic surgeons knew of all of the risks of the pleaded complications associated with the use of the devices. That proposition has been rejected above.

498 The second problem, as discussed, is that the appellants’ approach to the appeal is impermissible.

499 The third problem is that it cannot be said that the primary judge sidelined or failed to have regard to the evidence of the pelvic surgeons. The appellants’ submissions to this effect are without substance.

500 What is apparent from her reasons is that the primary judge had regard to the evidence of the other experts in addition to the evidence of the pelvic surgeons. This included the evidence of epidemiologists and biostatisticians: TJ [791]-[1336]. It also included the evidence of, amongst others, Professors Klosterhalfen and Klinge, who impressed the primary judge with their expertise and whose evidence she accepted (discussed further below): TJ [301]-[787].

501 The appellants contended that the evidence of the epidemiologists and biostatisticians was of no real utility, but the primary judge reached a different view: TJ [804]. She did so because she was satisfied that:

(1) witnesses who were pelvic floor surgeons but who lacked epidemiological or statistical expertise placed weight on study findings which were not statistically significant or which drew heavily on studies that were affected by one or more kinds of bias, without acknowledging the potential for bias: TJ [805]; and

(2) the evidence of the epidemiologists and biostatisticians also highlighted other weaknesses in the studies: TJ [805].

502 The appellants contended that the primary judge erred in giving weight to the opinions of the epidemiologists and biostatisticians in assessing how the published literature should be interpreted and applied: TJ [806]. The primary judge, however, recognised that there were some matters in respect of which the evidence of the pelvic surgeons should be given greater weight than that of the epidemiologists and biostatisticians: TJ [806]. Having regard to the evidence of the epidemiologists and biostatisticians, the primary judge reached the following conclusions:

(1) common complications (1 to 10% of patients) of SUI implantation included mesh exposure/extrusion/erosion, recurrent urinary tract infections, chronic pain, dyspareunia, difficulty voiding, *de novo* urinary incontinence, recurrence of stress urinary incontinence, bladder perforations (with retropubic slings) (uncommon but not rare with transobturator slings), reoperation or revision surgery associated with complications: TJ [1139]; and

(2) POP implantation complication rates involving these adverse effects were higher than for SUI implantation: TJ [1140].

503 The primary judge was also satisfied, having regard to the evidence of the epidemiologists and biostatisticians, that neither:

(1) in October 1999, when TVT was first supplied in Australia, nor at any time thereafter were any of the SUI devices proven to be safer or more effective in the long-term than the alternative treatments (open colposuspension, laparoscopic colposuspension and fascial sling repair): TJ [1336]; and

(2) in July 2003 when Gynemesh PS was first supplied in Australia nor at any time thereafter were any of the POP devices proven to be safer or more effective in the long-term than the alternative treatments (open colposuspension, laparoscopic colposuspension and fascial sling repair): TJ [1336].

504 It was not for the appellants to prove anything. This looseness of language, however, does not indicate a reversal of the onus of proof by the primary judge. The primary judge’s point was that the evidence of the epidemiologists and biostatisticians enabled her to reach certain conclusions about the incidence of a number of the pleaded complications and to conclude that neither the SUI devices nor the POP devices were safer or more effective than the alternative treatments. These facts are relevant to the respondents’ claims. They are part of the context within which the clams are to be resolved. The primary judge did not err in using the evidence of the epidemiologists and biostatisticians for these purposes.

505 According to the appellants, TJ [1336] wrongly assumes that it is possible to disregard the relative nature of any inquiry comparing treatments and that, as Professor Roovers explained, a patient with a specific combination of symptoms and objective findings “may receive 5 different treatment proposals at 5 different hospitals, which are all viable proposals, supported by scientific evidence”. As the respondents submitted, however, the finding at TJ [1336] should be understood as nothing more than that, on the evidence, none of the devices were safer or more effective than the alternative treatments in the long-term. There was ample evidence which supported that conclusion analysed by the primary judge at TJ [1284]-[1335]. Professor Roovers’ evidence does not expose any error in the primary judge’s conclusion at TJ [1336]. It may also be accepted that, as the appellants said, one or more alternatives might be unavailable for any given patient. This does not mean that the comparison which the primary judge was making is absurd or meaningless. The primary judge did not use the comparison as a definitive framework for analysis of the respondents’ claims. The conclusions merely formed part of the context in which her evaluation of those claims was made. Comparable efficacy and safety is a relevant part of the context.

506 The appellants’ reliance on the evidence of Professor Roovers to undermine the primary judge’s acceptance of the utility of the evidence of the epidemiologists and biostatisticians is similarly misconceived. It may be accepted that Professor Roovers gave the evidence identified in the appellants’ Annexure D about the different roles of epidemiologists and clinicians. However, the primary judge identified both difficulties with various aspects of the evidence of Professor Roovers – TJ [1042], [1043], [1046], [1047], [1048], [4929], [5419], [5431], [5475], [5631], [5637] – and parts of his evidence which undermined the appellants’ case – TJ [3770], [3771]-[3773]. It is also not apparent why the fact that the primary judge gave the evidence of the epidemiologists and biostatisticians greater weight than Professor Roovers would have allowed involves error.

507 Nor is it apparent why a small selection of the evidence of Professor Roovers (“[t]he physician is always responsible for whatever treatment he [or she] proposes to a patient” and “in the end physicians have to take decisions based on things that are clinically significant”) is indicative of any error by the primary judge. Professor Roovers was not saying that a manufacturer of a medical device was relieved of any obligation to disclose to doctors the known risks of the device nor that the pleaded complications were not clinically significant.

508 The appellants also referred to the second report of Professor Roovers to which the primary judge made no reference. There is no error established by the fact that the primary judge did not refer to this evidence. That evidence, about the limits Professor Roovers would wish to see placed on the evidence of epidemiologists and biostatisticians, also does not expose any error in the primary judge’s reasoning at TJ [803]-[806]. It may be accepted that Professor Roovers said:

(1) epidemiologists are not consulted to tell clinicians which surgical procedure to perform or how to balance the risks against the benefits of any particular surgical option for an individual patient;

(2) epidemiologists “rate the statistical value of a study, based on methodological characteristics…In contrast, having regard to the type and nature of the study, clinicians also assess the practical relevance of a study mainly on the clinical applicability of the presented study results to their own practice”;

(3) physicians need to assess studies from a clinical perspective, which may differ from epidemiologists;

(4) a study, such as the Ward Hilton trial, may be of lower statistical quality but be a key publication for the clinical profession;

(5) epidemiologists are not in a position to judge what is clinically (cf statistically) significant. For example, from a clinical perspective, mesh surgery is intended to reduce repeat surgery for recurrence, so this is a critical clinical integer of any study. Epidemiologists, who focus on statistical significance, would not appreciate this; and

(6) the question of the balance between risks and benefits acceptable for a product is best answered by clinicians.

509 This evidence, assumes, however, that the treating surgeon is able to identify the material risks of the available options, including the material risks of the devices. The very point of the evidence of the epidemiologists and biomaterials experts in the present case (supported by much of the evidence of the pelvic surgeons, it must be said) explained why pelvic surgeons were not in a position to identify the material risks of the devices. The appellants knew about those material risks. But pelvic surgeons, it must be inferred, did not.

510 The appellants referred in this context to their schedule of factual findings said to be the subject of challenge, but that schedule does not explain why any challenged finding is wrong. To challenge a finding it is not sufficient to merely dispute its correctness. It is necessary to identify why the finding is incorrect by reference to the evidence before the primary judge. In their schedule of challenged findings the appellants have eschewed this necessary task and confined their so-called challenges to findings, for the most part, to nothing more than a mere assertion of error. That approach is also impermissible.

511 The appellants’ contention that the primary judge disregarded the evidence of the pelvic surgeons or misapplied the evidence of the other experts is also inconsistent with a fair review of her reasons as a whole.

512 Part IV of the primary judgment (TJ [183]-[298]), headed “[t]he risks posed by the use of the Ethicon devices”, considered evidence from a number of urogynaecologists and a urologist – Professor Korda, Dr Agur, Dr Margolis, Professor Collinet, Professor Deprest, Professor Roovers, Assistant Professor Chugtai, Associate Professor Lam, Professor Blaivas, Dr Hinoul and Associate Professor Rosamilia and Mrs Gill’s treating gynaecologist, Dr Leake (at [213]-[298]). In addition, the primary judge took into account the evidence of “non-clinical experts”, Professors Klinge and Klosterhalfen and Professor Santerre. There is nothing in this part of the judgment to indicate that in reaching a conclusion as to the nature of the pleaded complications and the circumstances in which they can arise that the primary judge misapplied the evidence by somehow sidelining or failing to have regard to the evidence of the pelvic surgeons.

513 Part V of the primary judgment (at TJ [299]-[787]) is headed “[b]iocompatibility issues”. In this part the primary judge considered whether the biomechanical properties of polypropylene mesh contributed to the development of the pleaded complications. It was common ground that the biomechanical properties of the mesh and mesh stiffness were amongst the main reasons for the post-surgery complications of mesh implantations. For example, witnesses on both sides (including the pelvic surgeons Professor Deprest and Professor Korda) testified that exposure of polypropylene mesh, including the mesh used in the various devices, can cause infection: TJ [299].

514 In Part VI of the primary judgment, concerning the performance of the devices, there are numerous references to the evidence of the pelvic surgeons: see, for example, the references to the evidence of Associate Professor Lam at TJ [809], [811], [815] and [1029]; Associate Professor Rosamilia at TJ [821]-[823], [836], [854], [889], [893]-[894], [904], [911], [946], [948], [967], [1023], [1029] and [1112]; Professor Korda at TJ [818], [820], [825], [828], [834], [836]-[837] and [839]-[841]; Dr Hinoul at TJ [827], [840], [843], [848] and [850]; Assistant Professor Margolis at TJ [829]; Professor Deprest at [830], Professor Collinet at TJ [837] and [1078]; Professor Blaivas at TJ [891]-[893] and [959]-[960]; Professor Roovers at TJ [1041], [1043], [1046] and [1048], and Dr Agur at [1121].

515 The primary judge also considered numerous studies and papers which were authored or co-authored by pelvic surgeons. For example, Dr Agur, a urogynaecologist, and Dr Guerrero, a urogynaecologist, were co-authors of the Morling study (TJ [1017]); Brisbane-based urogynaecologist Professor Christopher Maher co-authored the 2004, 2007, 2010, 2013 and 2016 Cochrane reviews (TJ (2004): [1024], (2007): [1026], (2010): [1032]-[1036], (2013): [1074]-[1079], 2016: [1080]); Assistant Professor Chugtai, a urogynaecologist, and Professor Steven Kaplan, a urologist, amongst others, co-authored a paper in 2015 (TJ [1048]); Assistant Professor Chugtai co-authored a paper in 2016 with, amongst others, Dr Matthew Barber, a urogynaecologist, Dr James Forde, a urologist, Professor Sharon Lise Normand, a biostatistician: TJ [833]. Moreover, the studies noted above, as well as numerous papers referred to by the primary judge, reflect that often the studies involved collaboration between urogynaecologists, biostatisticians and specialists from other medical and public health disciplines. The fact that often the studies were co-authored by urogynaecologists points away from concluding that the views of pelvic surgeons were somehow sidelined by the primary judge.

516 The evidence for the respondents in relation to the biocompatibility issues was given by Professor Klosterhalfen, Associate Professor Guelcher and Dr Dunn, both biomechanical engineers, and Professor Klinge. The evidence for the appellants in relation to biocompatibility issues was given by Professor Wright, a pathologist, Professor Santerre, a biomaterials expert, and Dr MacLean, an engineer, as well as Professor Deprest, a urogynaecologist, TJ [301]. As is apparent, both sides relied upon the evidence of clinical and “non-clinical” experts. The primary judge preferred the evidence of the respondents’ experts on these issues, particularly that of Professors Klosterhalfen and Klinge. So much is hardly surprising given their unique knowledge of the devices and the use of mesh in abdominal and pelvic surgery. It is not for nothing that the primary judge noted at TJ [368] that:

Professor Klosterhalfen is a highly respected pathologist. He described himself as a world leader in understanding the mechanical properties of polypropylene mesh and the response of human tissue to it. The [appellants] did not quarrel with this description. His opinions on these matters are regularly sought by scientists, physicians, and industry. Those people who have had professional dealings with him have the utmost respect for his opinions and the quality of his work. That was apparent from a host of Ethicon documents. Amongst others, Professor Deprest sent explants to him. In cross-examination Professor Deprest said that he did not question Professor Klosterhalfen’s analyses of the explants and did not doubt his knowledge. Dr Hinoul described him in an email to colleagues at Ethicon as “the god of surgical pathology on the subject of textile implants in this solar system”.

(Citations omitted).

517 By contrast, the primary judge commented as follows about the appellants’ witnesses relating to these issues:

(1) Professor Wright was generally unimpressive, too eager to please the [appellants] and partisan and that his experience and expertise in the area of polypropylene mesh was inconsequential in comparison with that of Professors Klosterhalfen and Klinge. Where their opinions conflicted the primary judge preferred the evidence given by Professors Klosterhalfen and Klinge to that of Professor Wright: TJ [305]-[306], [308];

(2) Professor Santerre’s evidence read like an unqualified endorsement of Ethicon's products, it was in a number of instances internally inconsistent, and he often failed to respond directly to questions (at TJ [310]-[312]). Having said that, in the finish, Professor Santerre ultimately agreed with each of the central contentions of the respondents’ biomaterials case: TJ [313];

(3) initially Professor Deprest was generally impressive but in cross examination a number of matters emerged which led the primary judge to conclude that he was not as impartial as she first thought: TJ [314]-[318]; and

(4) Dr MacLean gave what appeared to be well-reasoned answers but he failed to fully disclose the relationship with Ethicon of his company and his colleagues. That raises doubts about his independence and the weight to be given to one of the studies on which he relied: TJ [324].

518 These matters cannot be overlooked in evaluating the appellants’ arguments in support of the appeal. The parties joined issue on the biocompatibility of the devices with the female pelvis. The primary judge strongly preferred the evidence of the respondents. Those conclusions cannot now be set to one side as irrelevant. Equally, it could hardly be concluded that the primary judge’s preference was contrary to the weight of the evidence. The fact that the appellants’ written submissions put that evidence to one side is telling. It is indicative of the appellants’ repeated attempts to re-run the matter with regard to only those parts of the evidence which suits their case.

519 Further, it is not apparent why the primary judge was bound to disregard the evidence of Professors Klosterhalfen and Klinge or to reject their evidence if it conflicted with the evidence of any pelvic surgeon. The primary judge said at TJ [390]:

Professors Klosterhalfen and Klinge expressed strong views about the unsuitability of the Ethicon devices for the purpose for which they were supplied and the deficiencies in the IFUs accompanying them.

520 The primary judge found their evidence compelling: TJ [405].

521 It may be accepted that neither Professors Klosterhalfen nor Professor Klinge was a pelvic surgeon. But the notion that they did not have expertise relevant to the assessment of the safety of the devices is far-fetched. They were experts on mesh implants, including pelvic mesh implants, whom the appellants themselves had engaged for their expertise over an extensive period: TJ [363]-[389]. Professor Klinge was also a very experienced abdominal surgeon: TJ [370]. They are both prolific researchers who published widely on the use of biomaterials in abdominal and pelvic surgery: TJ [367]. The appellants’ suggestion that the primary judge’s mere preference for their evidence over that of pelvic surgeons necessarily involves error must be rejected. It must also be said that the distinction which the appellants seek to draw between the evidence of the pelvic surgeons and the other expert evidence is somewhat artificial. The appellants plainly considered the work of Professors Klosterhalfen and Klinge highly useful to the issue of the safety and efficacy of use of mesh in the human body, including the devices: TJ [368]-[389], [407], [492].

522 The appellants’ contention that the non-clinical experts could not give any evidence relevant to aspects of the evidence of the pelvic surgeons cannot be accepted. The aspects on which the appellants relied were contained in their Annexure D which, as already noted, is selective. Our response to the items the appellants identified follows.

*Item 24: Surgeon’s decision to perform a procedure: Professor Korda gave evidence that it is the surgeon him or herself who needs to be satisfied they can do a particular procedure: “it is up to that particular surgeon to decide his own competence”. Professor Korda agreed that is generally still the case today.*

523 This may be accepted (although Professor Korda, it must be said, also gave evidence that he considered this fact to be unfortunate). However, it says nothing about the utility of the experts who were not pelvic surgeons. It does not suggest that such experts were incapable of giving useful evidence about the safety of a medical device.

*Item 28: Surgical preferences: “If a certain technique performs well in the hands of a surgeon, that surgeon is more likely to propose it as an option, and to teach it to his/her residents.*

*A patient with a specific combination of symptoms and objective findings at pelvic examination and additional diagnostic tests, may receive 5 different treatment proposals at 5 different hospitals, which are all viable proposals, supported by available scientific evidence. Over the years, pelvic floor surgeons (gynaecologists, urologists and colo-rectal surgeons), have tried to reduce symptoms of pelvic floor dysfunction (and thus improve quality of life) by improving anatomy. So there was consensus that a better anatomical repair, would result in a better functional outcome”: Professor Roovers.*

524 This evidence has been discussed above.

*Item 49: Bladder perforation – TVT: The most frequent complication to consider with TVT was the risk of bladder perforation during the blind passage of the needle in the retropubic space. This occurred in up to 5% of cases, yet more frequently during the learning curve or in case of previous retropubic surgery, when the bladder sticks to the front.*

*When a bladder perforation is recognised during the operation, the tape can be withdrawn and reinserted properly. If undiagnosed, a bladder perforation can potentially be serious. For that reason a cystoscopy is part of the procedure for retropubic TVT: TJ [259]: Professor Deprest*.

525 This evidence concerns risks during surgery. It does not concern the long-term risks of the implantation of the devices into the female pelvis. The evidence of Professors Klosterhalfen and Klinge specifically considered these long-term risks, as discussed by the primary judge at TJ [390]-[405]. Having regard to the nature of that evidence, it is not answered by a focus on surgical risks, surgical preferences, or the need for consultation between a pelvic surgeon and the patient. The same conclusion applies to items 67 to 70, 72 to 74 and 79 in Annexure D (on which the appellants relied), all of which concern surgical risks, surgical preferences, and the need for consultation between a pelvic surgeon and the patient. None of that evidence undermines the evidence of Professors Klosterhalfen and Klinge. Rather, the evidence of Professors Klosterhalfen and Klinge exposes why pelvic surgeons were not able to give patients adequate information about the pleaded complications despite the fact that the appellants were aware of all of them from the outset. A pelvic surgeon cannot be expected to know what Professors Klosterhalfen and Klinge knew about the long-term effect of the implantation of the devices in the female pelvis given the work they performed for Ethicon. Having failed in their attack against the reliability of the evidence of Professors Klosterhalfen and Klinge before the primary judge (TJ [406]-[449]), the appellants now seek to sideline that evidence altogether as of no use. That attempt is without merit. Their evidence was replete with information vital to any assessment of the safety of the devices but which could not have been known to pelvic surgeons. This included that:

(1) the pores of the mesh in the devices deform and collapse under minimal strain and this leads to fibrotic bridging, scar plate formation, excessive scarring through and around the mesh and a host of tissue complications that can lead to chronic pain, recurrence, erosions, dyspareunia and need for reoperation, to name a few, making it unsafe for its intended purpose of being permanently implanted in a woman’s pelvic tissue: TJ [519];

(2) bridging fibrosis can occur with all of the devices, a phenomenon which is of clinical significance: TJ [520]-[537];

(3) the mesh in the devices can contract causing numerous complications, a phenomenon which is of clinical significance: TJ [538]-[610];

(4) there is a mechanical mismatch between the elastic female pelvis and the non-elastic mesh in the devices: TJ [611]-[671]; and

(5) the mesh can entrap nerves in scar tissue, causing chronic pain: TJ [672]-[684].

526 The fact that the TVT devices (other than TVT Secur) remain on the market does not mean that the evidence of Professors Klosterhalfen and Klinge to this effect must be wrong. First, the proposition cannot apply to the POP devices or TVT Secur which are no longer on the market. Second, in respect of the SUI devices excluding TVT Secur, the primary judge found that the devices may only be supplied with the information identified in the answer to common question 18 (reflected in the terms of the Injunction the primary judge made). That information reflects the evidence of (amongst others) Professors Klosterhalfen and Klinge. Their evidence that the devices were not suitable for the purpose for which they are supplied, in context, must mean that they were not suitable for such supply without the pelvic surgeon and the patient being put on notice of the fact that any one of the complications may arise at any time in any patient implanted with one of the devices irrespective of surgical skill.

527 Nor do the oral submissions of the appellants challenging the Aachen Group’s pelvis data pool assist. The appellants said that Professor Klosterhalfen did not claim that his expertise trumped that of clinicians. This is true. But Professor Klosterhalfen did say that his data was the most powerful tool to understand the long-term complications of surgical meshes. The appellants said the data pool did not disclose the number of successful implants where there was no complication (that is, there was no “denominator”) and that the controls in the data pool were not randomised. The problem for the appellants is that they had their opportunity to challenge the reliability of the data pool and took it. The primary judge heard that evidence and resolved the relevant disputes at TJ [406]-[449]. Nothing in that process caused her to doubt the reliability of the evidence of Professors Klosterhalfen and Klinge. The appellants have not explained why the primary judge erred in her analysis at TJ [406]-[449].

528 The primary judge was aware that the data pool involved explants assessed against non-randomised controls: TJ [428]. It is not apparent how this undermines the primary judge’s observations that:

(1) in any case, the conclusions Professor Klosterhalfen reached and the opinions he formed, like those of Professor Klinge, were not based solely on the data in the data pool, let alone the pelvis data pool. Much of their thinking was informed by their animal studies, their observations of the tissue in which the mesh was embedded or encased, their tests, their extensive reading and research, and the studies of hernia explants: TJ [439];

(2) Professor Klosterhalfen was not challenged about many key opinions: TJ [444];

(3) a number of Professor Klosterhalfen’s opinions (his opinions about the foreign body reaction to polypropylene mesh implants, the extent to which the mesh shrinks or contracts in vivo, the occurrence of infection with erosion, and the possibility of late infections) were not seriously disputed: TJ [445]; and

(4) no attack was made on the hernia data pool: TJ [448].

529 Faced with these considerations, the appellants’ oral submissions about the data pool go nowhere.

530 The appellants’ focus on the key role of the pelvic surgeon in the process of obtaining the informed consent of a patient to the implantation of one of the devices is also misconceived. This submission pre-supposes that pelvic surgeons were aware of the pleaded complications, contrary to the conclusions above. This submission also fails to confront the true effect of the evidence of the pelvic surgeons as a whole and the evidence of the other experts which the primary judge was right to take into account (see above). It may be accepted that the treating pelvic surgeon has a critical role to perform in obtaining the informed consent of the patient to the implantation of any device. It may also be accepted that, ultimately, it is for the pelvic surgeon and the patient to balance the risks and benefits of any procedure having regard to the individual circumstances of the patient. But this does not undermine the fact that in order to perform this critical function the pelvic surgeon needed to understand that the devices could cause any of the pleaded complications in any woman at any time so that the pelvic surgeon could inform the patient accordingly. If that reality was not understood, the pelvic surgeon could not obtain the informed consent of the patient and could not balance the risks and benefits of any procedure having regard to the individual circumstances of the patient.

531 Accordingly, the appellants’ submission that the “treating surgeon’s knowledge of the risks and complications that may arise from the use of an Ethicon Device (as well as the risks and complications that may arise from the use of other treatment options) are an inherent part of the informed consent process” unjustifiably glosses over the fact that on the evidence pelvic surgeons in general were not aware of the pleaded complications. The appellants’ insistence on the critical role of the pelvic surgeon in obtaining the patient’s informed consent, on analysis, supports the respondents’ claims.

532 Contrary to the appellants’ submissions, various entries to the respondents’ version of Annexure D do not assist their case. It is true that Professor Hu is an epidemiologist. Items 144A and 144B in the respondents’ Annexure D disclose why this expertise is of clinical significance. The reporting of complications, their severity and incidence, so that pelvic surgeons may be aware of them, is relevant to clinical practice. The respondents do not suggest, and the primary judge did not conclude, that the evidence of pelvic surgeons was immaterial or irrelevant. The primary judge was right to consider the additional evidence. That evidence cannot be disregarded which is the effect of the appellants’ submission that this evidence should be seen through the ‘lens” of the pelvic surgeon. The same conclusions apply to items 4B, 65A, 105A, 135A, 140A, 140B, 140C, 140D, 140E, and 144C in the respondents’ Annexure D. These are not invitations to engage in an “analytically flawed” process of reasoning. They are opinions of experts qualified to express those opinions highly relevant to clinical practice. The evidence of Professor Gordon (“[h]ow these findings should be weighed is really a matter for a clinical expert”) does not make good the appellants’ case. For one thing, Professor Gordon was the only epidemiologist/biostatistician to give such evidence: TJ [804]. For another, the context of this evidence concerned the clinical significance of the rates of extrusion or erosion and bladder and/or urethral injury which his analysis indicated were more common with the SUI devices than alternative treatments: TJ [1297]-[1298]. Professor Gordon was not saying that his evidence should be disregarded.

533 On the basis of the evidence as a whole (rather than the parts of the evidence upon which the appellants focused), the respondents must be right that there are no “patient-specific factors” or patient “preferences for treatment” (AS [7]) or treating surgeon preferences (AS [12]) which confound the primary judge’s conclusions about the lack of adequate evaluation of the safety of the devices and the appellants’ failure to warn of the pleaded complications. The devices could cause the pleaded complications in any woman at any time. Every surgeon and patient preference needed to take into account that fact. No surgeon or patient preference could make that fact immaterial. The appellants’ focus on the respondents’ reference to any such factors not excusing the appellants from liability does not disclose any error by the primary judge. The primary judge did not reverse the onus of proof. Stray references to loose language, be it by the respondents or the primary judge, do not sustain that proposition. The fact that individual patients and surgeons will have preferences that will affect the availability and suitability of particular treatment options is immaterial if neither the patient nor the surgeon knew of the risks associated with the treatment option in question (the implantation of the device).

534 In any event, as the respondents noted, the appellants’ marketing of the devices did not depend on patient-specific factors. The primary judge’s finding at TJ [3260] was that:

The [appellants’] promotional material was designed to encourage surgeons to recommend the devices to patients and patients to accept those recommendations. The devices were marketed as safe and effective to treat either stress urinary incontinence or pelvic organ prolapse. As I noted previously, risks were minimised and some not mentioned at all. Notwithstanding the way the [appellants] put their case, a number of their product brochures told surgeons, in effect, that they could and should rely on the IFUs for “complete” contraindications, warnings, precautions, and adverse reactions.

535 The appellants contended that this conclusion involved error. We disagree. The evidence supports these statements. This is not to suggest that the IFUs were a pelvic surgeon’s only source of information. But it is to say that, on the evidence, the pelvic surgeons (reasonably) expected to be informed by the manufacturer about the complete contraindications, warnings, precautions, and adverse reactions associated with the devices themselves.

536 Further, at TJ [3264] the primary judge found that:

Doctors and patients alike were led to believe that complications were rare and, if they arose, they would be temporary, inconsequential, and/or easily treatable. The reality was different. While the evidence does not reveal complication rates for any of the SUI devices as high as those reported for the POP devices and, while certain complications were reportedly rare, many were not. Furthermore some complications could be permanent, disabling, and resistant to treatment.

537 Despite identifying these findings in their schedule of challenged findings, the appellants have not explained why the findings are said to be wrong. From the evidence we perceive no error in these findings.

538 The appellants’ marketing of the products also did not depend on surgeon-specific factors. The appellants submitted that “to determine the potential suitable treatment options to discuss with the particular patient an individual treating surgeon will take into account their medical expertise and surgical preferences” and supported that proposition by reference to Professor Korda’s evidence that he preferred vaginal over abdominal surgery due to his experience with vaginal surgery. As the respondents said, however:

(1) none of the material issued by the appellants about the devices identified that that variability in the skills, experiences and preferences of surgeons must be considered in determining whether to use the devices;

(2) a 2010 surgeon brochure for Prolift+M promoted the device as suitable for all surgeons of varying skills when Prolift+M was not a pelvic floor repair system that surgeons of any skill level could master: TJ [2780] and [2781]; and

(3) the appellants’ analysis of surgeons for marketing purposes for the devices was not calibrated by reference to the surgeon’s skill level, experience or preferences, but rather by their allocation to one of four groups – “Community Practitioner”; “Practice Driven”; “Technical Innovator”; and “Clinical Innovator”: TJ [2708]-[2709].

539 The appellants sought to support their contentions by reference to the experience of Mrs Gill who was informed that mesh was “probably not for her” as she wanted to retain the ability to have children: TJ [3906]. Dr Chapple also told Mrs Gill that he would “lean away” from a Prolift procedure as it was not recommended if there was a possibility of a future pregnancy: TJ [3916]. As the respondents submitted, however, this says nothing about the appellants’ “obligation to warn of clinically significant risks that may result from use of its product, to make plain that revision surgeries may be required, to identify that revision surgeries may not resolve complications and/or may result in further complications and to state that it may not be possible to remove the mesh once implanted inside a woman’s body”. It also does not tend to prove that Mrs Gill would not have listened to warnings about the pleaded complications had she been told of them. The context of the evidence is clear. Her surgeons did not favour Prolift if a woman wished to have children or further children. As TJ [3916] discloses, Mrs Gill did not in fact wish to have further children, but also did not wish to permanently exclude that possibility. The one thing she did not want was to have her uterus removed which excluded the option of hysterectomy as part of the treatment options: TJ [3913]. She was told that she could have further children by caesarean if necessary so decided to proceed with the implant surgery: TJ [4483], [4487]. This evidence does not mean that it may be inferred that Mrs Gill would have had the implant surgery even if she had been informed about the pleaded complications. There is no meaningful comparison that can be drawn about an issue that was satisfactorily resolved so that the advice that mesh was “not for her” was inapplicable and the likelihood of what Mrs Gill would have done had she been informed of the pleaded complications.

###### 4.6 The appellants’ concession about clinical significance of the pleaded complications

540 The appellants also contended that the primary judge made assumptions, not supported by the evidence, about the incidence and severity of complications (across the nine distinct devices) and equated an acceptance that the pleaded complications could be clinically significant with an acceptance that each complication was always clinically significant. This, said the appellants, was contrary to the expert clinical evidence, the published clinical literature, and her Honour’s own findings. It should be noted in this regard that the primary judge at TJ [1134] said this:

…any attempt to distil the evidence into a neat summary of incidence rates would be riddled with potential pitfalls. Mercifully, the respondents’ concession during oral argument that each of the pleaded complications is significant and their assurance that they would not take up any issue as to the precise rate of any complication makes it unnecessary to do so.

541 The problem for the appellants, as we have said, is that in closing submissions their senior counsel appropriately conceded in clear terms that each of the pleaded complications is clinically significant in terms of incidence, and also in terms of consequence, if it occurs. In relation to incidence, senior counsel said the appellants would not take any issue with the precise rates of complication associated with each device. In relation to consequence, senior counsel for the appellants acknowledged that this was part of the concept of clinical significance and was subject to the concession.

542 The concession was made in the following exchange between senior counsel for the appellants and the primary judge (TRA.500.076.0001 at 6060- 6061):

|  |  |
| --- | --- |
| [Senior Counsel]: | Now, if the Court, as I have said, decides that the product is defective because; (a) it has a characteristic…I will call it a complication to make it closer; and (b) the complication isn’t warned about, there is an interim question, of course, before you come to defect – I’ve been passing over this – there is still the relevance of the question about significance of the complication.  It might be that it has a feature which your Honour says, well, look, it had this feature. There wasn’t a warning about this, but it’s not defective because of that, because of the nature of that feature. It’s simply not significant enough. **Now, again, that’s a theoretical position which is correct but** **I don’t think your Honour is going to have to worry about that much in this case because the list of [pleaded] complications is such that there’s not one of them that I can say to your Honour, on the evidence, is not significant enough. And I’m not going to bother your Honour with percentages, it needs to be above one percent or five percent or 10 percent incidence.** |
| Her Honour: | **So each of the pleaded complications is significant.** |
| [Senior Counsel]: | **Yes.** |
| … |  |
| Her Honour: | So this isn’t a question of whether warnings need to be given of material risks or – these are material risks. |
| [Senior Counsel]: | There’s going to be a residual element from time to time of the – clinical significance is not quite the right term but your Honour understands what I mean by this. **The significance can be considered, again, conceptually, as a combination of two things: the perceived incidence of the problem, the degree to which it happens, and, secondly, the perceived or actual consequence of the problem, that is, how bad is it if it happens**… |
| … |  |
| [Senior Counsel]: | But in terms of…populating the list of risks, your Honour is not assisted by anybody saying, “You can draw a line at one percent incidence and above that line they are and below that line they are not.” Or any sort of exercise like that. **So I will identify for your Honour to the best I can those limited occasions where I say there is some relevant consideration of significance, if I can put it that - that your Honour needs to bring to the table. It’s not often, for obvious reasons, when your Honour looks at the table of risks.** |

(Emphasis added).

543 The concession thus concerned the issue of defect not causation. Senior counsel accepted that, except for those limited occasions where the appellants said there is some relevant consideration of significance which would be specifically identified to her Honour, each of the pleaded complications is clinically significant having regard to, first, the incidence of each complication and, second, the consequence of each complication if it came to pass. Before us, the appellants did not present any occasion where they specifically identified to her Honour that the concession did not apply. The appellants’ attempt in this appeal to walk away from senior counsel’s concession does them no credit.

544 The concession was not that the pleaded complications *could* be clinically significant. Contrary to the submissions for the appellants, the concession was not confined to the context of causation. Nor did the primary judge err by converting a concession of *potential* clinical significance to one of *certainty* of clinical significance. It may be accepted that the pleaded complications each involve a risk of an event. In that sense, there is uncertainty as to whether the risk will eventuate. The effect of the concession was to acknowledge that the incidence of each complication and the consequence, if a complication occurred, was clinically significant.

545 Given the context, the concession must mean that each of the pleaded complications was, as the primary judge put it, a “material” risk. That is, each pleaded complication was of sufficient significance that a reasonable medical practitioner would or should be aware that a patient, if warned of the risk, would be likely to attach significance to it: *Rogers v Whitaker* at 490. The fact that senior counsel for the appellants then confirmed that he would identify “the limited occasions” in which “there is some relevant consideration of significance” merely reinforces the true effect of the concession. Each of the pleaded complications was a material risk in respect of each device.

546 Moreover, consistent with the evidence of Dr Hinoul and otherwise, there was no suggestion that the concession applied only to some women and not to others. The pleaded complications were therefore a material risk for every woman implanted with any of the devices. The appellants’ belated attempts to confine the concessions in the appeal cannot be permitted. It follows that, contrary to the appellants’ submissions, it was not necessary for the primary judge to make findings about the incidence and severity of each pleaded complication for each device. For women implanted with one of the devices, each device presented a material risk of the pleaded complications.

547 It is not to the point that there was evidence that, in some or even most cases, the harm in fact suffered by an individual woman suffering from one of the pleaded complications could be less serious or even negligible. Thus, the fact that Professor Korda said that perforation of the bladder with the trocars used to implant the devices causes negligible injury may be accepted: TJ [3405]. But as the primary judge pointed out at TJ [3406]-[3407] bladder perforation can be a serious problem. So too, it may be accepted that Associate Professor Lam said that most erosions can be conservatively treated with oestrogen or can be excised in day surgery. The primary judge noted this about erosions at TJ [244] and [4622]. The point of the concession, however, is that each device presented a *risk* which was material, in terms of both incidence and severity. The fact that the risk might not eventuate in some women at all or in other women to a lesser extent does not alter the fact of the material risk to every woman implanted with one of the devices.

548 For these reasons, Annexure C to the appellants’ submissions is misconceived. The inescapable fact is that the primary judge correctly understood the true effect of the concessions. So much is obvious from the first section of the appellants’ Annexure C. It follows that the subsequent entries in the annexure to the effect that the primary judge made no finding about the incidence and severity of certain of the pleaded complications is both inaccurate and beside the point. As the respondents submitted:

(1) contrary to the appellants’ submissions, Annexure C does not identify any consequence of the alleged error by the primary judge in relation to the concessions;

(2) the fact that complications may not eventuate for every woman who is implanted with a device, or because the manifestation of a complication may not be as severe in some women as others, does not mean that each and every pleaded complication was other than a material risk of clinically significant harm for every woman implanted with any one of the devices – that is the true effect of the concessions;

(3) it is not necessary to prove that a complication will arise in all women, it need only arise in some. And it is not necessary to establish that on every occasion on which the complication arises it is of equal severity for the sufferer, it is sufficient that its severity may be clinically significant – the issue is one of risk and the materiality of the risk; and

(4) in any event, Annexure C is an incomplete and inaccurate review of the primary judge’s findings which included:

(a) the risk of chronic pain associated with the use of mesh implants was at least common: TJ [1142];

(b) the risk of reoperation or revision surgery associated with Mesh Complications, was at least common: TJ [1142];

(c) the risk of difficulty voiding after surgery implanting an SUI device was common: TJ [1139]; and

(d) the foreign body reaction is clinically significant and can cause many, if not all, of the pleaded complications: TJ [354].

549 As the respondents also pointed out, the appellants have not confronted the evidence of the other experts either in Annexure C or elsewhere. Nor does Annexure C confront those parts of the evidence of the pelvic surgeons which do not suit the appellants’ case (see above). In the respondents’ words that evidence included (as set out in the respondents’ revised Annexure D):

…evidence that surgeons ceased using mesh products because of the concerns they had upon seeing the impact on women suffering complications, that they had never seen before the type of complications and chronic refractory pain women were experiencing post implantation of the devices, that revision surgery was fraught with danger and often failed to alleviate symptoms or resulted in further complications, that the complication rate of the devices was unacceptable, that release of the devices on the market was premature, that they were unaware of the complications including chronic pain in relation to the devices at the time that they were not only using the products but training others on how to use them, that they expected that Ethicon would have informed them of such complications.

550 Accordingly, the primary judge was entitled to take the approach reflected at TJ [1134].

551 It is not open to the appellants to complain in this appeal that the primary judge should not have proceeded on the basis of the concessions which applied to all devices and all pleaded complications.

###### 4.7 Drugs v implants?

552 The appellants’ attempts to distinguish *Merck* on the basis that the safety and efficacy of a drug does not depend on the individual experience, surgical expertise and preferences of the treating surgeon are unsustainable. For one thing, the primary judge was right at TJ [4410] that a medical practitioner’s prescribing habits are influenced by the practitioner’s experience, expertise, and preferences. For another, this much is clear – the relevant area of discourse for the present case has nothing to do with the individual experience, surgical expertise and preferences of any treating surgeon. If the treating surgeon does not know of the risks of the devices themselves, separate and distinct from the risks of any pelvic surgery, then their individual experience, surgical expertise and preferences are all beside the point. They cannot make a properly informed decision about what treatment option is appropriate and cannot obtain the informed consent of the patient to the treatment. This is not a case of the devices involving risks if, but only if, the surgery miscarries or is not carried out in a particular way or the device fails. While the evidence was that the rate of complications caused by the devices was less if implanted by highly skilled and experienced surgeons, the evidence was also clear that the complications could occur in any woman at any time irrespective of the manner in which the surgery was conducted.

###### 4.8 Causation

553 The appellants made five general propositions about causation:

(1) the representative respondents did not call their treating surgeons so they could not prove either that those surgeons did not know about the pleaded complications or that, if the appellants had warned about them in the IFUs, they would have communicated those warnings to the representative respondents;

(2) the evidence was to the effect that the treating surgeons did not communicate to the representative respondents all of the information about adverse reactions in the IFUs which is said to support the inference that, had the appellants warned them of the pleaded complications, the treating surgeons would not have communicated those warnings to the representative respondents;

(3) the representative respondents had not proved that they would not have suffered the same injuries if they had undergone alternative treatment;

(4) the respondents had not proved that the devices would not have been on the market in Australia irrespective of the conclusion that the appellants’ application of the CE Mark to the devices (which enabled them to be registered on the ARTG) was the result of an inadequate and negligent pre-market evaluation of the safety and efficacy of the devices; and

(5) pelvic surgeons considered the SUI devices to be the “gold standard” for the treatment of SUI indicating that those devices would have been on the market irrespective of the lack of a CE Mark.

554 These issues are discussed in detail below, but the short answer to them is that:

(1) the primary judge inferred that the treating surgeons did not know about the pleaded complications. This inference involved no error and was appropriate on the evidence. The primary judge also inferred that if the treating surgeons had known about the pleaded complications, they would have communicated them to their patients. This inference also involved no error and was appropriate on the evidence. Further, in the circumstances of this case, where until Dr Hinoul gave evidence, the appellants denied the existence of the pleaded complications and said that given the state of scientific knowledge they could be known, there was no error in not drawing an inference adverse to the representative respondents by reason of the fact that they did not call their treating surgeons;

(2) the pleaded complications are different in kind from the adverse reactions disclosed in the various IFUs before their amendment in 2015. The differences of kind are such that it should be inferred that a pelvic surgeon would communicate the pleaded complications to their patient had the pelvic surgeon known about them. The primary judge’s inference to this effect is appropriate;

(3) it was not for the representative respondents to disprove mere speculation by the appellants that they might have suffered the same injuries if they had had alternative treatments instead of implantation of the devices. In any event, the primary judge was careful to confine the appellants’ liability to injuries caused by the devices;

(4) on the evidence the inference which should be drawn (and which the primary judge drew) was that the devices either would not have been on the market at all but for the appellants’ inadequate and negligent pre-market evaluation of the appellants and resulting application of the CE Mark to the devices (the POP devices and TVT Secur) or would not have been on the market at all or at least without warnings about the pleaded complications (the SUI devices excluding TVT Secur); and

(5) this evidence applies only to the SUI devices excluding TVT Secur. The evidence as a whole supports the inference that but for the appellants’ negligence those devices would never have been on the market at all or at least without warnings of the pleaded complications had the appellants’ pre-market evaluations not been negligent.

555 The specific grounds of appeal may now be considered. The observations above are expanded upon below where necessary and inform the consideration of all grounds other than those related to the limitation periods.

##### 5. DEFECTIVE DEVICES (GROUNDS 1 AND 2 AND NOTICE OF CONTENTION)

###### 5.1 Overview

556 The primary judge found that the appellants supplied the devices:

(1) with a “defect”, in contravention of s 75AD of the TPA in relation to the supply up to 1 January 2011; and

(2) with a “safety defect”, in contravention of s 138 of the ACL in relation to the supply on and from 1 January 2011.

557 In ground 1 the appellants allege that the primary judge erred in finding that the safety of each of the devices was not such as persons generally were entitled to expect as her Honour did not properly consider and give sufficient weight to the evidence of the pelvic surgeons in relation to clinical considerations, preferred the evidence of non-clinical experts, and did not properly consider the differences between the SUI devices and the POP devices. According to the appellants, had the primary judge properly considered this evidence her Honour would not have concluded that each device had a defect/safety defect because that evidence established that when viewed in the context of clinical considerations the benefit-risk profile of each device as such as persons were generally entitled to expect.

558 In ground 2 the appellants allege that the primary judge erred in using the requirements for the CE Marks to support the conclusion that the safety of the devices was not such as persons were generally entitled to expect because: (a) the case pleaded, particularised or advanced by the respondents was not based on the CE Mark or any representation said to be made by the CE Mark, (b) using conclusions of non-compliance with the requirements for CE marking was inconsistent with the primary judge’s finding that most surgeons would not have any appreciation of the path of regulatory clearance for medical devices, (c) the primary judge had no evidence as to any Australian surgeon’s or patient’s understanding or appreciation of the CE Mark and made no relevant finding (other than at TJ [3250]) as to a person’s understanding or appreciation of the CE Mark, and (d) contrary to the primary judge’s finding at TJ [3270], [3272] the CE Mark and clearance for sale was not a representation in Australia that the medical devices met “regulatory requirements and standards”. The appellants allege in the alternative that the primary judge placed too much weight on the requirements for a CE Mark in concluding that the devices had a defect/safety defect as provided for in the TPA and ACL.

559 The respondents contended that if the primary judge’s conclusion in relation to the existence of a defect in any product the subject of the proceeding below relied on the Court’s findings of non-compliance with the requirements for CE marking then the primary judge’s conclusion as to defect/safety defect should be upheld for each product on the basis of those of the primary judge’s findings other than non-compliance with CE marking requirements.

###### 5.2 The appellants’ submissions

560 The appellants submitted that the primary judge erred in holding that the safety of each of the devices was not such as persons were generally entitled to expect and thus had a defect within the meaning of the TPA or a safety defect within the meaning of the ACL.

561 As we have said, in written and oral submissions the appellants advanced a number of overarching contentions which relate to a number of appeal grounds. We summarised and dealt with the overarching contentions above, and need not set them out again. Having said that, where there is overlap between the overarching contentions and the submissions expressly relating to grounds 1 and 2, there is some unavoidable repetition.

562 First, the appellants submitted that the finding that none of the devices was safer or more effective than any of the alternative treatments (at TJ [1336]) is wrong and demonstrates her Honour’s analytically flawed approach. They said that the assumption that it is possible to make an assessment of safety and efficacy in these terms rather than relative terms is incorrect in light of the inherently individual nature of the inquiry: AS [20]. For example, abdominal sacrocolpopexy may be safer and more effective if done by the majority of treating surgeons, but may not be if done by Professor Korda as he is more comfortable with vaginal surgery. Abdominal sacrocolpopexy may not be suitable for a patient such as Mrs Gill, as it requires a hysterectomy. Dr Roovers explained that a patient with a specific combination of symptoms and findings “may receive five different treatment proposals at five different hospitals, which are all viable proposals, supported by scientific evidence.” This argument also forms part of the appellants’ overarching contentions and the submission at AS [28].

563 In oral submissions the appellants also said that the primary judge was wrong in stating (at TJ [3496]), that the appellants “represented that the benefits of using the POP devices outweighed the risks for women with any level of prolapse when the evidence did not support that”. They submitted that the benefits of using the devices in fact outweighed the risks for women with any level of prolapse. The appellants also said that the construct of “safer or more effective” is not an approach mandated by s 75AC, and that the stated requirement for safety “in the long term” revealed the problem in her Honour’s approach. They described the notion that medical goods could not be commercialised unless they had been used by a sufficient number of people to provide a statistically valid clinical trial for, say, 30 to 40 years, as “too silly for words and deeply counterproductive in relation to the public benefit to be gained.” They said that the statute does not require medical goods manufacturers to demonstrate exhaustively that use of the goods will or will not have a “certain frequency of certain kinds of complications” for decades before the goods can first be marketed.

564 Second, the appellants submitted that although prescription drugs also require the “input” of doctors, contrary to the primary judge’s finding at TJ [4410], the safety and efficacy of a prescription drug (and therefore its suitability) does not depend on the individual experience, surgical expertise and preferences of treating surgeons in the same manner as with the devices. Consequently, the analysis in *Merck* is distinguishable and the finding at TJ [4410] is wrong: AS [21].

565 Third, the appellants submitted that the primary judge misapplied the statutory test in relation to defect under ss75AC and 75AD: AS [25]-[27]. The assessment of whether a good has a defect is an objective standard as to whether the safety of the goods is “not such as persons generally are entitled to expect”, and ss 75AC and 75AD do not require goods to be absolutely free from risk. According to the appellants, the error in the primary judge’s approach to the statutory test is demonstrated at TJ [4401] where, on the appellants’ argument, the primary judge approached the test by considering whether there was an adequate warning of a list of pleaded complications, which had been developed by the respondents’ lawyers after the devices were released in the market and with the benefit of reading the materials accompanying the device. The primary judge’s reasons at TJ [4401], they said, show that her Honour reasoned that each device would have a defect if there was *any* risk that was not disclosed. Rather, said the appellants, the statutory test requires the consideration of all relevant circumstances, including a list of enumerated matters, only one of which is the warnings accompanying the good. The language of the statute mandates a consideration of the totality (“all”) of the relevant circumstances, which includes warnings and a host of other matters, in evaluating whether the safety of the good is as persons generally are entitled to expect.

566 On the appellants’ argument, the primary judge’s analysis ignored the critical question whether, having regard to the risks associated with the devices, the totality of the warnings and other information (including the knowledge of treating surgeons), and the nature of the implants as medical devices (which includes their relative benefits), their safety is not such as persons generally are entitled to expect. To similar effect, in reply submissions the appellants said that the primary judge wrongly proceeded on the premise that the statutory question is to be answered by creating a list of clinically significant risks with a not insignificant incidence rate and considering whether those risks had been the subject of sufficient warnings. On that premise, if there are residual risks then the goods are defective and the defect is the product with the propensity of the risk (the fact of the risk, the incidence of the risk, and the severity of the outcome). The appellants said that reasoning must be rejected.

567 In oral submissions the appellants also said that in finding the devices were defective the primary judge mistakenly proceeded on the basis that the patient brochures were a relevant circumstance under s 75AC, when there was no evidence that a representative respondent or any group member had seen any such brochure. They said that the finding (at TJ [3496]) that the appellants were “not candid with the public about the risks of, and contradictions [sic – contraindications] for, use of the devices or the limitations of the available data” showed that her Honour took into account an irrelevant consideration. The appellants argued that, in relation to information provided to them, the public were not entitled to expect the “sophisticated risk-benefit and trade-off material that doctors will have considered”.

568 Fourth, the appellants contended that in determining the safety of the devices, the primary judge did not properly consider and failed properly to take account of the significance of the evidence of the pelvic surgeons in relation to the clinical considerations and the different safety profiles of each of the devices, together with their safety profiles relative to other surgical and non-surgical alternatives: AS [28]-[30]. On their argument, the primary judge erred in failing to find (at TJ [806]) that the evidence of the pelvic surgeons should be preferred to the evidence of non-clinical experts, including the epidemiologists and biostatisticians. As we have said, this argument also forms part of the appellants’ overarching contentions and AS [20].

569 The appellants stressed that treating pelvic surgeons have a key role in considering and ultimately deciding upon, in consultation with the patient, the treatment options for that patient. It is those treating surgeons who are provided with the information and warnings in relation to each treatment option, including the devices, and they must apply their medical expertise and their understanding of the available medical literature to the individual circumstances of the patient, and to ultimately provide the relevant warning to the patient as part of obtaining the patient’s informed consent to the treatment.

570 Therefore, the evidence of the pelvic surgeons is a “relevant circumstance”, indeed a crucial consideration, in determining whether each device is defective. The appellants said the primary judge should have treated the evidence of other non-clinical experts (including epidemiologists, biostatisticians, biomaterials experts and pathologists) as evidence by persons with a limited understanding of the range and significance of the clinical issues, who do not treat patients with SUI or POP, and who are not involved in the process of obtaining informed consent. They argued that because of the primary judge’s approach to the evidence of pelvic surgeons, her Honour failed to properly consider evidence which, when viewed in the context of clinical considerations, showed that the benefit-risk profile for each device was such as persons generally were entitled to expect.

571 In written submissions in reply the appellants submitted that, although the respondents sought to disavow the importance of the treating surgeon, they implicitly relied on expert evidence concerning the knowledge of those treating surgeons. They said that this could be seen in the respondents’ references to “adequate” warnings, and to medical practitioners being “properly warned”, which recognises that there must be a qualitative assessment of the warning. On this argument the question then arises, proper or adequate according to whom and to what standard? The appellants said that the answer must be a warning sufficient to permit the recipient of the warning – the treating surgeons with the necessary clinical experience and expertise – properly to engage in the informed consent process with the particular patient. As a result, on the appellants’ argument, it is the evidence of pelvic surgeons, not the evidence of experts in pathology, biomaterials, regulatory frameworks, biostatistics and epidemiology, that is critical in determining whether the safety of a surgically implanted medical devices is such that persons generally are entitled to expect.

572 In support of this argument the appellants set out parts of the evidence which it submitted the primary judge failed properly to consider, and which it said established that the benefit-risk profile of each device was such as persons generally were entitled to expect. This evidence is identified and discussed below.

573 Fifth, the appellants submitted that the primary judge erred in converting the concessions made by the appellants about potential clinical significance to a finding of certainty of clinical significance, as shown at TJ [189]-[191]. While the appellants were aware that the devices had the potential to cause each of the pleaded complications and that the pleaded complications could be clinically significant, that does not mean that the complications are always clinically significant, and the finding was contrary to expert clinical evidence, published clinical literature and other findings of the primary judge: AS [31]-[33]. In this regard the appellants pointed to various matters including that:

(1) Professor Korda gave evidence that the clinical significance of one of the pleaded complications, bladder perforation, is limited;

(2) Associate Professor Lam gave evidence that most mesh erosion or exposure is not serious and can be conservatively managed, and similar conclusions were reached by Associate Professor Rosamilia; and

(3) the primary judge accepted that mesh erosions or exposure is not always clinically significant: TJ [244], [4622].

574 The consequence of this alleged error, the appellants said, is set out in the appellants’ Annexure C, which shows that there are a significant number of pleaded complications where no finding was made or could be made on the evidence as to their incidence and severity: AS [32]. For example, they said that no finding was made as to the following pleaded complications in relation to Gynemesh PS used abdominally: infection, chronic pain, dyspareunia, apareunia, difficulty voiding, offensive vaginal discharge, *de novo* or recurrent urinary incontinence, damage to surrounding organs, nerves, vessels, ligaments, tissue and/or blood vessels, haemorrhage, leg weakness, the need for reoperation or revision surgery associated with other pleaded complications, or the need to remove the implanted device or part of the implanted device, difficulty defecating, or recurrence of prolapse.

575 Sixth, the appellants submitted that the primary judge did not properly consider and failed properly to take account of the significance of the evidence as to the differences between each of the devices, as outlined in the appellants’ Annexure B: AS [33]. They said that the SUI devices differ in implantation technique (transobturator vs retropubic), size of mesh, and rates of success and complications, and the POP devices differed in the types of mesh (Prolene Soft vs Gynemesh M), quantities of mesh, and the method of implantation/support. The differences in the size of mesh in each device is significant given the primary judge’s finding that there is a relationship between the amount of the mesh implanted and the likelihood of complications: TJ [825]. They said that it necessarily follows from that finding that there would be a difference in the incidence and severity of the complications associated with each device, as is borne out by the clinical literature. It is said that the primary judge failed to grapple with this.

576 Seventh*,* the appellants submitted that in finding that each device had a defect the primary judge erred in relying on or placing too much weight on conclusions of non-compliance with the requirements of CE marking: AS [34]-[37]. They contended that there was no suggestion either by way of pleading or submission that the CE Mark of itself, or by way of representation made by displaying the CE Mark, formed a basis for finding that the devices were defective (see TJ [3458], [3496]) and that the respondents should be held to their pleadings.

577 They also argued that the primary judge had no evidence as to any understanding or appreciation of the CE Mark by an Australian surgeon or patient, and said that on that basis alone the finding that the CE Mark affected the safety that persons generally were entitled to expect was plainly wrong. That finding was also said to be inconsistent with the only relevant finding made by the primary judge where her Honour said (at TJ [3250]), “I doubt very much whether most surgeons would have had any appreciation of the path to regulatory clearance for medical devices”. The appellants said that no evidence was led as to what surgeons knew about how the regulatory process for medical devices worked and said that it must follow that the safety expectations of persons generally could not be affected by the CE Mark. Further, that the presence of the CE Mark was not a representation in Australia that the devices met Australian regulatory requirements and standards.

###### 5.3 Relevant principles

578 Section 75AD is in Part VA of the TPA. It was introduced into the TPA in 1992 through the *Trade Practices Amendment Bill 1992* (Cth) which established a product liability regime based on the 1985 European Community Product Liability Directive. The purpose of Part VA was to provide a “strict liability” regime under which a person who suffers personal injury or property damage as a result of a defective product has a right to compensation against the manufacturer without the need to prove negligence on the part of the manufacturer: Explanatory Memorandum, *Trade Practices Amendment Bill 1992* (Cth) (**EM**) at [1]-[3].

579 Section 75AD is concerned with losses suffered as a result of personal injury caused by defective goods. At all material times it provided as follows:

If:

(a) a corporation, in trade or commerce, supplies goods manufactured by it; and

(b) they have a defect; and

(c) because of the defect an individual suffers injuries;

then:

(d) the corporation is liable to compensate the individual for the amount of the individual’s loss suffered as a result of the injuries; and

(e) the individual may recover that amount by action against the corporation…

580 Section 75AC defines “defect”. It provides:

(1) For the purposes of this Part, goods have a defect **if their safety is not such as persons generally are entitled to expect.**

(2) **In determining the extent of the safety of goods, regard is to be given to all relevant circumstances** including:

(a) the manner in which, and the purposes for which, they have been marketed; and

(b) their packaging; and

(c) the use of any mark in relation to them; and

(d) any instructions for, or warnings with respect to, doing, or refraining from doing, anything with or in relation to them; and

(e) what might reasonably be expected to be done with or in relation to them; and

(f) the time when they were supplied by their manufacturer.

(1) An inference that goods have a defect is not to be made only because of the fact that, after they were supplied by their manufacturer, safer goods of the same kind were supplied.

(2) An inference that goods have a defect is not to be made only because:

(a) there was compliance with a Commonwealth mandatory standard for them; and

(b) that standard was not the safest possible standard having regard to the latest state of scientific or technical knowledge when they were supplied by their manufacturer.

(Emphasis added).

581 Through the *Trade Practices Amendment (Australian Consumer Law) Act (No. 2) 2010* (Cth), the consumer protection provisions of the TPA were moved into the ACL in Sch 2 of the CCA which came into operation on 1 January 2011 and applies to conduct on and from that date. The operation of the relevant provisions of the TPA was preserved in relation to conduct up to 1 January 2011.

582 Sections 138 and 9 of the ACL, which operate in relation to conduct on and from 1 January 2011, effectively replicate ss 75AD and 75AC of the TPA, except that the ACL provisions substitute the words “safety defect” for “defect”. There is no material difference between the provisions and the meaning of “defect” in the TPA and “safety defect” in the ACL is the same. For convenience we will usually refer only to the TPA provisions and references to “defect” should be taken to include “safety defect”.

583 The obligation under s 75AD is imposed on a corporation which, in trade or commerce, supplies goods manufactured by it. “Manufacturer” has an extended definition pursuant to ss 74A and 75AB. It was common ground before the primary judge that the appellants are corporations who in trade or commerce supplied the devices, and for the purposes of the TPA were all “manufacturers”: TJ [3163]. It is uncontentious that if two or more corporations are liable for the same loss, the corporations are jointly and severally liable: TPA, s 75AM.

584 Pursuant to s 75AC(1), goods have a defect “if their safety is not such as persons generally are entitled to expect”. This imposes an objective standard which depends upon what persons generally, that is, the public at large, are entitled to expect, not the expectations of the applicant in the proceeding or any particular individual: ***Carey-Hazell*** *v Getz Bros & Co (Aust) Pty Ltd* [2004] FCA 853; (2004) ATPR 42-014 (at [186] per Kiefel J as her Honour then was), *Merck* (at [191] per Keane CJ, Bennett and Gordon JJ).

585 It is for the Court to assess objectively what persons generally are entitled to expect, which may be more than or less than the actual expectation of the public: see *A v National Blood Authority* [2001] 3 All ER 289 (at [31] per Burton J) in relation to the almost identical definition of “defect” in the UK Consumer Protection Act (**CPA**), which implemented Art 6 of the 1985 European Community Product Liability Directive into the law of the United Kingdom.

586 The standard does not require goods to be absolutely free from risk. The level of safety required is that which the community is entitled to expect: EM at [21], *Merck* at [191].

587 Section 75AC(2) provides that in determining the extent of the safety of goods the Court must have regard to “all relevant circumstances”. What may be a relevant circumstance includes but is not confined by the matters specified in the non-exhaustive list in subs (2).

588 Obviously enough, the safety the public is entitled to expect in relation to goods may be, indeed is likely to be, affected by what the manufacturer says about the goods in its marketing or by way of any product instructions or warnings. This is recognised in s 75AC(2)(a) and (d) which provide that “the manner in which, and the purposes for which, they have been marketed” (s (2)(a)) and “any instructions for, or warnings with respect to, doing, or refraining from doing, anything with or in relation to them” (s (2)(d)) are mandatory considerations. In determining the extent of the safety of goods the Court must have regard to these matters, along with the other mandatory considerations and any other relevant circumstances.

589 In relation to s (2)(a) the EM noted at [17]:

The first factor listed is the manner and purpose of the marketing of the goods [paragraph 75AC(2)(a)]. This factor may be relevant where the product is marketed for professional or trade use. **The level of warnings and instructions required could be expected to be less for such products because the manufacturer can assume a certain amount of pre-existing knowledge on the part of the purchaser. [This is not to suggest that professional products require no warnings or instructions, merely that the type and pitch of any instructions and warnings will necessarily be different.)** An untrained consumer cannot expect to receive detailed instructions when purchasing a product only meant for use by trained persons. Similarly, consumers are entitled to expect a high degree of safety from goods which are marketed in a manner depicting simplicity and safety.

(Emphasis added).

590 In relation to s (2)(b)-(d) the EM said at [18]:

…Paragraphs 75AC(2)(b) to (d) require factors such as the packaging, markings, instructions and warnings to be taken into account. **In relation to goods which are known by the manufacturer to be potentially hazardous, instructions and warnings are particularly crucial**, as it is through these sources that the manufacturer can detail the nature and extent of the potential hazard and provide adequate instructions to assist consumers in avoiding the hazard.

(Emphasis added).

591 As was said in *Carey-Hazell* at [187], s 75AC encompasses a number of different types of defect. Paragraph 15 of the EM provides:

It should be noted that there are a number of different types of potential defects. Design defects relate to those matters such as the form, structure and composition of the goods. Manufacturing defects are those related to matters such as the process of construction and assembly. **Instructional defects are those caused by incorrect or inadequate warnings and instructions. All these categories of “defect” fall within the meaning ascribed to defect in section 75AC.**

(Emphasis added).

592 The Full Court decision in *Merck* is the leading authority on ss 75AC and 75AD. In that case the manufacturer supplied a prescription anti-arthritis drug, Vioxx, to doctors and pharmacists and it was prescribed for Mr Peterson by his treating doctor. Mr Peterson suffered a myocardial infarction and he brought a representative proceeding alleging, amongst other things, that Vioxx had a defect within the meaning of ss 75AD, because it presented an increased risk of myocardial infarction and Merck had not provided any information or warnings in that regard.

593 At first instance, in ***Peterson*** *v Merck Sharpe & Dohme (Aust) Pty Ltd* [2010] FCA 180; (2010) 184 FCR 1 at [917], Jessup J held that Vioxx had a defect, which his Honour characterised as being the increased risk that a person using the drug would experience a myocardial infarction “absent the provision of any information, advice or warnings as to this risk”. In *Merck* (at [201]) the Full Court endorsed that finding. The Court held that:

…the better view is that Vioxx had a defect within the meaning of s 75AC. The defect was one which affected some people, not all. The defect was that in some people, by a mechanism not known and the subject of no hypothesis, it increased the risk of [myocardial infarction] and provided no information, advice or warning as to this effect.

594 The Full Court held that “[i]n the absence of any information, advice or warning, *addressed to a particular group member* *or to his or her medical practitioner*, to the effect that the consumption of Vioxx materially increased the risk of myocardial infarction” the goods had a defect within the meaning of s 75AD (emphasis added): see the answer to common question 20.

595 The Full Court accepted (at [196], [198]) that Jessup J was correct in holding (at [917]) that although persons generally are entitled to expect that to the extent that a drug has the potential for a side effect (particularly of a serious nature), medical practitioners will be furnished by the drug supplier with an appropriate warning of that risk.

596 Mr Peterson’s claim under s 75AD failed on causation, however. The Full Court held that Mr Peterson failed to demonstrate that the increased risk of myocardial infarction presented by Vioxx affected him, in the sense that the myocardial infarction he suffered was caused by his consumption of the drug: *Merck* at [165], [201]. His claim also failed because the primary judge held (at [927]), upheld on appeal, that the state of scientific or technical knowledge at the time when Mr Peterson took Vioxx was not such as to enable the defect to be discovered by Merck: see s 75AK(1)(c) of the TPA: *Merck* at [208].

597 Relevantly to the present case, *Merck* is authority for the proposition that goods may have a defect because they present a risk of injury and the manufacturer fails to provide any or any sufficient information, advice or warning in relation to that risk: *Merck* at [201].

598 It follows that although a product presents a risk of injury, it may nevertheless not have a defect under s 75AC if the manufacturer provides appropriate information, advice or warnings about that risk in its marketing or product information. That is, the fact that goods present a risk of injury does not, of itself, establish the existence of a defect.

599 The defect must, of course, exist in the particular goods which presumptively caused injury to the individual: *Peterson* at [912].

600 It is not necessary to show that any risk to safety associated with the goods may affect all persons who are supplied with them. It is sufficient to show that the defect affects some people: *Merck* at [201].

601 The risk to safety that goods present need not be high to constitute a defect. In *Merck* Vioxx was found to present a 0.5% increased risk of myocardial infarction, and in the absence of a warning that was held sufficient to constitute a defect. But the extent of the risk required to establish defect may vary depending upon the severity of the consequence if the risk eventuates. In *Merck* the potential consequences were serious, indeed potentially fatal.

602 The role played by intermediaries may also be a relevant circumstance under s 75AC, particularly in relation to the adequacy of any information advice or warnings provided by the manufacturer to the learned intermediaries in respect of any risk of injury presented by the goods. In *Merck* at [191]-[192] the Full Court explained:

[191] …“defects” in prescription pharmaceuticals raise their own issues. As was explained in the EM at [21] and [24]:

… [T]he court must take all relevant circumstances into account in determining the safety of goods. Safety expectations may also depend on matters such as the nature of the product and community knowledge of that product. For example, there are a number of known negative side effects associated with certain pharmaceuticals and vaccines. It is also generally accepted and known that these side effects cannot be avoided. Such products are known to confer substantial benefits which flow to the wider community at large. The small statistical chance of injury associated with them does not of itself mean that they are “defective”.

…

**The role which intermediaries may play in the supply of goods may also need to be taken into account.** For example, prescription pharmaceuticals are supplied to the consumer by a qualified pharmacist and only on the prescription of a qualified medical practitioner. **Due to the complex nature and effects of these products, complete instructions and warnings may not be provided to the consumer by the manufacturer. However, detailed product information is provided to doctors and pharmacists by the manufacturer so these learned intermediaries are sufficiently informed to be able to decide whether or not it is appropriate to dispense pharmaceuticals to particular consumers.** This factor will be relevant in determining whether a pharmaceutical is defective, particularly where a claim of a defect in information provided is made.

[192] As the statute expressly provides (reinforced by the EM), goods are “defective” if they do not have the degree of safety which persons are generally entitled to expect in all the circumstances and, in the context of a prescription drug, those circumstances may include the [Product Information] and information provided to doctors and pharmacists by the manufacturer.

(Emphasis added).

603 The EM further explained at [50], in respect of the defence in s 75AK(1)(a):

As noted above in relation to matters relevant to determining whether goods are defective, due to the complex nature of pharmaceuticals, detailed product information is provided to the qualified intermediaries rather than directly to the consumer. **The information is provided with the expectation that it will be used to properly inform the consumer about the product as the doctor or pharmacist sees fit.** A product cannot be considered to be defective if it acts in an injurious or damaging manner due to the failure of the intermediary to properly inform the consumer, **provided that the proper information is provided by the manufacturer to the intermediary**.

(Emphasis added).

604 In relation to the question of defect, the primary judge said in relation to the statutory claims (at TJ [3216]) that “to the extent that the respondents argue that manufacturers are excused from liability with respect to risks or complications that should be known to doctors or which they are able to discover for themselves, that argument should be rejected.” Similarly her Honour said (at TJ [3313]) “I reject the proposition that it is unreasonable to expect manufacturers to include in an IFU warnings about matters of which they were aware because the surgeons should also have been aware of them or could have discovered them by other means or from other sources”: see also TJ [3313], [3317].

605 Consistently with the views in our overarching observations, a problem with her Honour’s statements is that they are expressed at a level of generality which is inapt for the resolution of the issues in the case. Putting to one side questions of causation, an objective assessment of the safety expectations of the public at large in relation to a medical device cannot depend on the knowledge of a particular treating pelvic surgeon. However, in relation to the knowledge of pelvic surgeons in general, in the factual context of the present case, it is difficult to accept that a device is defective merely because the manufacturer did not notify learned medical intermediaries of a risk that is so obvious that it goes without saying. However and importantly, the appellants did not suggest below or before us that the pleaded complications involved obvious risks as defined in either the CLA or the Wrongs Act.

606 Beyond this class of obvious risk, the relevance and/or significance of the knowledge of pelvic surgeons generally is a question which must be answered on the facts and not at the level of principle.

607 That said, and consistently with our views in our overarching observations, we do not accept that in enacting s 75AC Parliament intended to permit that the product information or warnings to be provided by manufacturers to doctors in respect of medical devices supplied to them rather than to patients directly would depend on the subjective, potentially idiosyncratic, view of manufacturers as to what the relevant medical community knew, ought to have known, or could have discovered through further inquiry, in relation to that risk. In our view it is erroneous to approach such matters as central. Doing so is apt to mislead as it tends to divert attention from the test under s 75AC, being whether the safety of the goods is not such as “persons generally are entitled to expect”, having regard to “all relevant circumstances”.

608 Having regard to the EM it is clear that Parliament intended that, in relation to medical goods supplied to doctors rather than directly to patients, manufacturers provide doctors with sufficient information, advice and warnings about any material risk of harm presented by goods so as to properly inform the doctor about the risk, in order that the doctor can appropriately inform or warn his or her patient. The EM explains that:

(1) where goods are marketed and supplied to professionals for use (which we interpolate includes medical devices supplied to doctors for use in relation to their patients) a manufacturer can assume a “certain amount of pre-existing knowledge on the part of the purchaser”. But that “is not to suggest that professional products require no warnings or instructions, merely that the type and pitch of any instructions and warnings will necessarily be different”: at [17];

(2) it is expected that “detailed product information is provided to doctors…by the manufacturer so *these learned intermediaries are sufficiently informed* to be able to decide whether or not it is appropriate to dispense pharmaceuticals [and we interpolate other medical goods] to particular consumers”: at [24];

(3) information and warnings are provided by the manufacturer to doctors and pharmacists in “the expectation that it *will be used to* *properly inform the consumer* about the product as the doctor…sees fit”: at [50]; and

(4) a product that causes injury cannot be considered to be defective “due to the failure of the intermediary to properly inform the consumer, provided that *the proper information* *is provided by the manufacturer to the intermediary*: at [50].

(Emphasis added).

609 This approach is consistent with Jessup J’s finding in *Peterson* at [917] as follows, which was not disturbed on appeal:

Persons generally are, in my view, entitled to expect that, to the extent that a drug is known or believed to have side‑effects, or to carry the potential for side‑effects (particularly of a serious nature), practitioners will, in whatever terms, and by whatever means, are appropriate, be furnished by the drug supplier with information or warnings sufficient to permit a balanced, cautious and informed judgment to be made.

We take the same view.

610 The statement in *Peterson* concerned prescription drugs but the same can be said in relation to medical devices and accompanying IFUs supplied to doctors and hospitals and not directly to patients. We consider that persons generally are entitled to expect that to the extent that a medical device is known or believed to present a risk of harm, particularly significant harm, the manufacturer of the device will furnish doctors with sufficient information, advice and warnings to permit a balanced, cautious and informed judgment to be made by the doctor and an informed choice by the patient. We agree with the primary judge’s explication of the warnings that persons generally are entitled to expect at TJ [3376].

611 The final specified matter in the list of mandatory relevant circumstances under s 75AC(2) is subs (f) which concerns “the time when [the goods] were supplied by their manufacturer”. Although the primary judge identified some ambiguity in the meaning of “supplied” in cases like the present (TJ [3167]), her Honour concluded that the time when goods are supplied refers to the time when the goods were put into circulation by the manufacturer: TJ [3169]. There is no challenge to that finding. As her Honour noted, that conclusion is consistent with the EM (at [20]) which states that “[t]he critical time is when the alleged defective goods which caused the loss was put into circulation by its manufacturer”. It is also consistent with the approach taken in the English authorities, when interpreting an analogous provision, s 3(2) of the CPA: see, e.g. *Wilkes v DePuy International Ltd* [2016] EWHC 3096 (QB); [2017] 3 All ER 589 at [79] per Hickinbottom J. We take the same view.

###### 5.4 Discussion

612 Grounds 1 and 2 of the appeal must be dismissed.

613 The first alleged error is that the primary judge’s finding at TJ [1336] that none of the devices was safer or more effective than any of the alternative treatments is wrong and demonstrates her Honour’s analytically flawed approach. The appellants alleged that in light of the inherently individual nature of the inquiry her Honour erred in making an assessment of safety and efficacy in these terms.

614 As we said in our overarching observations, while we accept that the appellants did not have to prove anything, this submission must be rejected.

615 First, at TJ [1336] the primary judge said only that none of the devices had been proven to be safer or more effective than the alternative available treatments for SUI and POP. Her Honour did not say that in all patients and in all circumstances alternative treatments, particularly native tissue repair surgery, were safer or more efficacious than implantation of one of the devices. We have no difficulty in accepting that one or more alternative treatment options might be unavailable to a particular patient because of her individual circumstances, nor that having regard to a patient’s individual circumstances implantation of one of the devices may benefit the patient. But the primary judge did not say otherwise. Professor Roovers’ evidence does not expose any error in her Honour’s conclusion.

616 Second, the appellants said that the benefits of using the POP devices outweighed the risks for women with any level of prolapse. But mere disagreement with a finding does not establish error and there was ample evidence which supported her Honour’s conclusion at TJ [1284]-[1335]. The appellants fell well short of establishing that her Honour erred in finding that none of the devices had been proven to be safer or more effective than the alternative available treatments, or in finding (at TJ [3496]) that the evidence did not support the conclusion that the benefits of using the POP devices outweighed the risks for women with any level of prolapse.

617 Third, we give little weight to the appellants’ argument when, as the respondents submitted:

(1) the appellants decided to withdraw TVT Secur and the POP devices from the market because of the high failure rate of TVT Secur and rather than performing the post-market surveillance studies of the POP devices which the regulatory authorities required : TJ [2445], [2491], [2498], [2500];

(2) one of their witnesses, Associate Professor Rosamilia, gave evidence that the key long term study of the TVT products said to support the products’ safety and efficacy was a poor review from which it was difficult to draw reliable conclusions: TJ [911]; and

(3) the primary judge’s conclusion was reached having regard to Cochrane reviews which the appellants relied on to support their contention that synthetic suburethral slings such as the TVT products were equally or not materially less safe and effective than traditional laparoscopic colposuspension (TJ [1322]-[1336]), and the appellants did not identify any error in the primary judge’s analysis of the Cochrane reviews.

618 Fourth, there is no substance in the appellants’ contention that the primary judge approached the question of defect on the basis that they were required to “exhaustively demonstrate” that use of the devices would not cause a “certain frequency of certain kinds of complications”, for decades before the devices could first be marketed. There is nothing in her Honour’s findings to indicate that her Honour required that of the appellants. Dr Hinoul conceded that the appellants knew from the time the devices were first supplied anywhere in the world that they could cause the pleaded complications. Having regard to that, and the concession that each of the complications was clinically significant, her Honour decided that the devices presented a risk of harm about which the appellants provided no or no adequate warning. That, in combination with the other relevant circumstances to which her Honour referred, strongly supported the finding that the devices are defective. The other relevant circumstances included that: (a) none of the POP devices was the subject of an adequately powered clinical trial before it was released to market (TJ [3496]), (b) the appellants represented that the devices met the essential requirements for CE marking, which included adequate pre-market clinical evaluation, when they had not done so (TJ [3458], [3496]), and (c) an appropriate warning would have included any limitations of the available clinical data in relation to the devices (TJ [1336]). We can see no error in that approach.

619 The second alleged error is that the primary judge erred at TJ [4410] in failing to distinguish the remarks in *Merck* at [191]-[192].

620 In those paragraphs, in particular at [192],the Full Court concluded that in the context of a prescription drug, the relevant circumstances under s 75AC may include the product information and warnings provided to doctors and pharmacists by the manufacturer. The appellants did not challenge the Full Court’s approach but argued that the present case is distinguishable because medical devices are unlike prescription drugs in that “the implants involve the further input of the surgeon with whom the patient elects to have the index surgery, including his or her preferences, training and capacity”. Her Honour rejected that argument at TJ [4410], doing so on the basis that the prescription of drugs also required the input of the treating doctor including his or her preferences, training and capacity, and that the distinction proposed by the appellants was unwarranted.

621 We do not consider the primary judge erred as alleged and we can see no basis to distinguish the remarks in *Merck* on the facts of the present case*.* The role of a doctor in deciding whether to recommend use of a medical device (whether or not for implantation) is relevantly analogous to that of a doctor deciding whether to recommend use of a prescription drug. In both settings the manufacturer supplies the goods and any accompanying product information or instructions for use to the doctor, not to the patient. The goods will be used by the patient only upon receipt of medical advice and a recommendation, which can be expected to include an appropriate warning about any risks associated with the goods. In both settings the doctor is required to exercise medical expertise and professional judgment in providing medical advice and a recommendation, which can be expected to be tailored to the patient’s individual circumstances and may in some circumstances take into account the doctor’s personal preferences.

622 In any event, under s 75AC it is mandatory to consider “any instructions for, or warnings with respect to” the relevant goods, and thus to consider any information, advice or warning provided by the manufacturer to doctors. That is what her Honour did.

623 The third alleged error is that the primary judge misapplied the statutory test, as demonstrated at TJ [4401]. The appellants argued that the primary judge approached the statutory test by considering whether there was an adequate warning of a list of pleaded complications and then reasoning that each device would have a defect if there was *any* risk that was not disclosed.

624 The primary judge said the following (at TJ [4401]):

The role of a safety warning is to alert the consumer to the risks associated with the use of the product to protect her or him from harm. In the case of a medical device, warnings as to adverse events and contraindications, and advice as to the limits of the available information serve to assist patients to make an informed decision about whether to undergo surgery with such a device. **Where a medical device, when used as intended, exposes consumers to a risk of significant harm, then the device will have a defect unless it is accompanied by warnings sufficient to alert patients to that risk. In such a case, the defect is not the absence or inadequacy of the warnings, as the respondents contended, but the fact that the device has a propensity to cause harm that persons generally would not reasonably expect.**

(Emphasis added).

625 The appellants relied on the highlighted passage.

626 This submission has no merit.

627 First, contrary to the appellants’ submissions, the primary judge recognised that ss 75AC and 75AD do not require that goods must be absolutely free from risk. So much is clear (at TJ [3191]) where her Honour said “[i]mportantly, the law does not require that goods be “absolutely free from risk”” citing *Merck* at [191].

628 It cannot be said that the primary judge approached the question of defect on the basis that the existence of *any* risk meant that the devices were defective when her Honour: (a) recognised that goods need not be absolutely free from risk, (b) recognised that all surgical treatments carried risks (e.g. TJ [60] and [130]), (c) referred to a “risk of significant harm” at TJ [4401], and (d) made numerous findings addressed to the incidence and severity of the pleaded complications. There is nothing in her Honour’s reasons to suggest that she proceeded on the basis that the devices were defective if their implantation presented any risk, and there are many parts of the reasons which show to the contrary.

629 Second, the primary judge’s remarks at TJ [4401] were made under the subheading “Causation under the Trade Practices Act”. At TJ [4398] her Honour set out a statement in *Merck* at [104] that to establish causation “a plaintiff must establish as a necessary condition of recovery that he or she would not have suffered loss but for the defendant’s actionable misconduct”. At TJ [4399] her Honour said:

…the [appellants] argued that if there were a defect then it comprised the absence of suitable warnings in that the [respondents] needed to prove that the loss or damage was caused by the absence of warnings. The [respondents], on the other hand, argued that the defect was the risk of harm posed by the goods, not the absence of a warning.

In the following paragraph (TJ [4400]) her Honour remarked, in relation to causation, that everything turned on how the defect is properly characterised.

630 It is in that context that the remarks at TJ [4401] must be understood. They were directed to the rejection of the appellants’ argument on causation, not to the statutory test in relation to defect. To the extent that there is some looseness of language in her Honour’s remarks at TJ [4401] it is not material to the finding of defect, which was not made in that paragraph and instead made earlier in her Honour’s reasons at TJ [3458], [3496] and [3499]. As we explain below those paragraphs of the reasons reveal no error. As we later explain in dealing with causation, the primary judge’s statements of principle about causation for statutory defect are immaterial because she found, in fact, that the injuries suffered by each of the representative respondents were caused by the defects in the relevant devices.

631 Third, the primary judge correctly applied the statutory test, doing so by reference to the decision in *Merck*. Her Honour said the following (at TJ [3172]-[3175]):

[3172] …Since the question of whether there is a defect requires consideration of the way goods are marketed and instructions or warnings that have been given with respect to their use, the expectations persons generally are entitled to have about the goods will be affected by what the manufacturer has said about them. Thus, even if a product presents certain risks, that product may well not have a defect if the manufacturer gives appropriate warnings about those risks, defines appropriate limitations on the indications for use, and does not promise more in terms of safety than the product can deliver. The applicants conceded as much. The instructions or warnings mentioned in s 75AC(2)(d) relate to the doing or refraining from doing something with, or in relation to, the goods. In the present case that would encompass instructions or warnings about use in relation to pregnant women or women of child-bearing years, for example, or about implantation in certain other kinds of patients. It would ordinarily not encompass warnings or advice about potential adverse effects. Nevertheless, it was common ground and properly so, consistent with the judgments in *Peterson v Merck Sharpe & Dohme (Aust) Pty Ltd* (2010) 184 FCR 1 (Jessup J) and on appeal in *Merck* (together, the Vioxx case), that information or warnings given by a manufacturer about the potential adverse effects of the use of a product are also relevant since they could affect the level of safety that persons generally are entitled to expect.

[3173] Naturally enough, the defect must exist in the particular goods that are alleged to have caused injury to the individual: *Peterson* at [912]. Consequently, the applicants must prove that the particular Ethicon devices had such a defect.

[3174] It has been clear at least since the Vioxx case that a product may be defective even if the defect is one which only affects some people. In endorsing the primary judge’s decision that Vioxx had a defect within the meaning of s 75AC, the Full Court in *Merck* at [201] described the defect in this way:

The defect was one which affected some people, not all. The defect was that in some people, by a mechanism not known and the subject of no hypothesis, it increased the risk of [myocardial infarction] and provided no information, advice or warning as to this effect.

[3175] It also follows from *Merck* that the risk need not be high, although the extent of the risk posed by the product which will render a product defective may vary from case to case. The relevant risk in that case was very low (0.5% risk of myocardial infarction) but the potential consequences were grave, indeed fatal.

632 Her Honour also said at TJ [3188]:

In *Carey-Hazell (2004)*, a case about an allegedly defective prosthetic mitral valve, Kiefel J (as her Honour then was) observed at [199] that without a warning or instruction the use of a product might be unsafe and a warning is necessary to remove “some inherent dangerous quality”. In *Peterson*, Jessup J held at [915]-[918] that the safety of the drug was less than persons generally were entitled to expect because the consumption of the drug had the potential to increase the risk of myocardial infarction in circumstances which included the absence of any relevant information or warning from the manufacturer.

633 Consistently with the approach in *Merck*, the primary judge evaluated the risk of the pleaded complications. Her Honour did so against the background that:

(1) Dr Hinoul conceded that from the time each of the devices was first supplied anywhere in the world the appellants knew of the potential of the devices to cause each of the pleaded complications: TJ [189]-[191], [3200];

(2) the appellants conceded that each of the pleaded complications was clinically significant: TJ [191], [1134];

(3) any “attempt to distil the evidence into a neat summary of incidence rates would be riddled with potential pitfalls” and it was unnecessary to do so because of the appellants’ concession that each of the pleaded complications was clinically significant, and that they would not take any issue as to the precise incidence of the complications: TJ [1134]; and

(4) the weight of the evidence indicated that the use of mesh caused complications of a kind, degree or rate different from or greater than those associated with traditional forms of pelvic floor repair: TJ [199].

634 Having regard to the pitfalls in distilling the evidence into a neat summary of incidence rates (TJ 1134), and given the appellants’ concessions, it was unnecessary for the primary judge to make evidentiary findings in relation to the incidence of the pleaded complications. Nevertheless her Honour referred to a “snapshot” of the evidence which showed the prevalence of the pleaded complications (TJ [1137], see also TJ [1143]-[1283]) and made numerous findings, including that:

(1) pain and dyspareunia can be both more severe and more enduring after repair procedures involving the use of mesh than after traditional prolapse surgery: TJ [228];

(2) the severe chronic and intractable pain that can occur after mesh surgery was virtually non-existent or not encountered after native tissue repair: TJ [233], [236];

(3) chronic pain was common (1-10% of cases) after implantation of SUI devices: TJ [1139], [1167];

(4) to the extent there was evidence of chronic pain after native tissue SUI repair, such pain was treatable: TJ [1168];

(5) dyspareunia and apareunia were likely to be common after implantation of the POP devices: TJ [1234];

(6) erosion is a serious adverse event in the case of SUI devices when surgical intervention is required (TJ [1143]) and the reported rate of erosion across the studies was around 2 to 5%: TJ [1144];

(7) erosion is common to all of the SUI devices: TJ [1151]; and

(8) erosion rates in POP devices was around 10 to 12% (TJ [1208]) and is at least common after transvaginal implantation of any and all of the POP devices: TJ [1216].

635 The primary judge’s reasons are replete with examples which show that she understood that in determining the extent of the safety of the devices under s 75AC the Court is required to consider “all relevant circumstances”: e.g. TJ [3165], [3171], [3191]. It is plain from the reasons that her Honour’s consideration did not involve simply comparing the list of pleaded complications against the warnings provided by the appellants. This can be readily seen at:

(1) TJ [3458], where the primary judge held that at all material times all the SUI devices had a defect having regard to the following relevant matters:

(a) the nature and extent of the risks associated with the devices;

(b) the deficiencies of the Ethicon’s warnings and the other information they provided;

(c) the repeated failure to comply with the requirements for CE marking; and

(d) the way in which the devices were marketed; and

(2) TJ [3496] and [3499], where the primary judge held that at all material times the POP devices and Gynemesh PS had a defect having regard to the following relevant matters:

(a) each of them exposed women to significant risks of injury;

(b) against which risks inadequate warnings were given and in respect of which misleading representations were made including that:

(i) Ethicon was not candid with the public about the risks of and contraindications for use of the devices or the limitations of the available data; and

(ii) Ethicon represented that the benefits of using the POP devices outweighed the risks for women with any level of prolapse when the evidence did not support that;

(c) none of the POP devices was the subject of an adequately powered clinical trial before it was released to market;

(d) Ethicon represented that the devices met the essential requirements for CE marking when the material upon which they relied to affix and maintain the CE Mark was insufficient to satisfy those requirements;

(e) Gynemesh PS was defective because:

(i) its implantation exposed women to the risk of significant injury;

(ii) the warnings given by Ethicon were insufficient to protect users from those risks;

(iii) the information supplied with and about the device was liable to lull users into a false sense of security; and

(iv) the limitation made to the indication for use for the device (which came into effect on 16 March 2013) might have lessened the complication rate but the product was still defective, because the information accompanying the device was still insufficient to put users on notice of the true nature and extent of the risks.

636 The primary judge also had regard to the following relevant circumstances:

(1) the purpose of the devices is to treat SUI and POP, neither of which is a life-threatening condition and treatment, including surgery, is elective: TJ [3369];

(2) the use of the devices involved permanent implantation in the female pelvis: TJ [3369];

(3) even if surgery is chosen, there are well-established and well accepted alternative forms of surgical treatment that do not involve the use of mesh : TJ [3369]; and

(4) the POP devices were promoted as safe and effective treatments first-line treatments for pelvic organ prolapse: TJ [3466].

637 Her Honour approved Dr Elliott’s remark in a 2012 article (Elliot D, “Con: mesh in vaginal surgery: do the risks outweigh the benefits?” (2012) 22 Curr Opin Urol 2012 276–281 at 280 (SHI.MESH.00033536 at 3540)) where he said, in relation to transvaginal mesh kits for prolapse repair, that “[i]t is one thing to have a high complication rate when dealing with life or death issues without suitable alternatives — in this situation a complication, even a severe one, may be acceptable when a patient has no other choice and his or her life is at stake”; it is another where the patient has a choice and her life is not in danger: TJ [3369].

638 Fourth, as we have said, there is no substance to the appellants’ contention that the primary judge ignored the critical question whether having regard to: (a) the risks associated with the devices, (b) the totality of the warnings and other information (including the knowledge of treating pelvic surgeons), and (c) the nature of the implants as medical devices (which includes their relative benefits), the safety of the devices is not such as persons generally are entitled to expect.

639 It is plain from her Honour’s reasons that she considered each of those matters. Given the comprehensiveness of her Honour’s reasons as previously summarised, and that we have previously dealt with some of these matters it is not necessary to set out all the ways in which this contention can be shown to have no proper basis. It suffices to note the following.

640 In relation to “the risks associated with the Ethicon devices” the primary judge’s reasons are replete with her consideration of the evidence concerning that issue, and her findings, including:

(1) in Part IV (TJ [183]-[298]) under the heading “the risks posed by the Ethicon devices”, in which her Honour noted Dr Hinoul’s concession that at all material times the appellants knew of the potential of each of the devices to cause the pleaded complications and the appellants’ concession that each of the pleaded complications was clinically significant. Her Honour also made findings as to the nature of the pleaded complications and the circumstances which they arise;

(2) in Part V (TJ [299]-[787]) under the heading “[b]iocompatibility issues” her Honour made findings regarding the problems associated with the biocompatibility of polypropylene mesh implanted in human tissue. Amongst other things, her Honour accepted the evidence of Professors Klosterhalfen and Klinge that implantation of the devices gave rise to a risk of chronic inflammation, infection, erosion, contraction and chronic pain: TJ [788]; and

(3) in Part VI (TJ [788]-[1336]) under the heading “[t]he performance of the devices” her Honour evaluated the weight to be given to the conclusions of the various medical or scientific studies upon which the parties relied, made findings including as to the incidence and severity of the complications caused by pelvic mesh, and considered the comparative benefits and risks of the devices as against traditional native tissue repair surgery. Her Honour found that none the devices had been proven to be safer or more efficacious than other alternative treatments in the long-term.

641 Her Honour also gave detailed consideration to the evidence and made findings regarding “the totality of the warnings and other information” including:

(1) Dr Hinoul gave evidence that: (a) the IFUs accompanying the devices represented Ethicon’s official statement as to what it said were the adverse reactions associated with the products (TJ [2584]), (b) a doctor would be entitled to expect that the company supplying the product would have access to more knowledge about its product than others in the medical community (TJ [2584]), (c) the IFU was an important document from Ethicon’s point of view to ensure that the user of its devices had a means to know exactly what Ethicon regarded as the risk associated with the device, and (d) it was important for all risks associated with the implantation of the device to be included in the IFU;

(2) since the commencement of the Medical Devices Regulations on 4 October 2002, there has been an unqualified statutory obligation to provide certain information with any medical device including “[a]ny warnings, restrictions, or precautions that should be taken, in relation to use of the device” and IFUs were required to include “[a]ny contra-indications, warnings, restrictions, or precautions that may apply in relation to use of the device” and “[f]or an implantable medical device - information about any risks associated with its implantation: TJ [3840] and [3841];

(3) the contents of the IFUs for the SUI devices at TJ [2586]-[2628] and the POP devices: TJ [2629]-[2655];

(4) the interventions by the US, Canadian and Australian regulators which led to some late, but in her Honour’s view, inadequate improvements in the warnings provided in the IFUs: TJ [2656]-[2681];

(5) the training the appellants provided to surgeons in relation to operations to implant the devices, finding that the training was not provided to all surgeons and was insufficient to adequately equip those who received it with the skills and information to conduct the operations with minimal risk of injury: TJ [2682]-[2705]; and

(6) the appellants’ marketing of the devices (TJ [2708]-[2809]) including through product brochures for patients and for surgeons for the SUI devices (TJ [2719]-[2758]) and for the POP devices: TJ [2759]-[2797].

642 Her Honour made detailed findings regarding the inadequacy of the appellants’ warnings and other information provided about the risk of the pleaded complications associated with the SUI devices (TJ [2814]-[2939]) and the POP devices: TJ [2940]-[3028]. She accepted Dr Pence’s evidence that at the time of her report the IFUs for the SUI devices were deficient (TJ [2622]-[2628]) as were the IFUs for the POP devices: TJ [2645]-[2655]. Having regard to other evidence and Dr Hinoul’s testimony that from the time each of the devices was first supplied anywhere in the world Ethicon knew of their potential to cause the pleaded complications, her Honour concluded that warnings of the pleaded complications should have been provided with the devices from the time that each was made available for sale: TJ [2628], [2655]. Her Honour found that at all material times the warnings and other information provided by the appellants about all the devices were deficient: TJ [3029]-[3034].

643 In relation to “the knowledge of treating pelvic surgeons”, we have previously set out her Honour’s discussion of the evidence and her inference that treating pelvic surgeons in general were not aware of the risk of the pleaded complications. As previously explained, we are not persuaded that her Honour erred in that regard. Further, in our view the finding accords with the weight of the evidence.

644 In relation to “the nature of the implants as medical devices (which includes their relative benefits)” it was uncontroversial that the devices were intended and used for permanent implantation in the pelvis of women suffering either from SUI or POP. It was also uncontentious that these are complex medical conditions for which a variety of different treatment options are available, and the selection of the appropriate treatment option will depend on the individual circumstances of the patient. Against that background, one of the matters the primary judge considered was the comparative risks-benefits of traditional native tissue repair surgery as against repair using one of the devices. It is unnecessary to go to every finding in that regard and it suffices to note the following findings:

(1) all surgical treatment options for POP are associated with risks, but that complications from native tissue repair are generally short-lived and treatable: TJ [130];

(2) the weight of the evidence indicates that the use of mesh causes complications of a kind, degree or rate different from or greater than those associated with traditional methods of pelvic floor repair, which complications cannot wholly be explained by insufficient surgical training or experience. Other factors, including product design, mesh porosity, the quantity of mesh used, the route and methods of implantation and patient-specific factors cause or contribute to the development of adverse reactions following the implantation of synthetic mesh, including the various devices: TJ [199];

(3) pain can be both more severe and more enduring after repair with procedures involving the use of mesh than after procedures which do not: TJ [228];

(4) in contrast with native tissue repair, pain after mesh surgery can arise well after surgery including many years later: TJ [216], [232];

(5) removal of the mesh which may be required in cases of mesh exposure, extrusion, erosion, chronic pain, or recurrent prolapse, (which does not arise in native tissue repair) presented additional problems, and the mesh is difficult, if not impossible, to remove entirely as it is or becomes integrated in the connective tissue, and that removal surgery may not relieve pain: TJ [244] and [246];

(6) it was appropriate to accept the evidence of Professor Korda who said that polypropylene mesh implants carried a risk of certain complications that were unknown to pelvic surgeons versed in native tissue repair. He said that severe, chronic and intractable pain that can occur after mesh surgery was “virtually non-existent” after native tissue repair (TJ [233]) and that “complications such as mesh erosion, mesh contracture, bunching, severe chronic pelvic pain, severe dyspareunia and pain on movement, sitting, standing were not seen before the introduction of mesh surgery”: TJ [3235]; and

(7) her Honour was not satisfied on the evidence that at any time after each of the SUI and POP devices were first supplied in Australia that the devices were proven to be safer or more effective in the long-term than the alternative treatments: TJ [1336].

645 This is not to reject the proposition that for many women the devices had benefits. We can accept that for many, perhaps a majority of women, the devices proved to be an effective treatment of the SUI or POP they suffered. But the appellants’ contention as to the benefits of the devices failed to engage with the fact that a fundamental mater underpinning the findings of defect is that each of the devices presented a risk of causing the pleaded complications in any woman implanted with a device, against which risk the appellants provided no or no adequate warning. In combination with the other relevant circumstances her Honour relied on, the devices were found to have a defect because they presented a risk of injury through the pleaded complications and the appellants failed to provide any or any sufficient warning in relation to that risk. The fact that the risk only eventuated in some women implanted with the devices, rather than all women, does not mean that the devices have the safety persons generally are entitled to expect: *Merck* at [201].

646 Fifth, as we said in our overarching observations, we are not persuaded that her Honour was mistaken in treating the patient brochures as a relevant circumstance under s 75AC when there was no evidence that a representative respondent or any group member had seen such brochures. The patient brochures were not central to the finding of defect and it was open to the primary judge to infer that the appellants produced the patient brochures intending that they should be given to surgeons and seen by patients: TJ [3267]. The brochures are relevant to the appellants’ views about the state of knowledge of pelvic surgeons and of patients generally regarding the risks associated with the devices. Having regard to their contents, the brochures tend to show that the appellants did not believe that pelvic surgeons or patients generally knew about the pleaded complications. It can be accepted that warnings provided to patients through such brochures may be different in type, pitch and complexity to those provided to treating surgeons but that is beside the point. As the Full Court said in answer to common question 20 in *Merck*, where goods present a risk of harm,“[i]n the absence of any information, advice or warning addressed to a particular group member or to his or her medical practitioner” to the effect that use of the goods presents a risk of harm, particularly serious harm, goods may have a defect.

647 The fourth alleged error is that in determining the extent of the safety of the devices the primary judge did not properly consider and failed properly to take account of the significance of the evidence of the pelvic surgeons in relation to clinical considerations and the different safety profiles of each of the devices, together with their safety profiles relative to other surgical and non-surgical alternatives. It is said that the primary judge erred by failing to find that the evidence of pelvic surgeons should be preferred to the evidence of non-clinical experts, including the epidemiologists, biostatisticians, biomaterials experts and pathologists.

648 We do not accept that the primary judge erred as alleged.

649 First, as the respondents submitted, the appellants’ argument seeks to sidestep the statutory question. A product has a defect within the meaning of s 75AC if its safety is “not such as persons generally are entitled to expect”. Persons generally are entitled to expect that medical devices supplied to doctors and hospitals and not directly to patients, do not present a risk of injury, particularly significant injury, of which the manufacturer gives no or no sufficient warning. Persons are generally entitled to expect that the manufacturer will provide appropriate warnings to medical practitioners and/or directly to patients in respect of such risks.

650 Her Honour said at TJ [3376], and we agree that:

…where a medical device carries risks when used as intended, persons generally are entitled to expect that the manufacturer would provide medical practitioners with the information and warnings necessary to enable them to make a balanced, cautious, and informed judgment about whether to recommend implantation with one or other of the devices to their patients and to enable patients to make a balanced, cautions, and informed decision about whether to consent to such a procedure. That includes information about known and foreseeable risks. It includes information about those patients who are particularly at risk. It includes information about the true state of affairs, including the real risks of implantation with the device, the extent of the risks in the short and the long-term, and the limitations, if any, of the available data. Persons generally are entitled to expect that manufacturers are not selective about which risks or other information to disclose.

651 We accept the appellants’ contention that the treating pelvic surgeons of women suffering SUI or POP played a key role in providing individualised medical advice and recommendations to them in relation to their treatment options, including in respect to the implantation of a device. It was those surgeons who were provided with the IFUs. They were obliged to apply their medical expertise and professional judgment in recommending the appropriate treatment options. As part of obtaining the patient’s informed consent to the treatment they could be expected to provide appropriate warnings to their patients in respect of any risk of harm associated with the treatment options to which a reasonable person in the patient’s position would attach significance. However, the fact that the treating pelvic surgeons occupied this key role does not address the statutory question and does not show the primary judge erred in finding that the devices were defective. Indeed, the fact that the treating surgeons occupied this critical role only serves to underscore the importance of the appellants providing frank and candid warnings to the surgeons as to the risk of the pleaded complications presented by the devices. Dr Hinoul conceded that from the time each of the devices was first supplied anywhere in the world Ethicon knew of its potential to cause the pleaded complications. Absent sufficient warnings from the appellants it would be left to chance that a particular treating surgeon would, in fact, know about the risk of the pleaded complications. That is not the extent of safety persons generally are entitled to expect.

652 Second, the asserted error is based in an assumption that at all material times the cohort of treating pelvic surgeons were aware of the risk of the pleaded complications associated with implantation of the devices, and could be expected to bring that knowledge to bear in recommending the implantation of an device. The appellants submitted that there was no requirement for them to warn surgeons of risks of which they were already aware, and they contended that it could never been the case that pelvic surgeons assumed that the appellants’ IFUs carried a complete statement of all the risks associated with implantation of the devices.

653 However, as we have explained, that is contrary to the primary judge’s inference that pelvic surgeons did not know of the risk of all the pleaded complications: TJ [3228]-[3248]. It is also contrary to the finding, amongst others, that:

(1) the IFUs were important to surgeons as a statement of the manufacturer’s knowledge of the risks of the devices which meant that it was important that all risks associated with the implantation of the devices must be included in the IFUs: TJ [3315], [3371]-[3373];

(2) it was appropriate to accept Dr Pence’s evidence that the manufacturer will know more about the risks associated with the use of their products than surgeons and that they are obliged to disclose what they know in the instructions for use: [TJ 2580]; and

(3) an average reasonably competent pelvic surgeon would expect the manufacturer to provide [the surgeon] with information about the use, surgical technique, risks of adverse events, and studies supporting safety and efficacy: TJ [3249].

654 Further, as we have also previously noted, each of the pelvic surgeons who gave evidence is a highly credentialed, trained, experienced, clinical professor with a research interest in mesh surgery, and both individually and as a cohort their knowledge must have materially exceeded that of pelvic surgeons in general. Even so, the evidence shows that their understanding of the risks associated with implantation of the SUI and POP devices developed over time through experience, research and engagement with injured patients. It also must be kept in mind that the relevant time for determining whether each of the devices has a defect is when each of them came onto the market: TJ [3169]. That is also the time when Dr Hinoul said Ethicon was aware of the potential for each device to cause the pleaded complications.

655 Once it is understood that pelvic surgeons in general did not know about the pleaded complications at any material time, the manifest weakness of the appellants’ contention that the primary judge erred by failing to give proper regard to the evidence of pelvic surgeons is apparent. The appellants submitted that the requisite warning was one which was sufficient to permit treating pelvic surgeons with the necessary clinical experience and expertise properly to engage with their patient and obtain informed consent in relation to implantation of a device. However, as previously discussed, a treating pelvic surgeon could not make a properly informed judgment in deciding between the available treatment options, nor properly engage with his or her patient in obtaining informed consent to implantation of a device, if the surgeon was not aware of the risk of the pleaded complications associated with the device.

656 It is clear on the evidence that:

(1) as Dr Hinoul conceded in cross-examination, at all material times the appellants knew that implantation of all of the devices presented a risk that one or more of the pleaded complications might arise;

(2) as the appellants conceded, each of the pleaded complications was clinically significant;

(3) the devices and accompanying IFUs were supplied to doctor and hospitals, not directly to patients;

(4) at all material times treating pelvic surgeons in general were not aware of the risk of the pleaded complications;

(5) it was therefore necessary for the appellants to provide treating surgeons with sufficient information, advice and warnings about the pleaded complications to allow them to make a balanced, cautious, and informed judgment about whether to recommend implantation of a devices and to enable their patients to make a balanced, cautious, and informed decision about whether to consent to such a procedure: TJ [3376]; and

(6) the warnings and other information the appellants provided treating surgeons about those risks were seriously inadequate: see in relation to the SUI devices (TJ [2812]-[2839]) and in relation to the POP devices (TJ [2940]-[3028]).

657 In combination with the other relevant circumstances to which the primary judge referred at TJ [3458], [3496] and [3499], the fact that at all material times the devices presented a risk of harm through the pleaded complications, and that the appellants provided no or no adequate information, advice or warnings in relation to that risk, meant that at all material times the devices were defective.

658 Third, the asserted error is based in the contention that the primary judge failed properly to consider certain evidence which established that, when viewed in the context of clinical considerations, the benefit-risk profile for each device was such as persons generally were entitled to expect. The appellants relied on the following matters at AS [30]:

(a) The statements of multiple professional organisations indicating that midurethral slings (which include the SUI Implants) are the “operation of choice” (RANZCOG in March 2014 [ETH.MESH.16308855 at .16308856] and May 2017 [PUB.MESH.00009294 at .00009296] and IUGA in July 2014 [PUB.MESH.00001813]) or the “gold standard of care” (AUGS in March 2013 [SHI.MESH.00003903 at .00003905] and in 2014 [ETH.MESH.14481429 at .14481429]). In making these observations, these professional organisations indicated that the major advantage of the mid-urethral sling is that it has lower rates of complications when compared to other more invasive traditional surgery (RANZCOG ‘Position statement on midurethral slings’ (March 2014) [ETH.MESH.16308855 at .16308856]; AUGS ‘Position Statement on Mesh Midurethral Slings for Stress Urinary Incontinence’ (2014) [ETH.MESH.14481429 at .14481430], International Urogynaecological Association, ‘Position Statement on Mid-Urethral Slings for Stress Urinary Incontinence’ (July 2014) [PUB.MESH.00001813]).

These statements were criticised by the primary judge, largely on epidemiological grounds (TJ, [2511]-[2515]). As set out above, epidemiologists are not in a position to judge what is clinically (as distinct from statistically) significant.

(b) Abdominal sacrocolpopexy (which includes the use of mesh (and, specifically, was one purpose for which Gynemesh PS was used)) was described as the “Gold Standard” for addressing vault POP (Korda 1, p.73 [EXP.010.078.0001\_3 at .0075\_3]; Collinet 1, pp.28, 31 [EXP.020.005.0001\_4 at .0028\_4, .0031\_4]).

(c) The fact that the Ethicon Devices are, in a high percentage of cases, effective and, in many cases, have lesser occurrence of other events, such as hospital stay and wound morbidity (and can be complication free).

(d) It is the pelvic surgeons who have the role of assessing the appropriate treatments and their relative safety and efficacy for their individual patients, together with the application of their knowledge in tailoring the informed consent discussions with individual patients (as explained above).

(e) The fact that no Australian treating surgeon gave evidence that the products were unsafe or should be taken off the market. Professor Blaivas (an American pelvic surgeon called by the Representative Applicants) indicated that it was not his position that the SUI Implants should be taken off the market (T723.15-17 [TRA.500.008.0001\_2 at .0112\_2]). Professor Korda accepted that mesh could be used in circumstances where the natural tissues are so compromised that they cannot be used to effect a repair and noted that it will be up to the individual surgeon to determine whether the tissues of a particular patient are so compromised (T1253.01-14 [TRA.500.015.0001\_2 at .0036\_2]). Implicit in this statement is the rejection of the proposition that the complication profile – the safety – of mesh repair is not what persons generally are entitled to expect. The primary judge seemed to overlook the fact that Professor Korda did not suggest that no doctor should treat POP using transvaginal mesh. If the safety of the Ethicon Devices is not what persons are generally entitled to expect, the pelvic surgeon experts called by the Representative Applicants would have given evidence to that effect. They did not. The evidence was the opposite: some treating surgeons use it, some use it in some circumstances, some do not use it. By way of example, Professor Korda continues to use the TVT-O (T1197.14-21 [TRA.500.014.0001\_2 at .0069\_2]).

(f) Midurethral slings (which included the SUI Devices) are the most studied treatment for female SUI and were the least invasive surgical option to treat SUI (T711.40-712.08 [TRA.500.008.0001\_2 at .0100-.0101]).

(g) Professor Korda indicated that minimally invasive sub-urethral sling procedures (which included the SUI Devices) are the “gold standard” surgical treatment for urodynamic stress incontinence (T1211.03-18 [TRA.500.014.0001\_2 at .0084\_2]. They are used “almost solely” by gynaecologists and urologists (Collinet 1, p.32[EXP.020.005.0001\_4 at .0032\_4]).

(h) Although a vaginal sling operation (which included the SUI Devices) carries a number of graft-related complications, it is the standard of care in Prof Deprest's centre (Deprest 1, [109] [EXP.020.006.0001\_4 at .0023\_4 - .0024\_4]).

(i) Professor Blaivas agreed that merely because an operation has the possibility of complications in due course does not mean it is not safe and efficacious (T601.38 -T602.05 [TRA.500.007.0001\_2 at .0093 - .0094]).

(j) Professor Roovers opined that he had no doubt that mid-urethral slings are the surgical treatment of first choice for SUI (Roovers 1, pp.6-7 [EXP.020.033.0001\_4 at .0008\_4 -.0009\_4]).

659 We have previously dealt with some of this evidence in dealing with the appellants’ overarching contentions and it is again worth noting that the appellants’ use of these parts of the evidence is highly selective, and reflects their attempt to conduct the appeal only on the basis of the parts of the evidence which suit them. That is impermissible. In any event, this evidence does not show that the primary judge erred in finding that the devices were defective The weight of the evidence strongly supports her Honour’s finding that at all material times each of the devices had a defect under s 75AC.

660 As the respondents submitted, none of the evidence referred to by the appellants engaged with a fundamental matter underpinning the finding of defect, being that at all material times implantation of each of the devices presented a material risk of harm against which the appellants provided no or no sufficient warning.

661 The statutory test is an objective one as to the safety “persons generally are entitled to expect”. *Merck* (at [201]) stands for the proposition that goods may have a defect because they present a risk of injury and the manufacturer fails to provide any or any sufficient information, advice or warning in relation to that risk. But goods that present a risk of harm may nevertheless not be defective under s 75AC, if the manufacturer provides appropriate information, advice or warnings about that risk. *Merck* does not suggest that a product which presents a material risk of harm cannot remain on the market or even be a product of choice for a medical practitioner, provided that the risk of harm is the subject of an appropriate warning by the manufacturer. Thus, it does not address the statutory test that some pelvic surgeons gave evidence, or that relevant professional organisations made statements, that a particular device is the “gold standard” or the preferred method of treatment, that the device continues to be used by surgeons, or that the device has advantages in comparison to alternative treatment options: see AS [30(a), (b), (f), (g), (h), (j)].

662 Turning specifically to some of the other matters raised by the appellants in AS [30]:

(1) in relation to AS [30(a)], the introduction of a discussion of complications, including chronic pain, is the notable difference between the 2014 and 2017 RANZCOG position statements on midurethral slings. As we have said above, the stark differences between the two documents shows that knowledge of a number of the pleaded complications emerged over time and very late in the life of the devices. The decision of RANZCOG to re-issue the statement in 2017 to introduce a discussion of risks such as chronic pain tends to show that the organisation did not consider those risks to be well known at that point, and therefore not well-known when the 2014 position statement was made. As the respondents submitted, other statements as to the benefits of mid-urethral slings by professional organisations similarly do not advance the appellants’ position (particularly those omitted from AS [30], such as IUGA’s expert report of 2015 which rejected the proposition that polypropylene is suitable for vaginal use without consideration of other materials because there was neither translational nor clinical evidence to support that view: SHI.MESH.00045854). For the reasons previously explained, we can see no force in the criticism that epidemiologists are not in a position to judge what is clinically as distinct from statistically significant. As we have said, the primary judge did not err in finding that the evidence of the epidemiologists, biostatisticians, biomaterials experts and pathologists had utility, and in using it for the purposes that her Honour did;

(2) in relation to AS [30(c)], it may be accepted that for many women the devices proved effective and may have given rise to a lesser occurrence of other events such as hospital stay and wound morbidity compared to native tissue repair surgery, and that in many cases implantation of the devices can be complication free. The proposition that this is so in a “high” percentage of cases need not be debated. But even assuming that is the case, it does not show error in the finding of defect. The respondents were not required to show that the risk to safety associated with the devices affected all persons who were implanted with them (although the evidence did show that the pleaded complications *could* be suffered by every woman implanted with one of the devices: TJ [405]). It is sufficient to show that the defect affects some people: *Merck* at [201]. That in a high percentage of cases the devices are effective does not preclude a finding of defect. In *Merck* Vioxx was found to present a 0.5% increased risk of myocardial infarction, and in the absence of a warning that was held sufficient to constitute a defect. In the present case a number of the pleaded complications were found to be “common” (1% to 10%) on the scale used by the Royal College of Obstetricians and Gynaecologists (TJ [808]) and no adequate warning was provided;

(3) in relation to AS [30(d)], as we have said, we have no difficulty in accepting that treating pelvic surgeons of women suffering SUI or POP played a key role in providing individualised medical advice and recommendations to them, and in obtaining their informed consent to implantation of a device. But that only serves to underscore the importance of the appellants warning the surgeons of the potential for each of the devices to cause all of the pleaded complications, which Dr Hinoul conceded the appellants were aware of from the time the devices were first supplied anywhere in the world, and which complications the appellants conceded were clinically significant;

(4) in relation to AS [30(e)], there was evidence that Australian surgeons considered the POP devices had no justification for use and the SUI devices should be used in far more limited circumstances and subject to far more extensive warnings than the appellants provided. In any event, the appellants’ proposition does not show error in the finding that the devices have a defect. It may, of course, be relevant evidence that some treating surgeons do not consider a particular device to be unsafe, or that some treating surgeons wish to continue to use the device. But the statutory test is an objective one as to the safety “persons generally are entitled to expect” having regard to all relevant circumstances. To establish the devices were defective the respondents did not need to adduce evidence from surgeons that the devices were unsafe or should be taken off the market. Safety is a relative concept, and although goods present a risk of injury they may nevertheless not have a defect if the manufacturer provides appropriate information, advice or warnings about that risk. Again, the appellants failed to properly engage with the fact that a fundamental matter underpinning the finding of defect was that at all relevant times implantation of each of the devices presented a risk of harm through the pleaded complications, against which risk the appellants provided no or no sufficient warning; and

(5) the same can be said in relation to AS [30(i)]. We have no difficulty in accepting that merely because an operation involves the possibility of complications does not mean it is not safe and efficacious. In this argument the appellants again failed to engage with a fundamental matter underpinning the findings of defect, being their failure to provide any or any adequate warning in relation to material risks presented by the devices of which they were aware.

663 The fifth alleged error is that the primary judge erred in converting the concession by senior counsel for the appellants of *potential* clinical significance to a finding of *certainty* of clinical significance, as shown at TJ [189]-[191]. This is said to have led the primary judge into error as there are a number of pleaded complications where no finding was made, or could be made on the evidence as to their incidence and severity.

664 As previously discussed, this submission is without foundation. The appellants conceded in clear terms each of the pleaded complications is clinically significant having regard to, first, the incidence of each complication and, second, the consequence of each complication if it came to pass (except for those limited occasions where the appellants said there was some relevant consideration of significance which would be specifically identified to her Honour). In relation to incidence, senior counsel said that the appellants would not take any issue with the precise rates of complication associated with each device. In relation to consequence, senior counsel for the appellants acknowledged that this was part of the concept of clinical significance and was subject to the concession. For the reasons earlier given, the appellants’ Annexure C is misconceived. Given the appellants’ concessions, it was unnecessary for the primary judge to make evidentiary findings in relation to the incidence of the pleaded complications. Nevertheless her Honour referred to a “snapshot” of the evidence (TJ [1137]) and made some limited findings. There is no error in that. Otherwise, the appellants’ reference to evidence of some of the pleaded complications being minor (bladder perforation and mesh erosion), as already discussed, is also confounded by other considerations: (a) the evidence is selective, (b) the references to the evidence fail to identify other findings of the primary judge to the contrary, and (c) the contention fails to recognise that the pleaded complications involve a *risk* which is material for every woman considering implantation with one of the devices. The materiality of the risk is not affected by the fact that the occurrence of the risk in any individual woman may involve a lesser degree of seriousness of injury.

665 The sixth alleged error is that the primary judge did not properly consider and failed properly to take account of the significance of the evidence as to the differences between each of the devices, as outlined in the appellants’ Annexure B.

666 We accept that there are differences between each of the devices, including the method of implantation and the quantities of mesh, and that the type of mesh used in POP devices differed. It may also be accepted that there is a basis in the evidence for concluding that there is a relationship between the size or amount of the mesh used and the likelihood of complications, as the primary judge said at TJ [825].

667 The fact remains, however, that the appellants conceded in relation to each of the devices that each of the pleaded complications was clinically significant in terms of incidence and severity. They said that they would not take up any issue as to the precise rate of incidence of any complication: TJ [1134]. In those circumstances it was not necessary for the primary judge to make findings about the incidence and severity of each pleaded complication for each device; any difference in the incidence and severity of complications between the different devices was subsumed by the concession.

668 The seventh alleged error is based on appeal ground two, in respect of which the respondents filed a notice of contention. The appellants submitted that in finding that each device had a defect the primary judge erred in relying on, or placing too much weight on, conclusions of non-compliance with the requirements of CE marking. They contended that there was no suggestion either by way of pleading or submission that the CE Mark by itself, or by way of representation, formed a basis for finding that the devices were defective, and the respondents should have been held to their pleading.

669 This ground of appeal must also be rejected.

670 It can be accepted that the 5FASOC did not plead that the devices had a defect based on the CE Mark or any representation said to be made by the CE Mark. The closest the pleading came is at [26(b)] and [61] where it was alleged that the safety of the POP devices and the SUI devices respectively was not such as persons generally were entitled to expect because, amongst other things, prior to the supply of the devices in Australia the appellants did not undertake any, or any adequate, clinical or other evaluation of the risks and effectiveness of the devices, including their long-term risks and effectiveness (called the Mesh Evaluation Matters and the Tape Evaluation Matters). We note that the primary judge’s conclusion that a CE Mark should not have been applied to the devices was to a significant extent based in a finding that the appellants’ failed to conduct any appropriate clinical trials before releasing the devices to the market.

671 It was uncontentious below that the devices received regulatory approval in Australia based on the strength of the CE marking. In opening at trial, the appellants’ senior counsel informed the Court that registration of the devices in Australia “piggybacks off the CE authorisation”, confirming that “if a device is good enough for the European community, it’s good enough” for Australian regulatory purposes. The appellants said the same in written opening submissions. That reflected the fact that the essential principles in the Medical Devices Regulations in Australia were harmonised with international standards established by a Global Harmonisation Task Force (**GHTF**): TJ [1371]. The European Essential Requirements are substantially identical to the Australian essential principles: TJ [1404]-[1405]. Once a manufacturer has declared – by CE Mark – that their product complies with the European Essential Requirements, the product is permitted to be recorded on the ARTG. The system is, in substance, self-regulating: TJ [1408].

672 Although it was not pleaded, the controversy between the parties included a claim advanced by the respondents that the devices carried a CE Mark, which they should not have as the appellants had not, in fact, complied with the requirements and standards to obtain the CE Mark, which was relevant to the question of defect.

673 First, whether or not it was pleaded, the primary judge was obliged to consider the CE Mark. Section 75AC(2)(c) provides that in determining the extent of the safety of the relevant goods “the use of any mark in relation to” the goods is a mandatory consideration. Each of the devices carried the CE Mark and the primary judge was required to take that into account in deciding whether the devices had a defect.

674 Second, a product is defective under s 75AC if its safety is less than persons generally are entitled to expect having regard to “all relevant circumstances”. As the primary judge said at TJ [1342], one matter that will have a bearing on the safety expectations of the public at large is whether the devices satisfied relevant regulatory requirements and standards. Persons generally are entitled to expect that medical devices have, in fact, satisfied all regulatory requirements and standards which apply to their supply in Australia. In the circumstances of the present case it should have been plain to the appellants that the evidence of the respondents’ regulatory experts as to the appellants’ failure to comply with the requirements and standards for obtaining and retaining the CE Mark on each of the devices, and thus obtaining and retaining Australian regulatory approval, would be a relevant consideration for the Court under s 75AC.

675 Third, the respondents pleaded that the devices had a defect but did not raise the CE Mark. In the circumstances of the case we are not persuaded that their failure to plead that the existence of the CE Mark was a relevant circumstance in relation to defect means that issue was not before the Court for consideration. It plainly was in issue given the evidence and the course of the forensic contest.

676 The appellants were on notice that the respondents’ regulatory experts would give evidence that, in a regulatory system which, in substance, depended on the manufacturer’s own certification that it had met the requirements and standards for a CE Mark, the appellants should not have so certified, because they had not met the requirements. Having regard to the respondents’ regulatory experts’ evidence the appellants must have understood that part of the respondents’ case was that the appellants had insufficient clinical evidence to apply the CE Mark to the devices, and thus to obtain regulatory approval to market the devices in Australia. They must therefore have understood that the application of the CE Mark to the devices was a relevant circumstance under s 75AC in deciding whether the safety of the devices was such as persons generally were entitled to expect.

677 It is noteworthy that although the appellants submitted that the respondents should be held to their pleading, they did not contend that they were taken by surprise, nor that they suffered any prejudice. In our view they could not do so when in written opening submissions at trial the respondents said (at [41]):

The regulatory evidence will establish that the [appellants] did not have adequate clinical evidence to support CE Marking of its Implants, did not adequately justify its reliance on existing clinical data, and should have conducted clinical investigative studies.

678 The respondents in written opening submissions also said (at [42]-[45]) that following the release of the devices onto the market, the appellants should have but did not conduct post-market clinical follow-up studies for the devices, should have but did not have in place proactive post-market surveillance programs which included post-market clinical follow-up studies, should have but did not have effective procedures for systematic review information received by it, of the scientific literature, and for the active collection of information relevant to the devices. Further, despite the fact any complaints should have been the subject of close analysis by the appellants, the evidence indicated that mishandling of complaints was not rare and the appellants’ systems allowed “unconfirmed” reports to be discounted and therefore not analysed, even when injury was reported.

679 Under the heading “[w]ere the Implants defective?” the respondents said in opening (at [109]):

In their haste to get the Implants to market and sold as quickly and profitably as possible, the [appellants] made inadequate efforts to evaluate the safety of the Implants, or to give proper warnings about them … They also failed to keep up-to-date with advances in knowledge after the product went to market.

680 Those submissions were supported by expert evidence filed by the respondents in advance of the hearing. For example:

(1) Dr Allman, a clinical biochemist from the United Kingdom, had extensive relevant experience in regulatory affairs, having had a 30 year career in the medical device industry. His responsibilities included achieving or remedying compliance with the European medical devices directives, implementing processes for post-market surveillance, managing relationships with notified bodies, and advising on European clinical evaluation and investigation requirements: TJ [1348]. In his first report dated 8 September 2016, he said that, although Ethicon had procedures in place that were intended to meet regulatory requirements for obtaining CE marking for each of the devices, it did not in fact have adequate clinical evidence and did not have sufficient justification to affix a CE Mark to any of them. He concluded that Ethicon did not comply with the steps that a reasonable manufacturer would undertake to ensure that it was appropriate for the devices to maintain their CE marking once released onto the market: TJ [1480]; and

(2) Ms Holland, a biomechanical engineer and quality assurance consultant from the United States, had some 30 years’ experience in regulatory compliance, quality systems development, auditing, and regulatory affairs in the medical device industry. She regularly analysed the design control and risk management processes and documentation of medical device manufacturers to identify their strengths and weaknesses and to evaluate whether the documentation complies with industry standards and practices. She also regularly examined their quality processes to determine operational effectiveness and compliance with regulations applying in the United States and the European Union: TJ [1349]-[1350]. In her report dated 24 August 2016 she was highly critical of Ethicon’s approach to quality assurance and risk management. She said that Ethicon did not adhere at any time to EU or US industry requirements and regulatory standards in any of the following areas: design validation, evaluation of complaints, and management responsibility or risk management. She also said that during the development of both the SUI and the POP devices, no overarching, cohesive risk management system was in place. She described Ethicon’s design validation process as flawed because it did not adequately represent the population of surgeons using the devices and feedback from surgeons was not fully evaluated or implemented: TJ [1501].

681 The appellants joined issue with the merits of the respondents’ regulatory evidence in their written opening submissions at trial: at [63]-[68]. They submitted that “[t]he evidence of the [respondents’] regulatory and Quality Assurance experts overstates the requirements for pre- and post-market assessment of the Implants.” They argued that their certification for the CE Marks “followed audits of the relevant design and risk assessment documentation for each Implant to confirm compliance with the applicable international standards”. They said that Ethicon:

…appropriately relied upon its prior knowledge of the risks associated with Prolene sutures and mesh in conducting its risk assessments, and applied the design controls and risk mitigations in place for existing mesh products and Implants to new versions of the Implants, which is entirely consistent with clinical practice and the intent of the standards.

They submitted that “[m]aintenance of the CE Markings (and ARTG inclusion) for the Implants has involved ongoing clinical reviews, post-market surveillance and complaint monitoring”: at [64]-[68].

682 In written closing submissions at trial (chapter 2, [47]) in a section headed “[l]egal issues common to each claim”, the appellants described the evidence of the respondents’ regulatory experts as “of no assistance to the Court” and “of peripheral relevance”. Those submissions only make sense if the appellants understood that the controversy before the Court included the respondents’ claim that the devices carried a CE Mark, which they should not have as the appellants had not, in fact, complied with the requirements and standards to obtain the CE Mark, which was relevant to the question of defect.

683 Her Honour rejected the appellants’ contention that the evidence of the respondents’ regulatory experts was not relevant at TJ [1356]-[1358], including because the evidence disclosed that the regulatory system is largely dependent on the manufacturer being frank with the regulators.

684 The primary judge also rejected the appellants’ contention that the evidence of the respondents’ regulatory experts was of little assistance because the respondents did not plead that or how the foreign regulatory environment informed the appellants’ obligations: TJ [1359]. Her Honour rejected that contention on two bases, first, that the relationship between the European and the Australian regulatory regimes was not a matter that needed to be pleaded. It was a matter for evidence. Second, Dr Beech gave unchallenged evidence that the Australian system is very similar to the European system and that Australia accepts European certification: TJ [1360]-[1362].

685 It is clear from her Honour’s reasons that she considered the evidence of the appellants’ regulatory non-compliance to be relevant to both the statutory and the common law claims. At TJ [1360] her Honour rejected the appellants’ contention that the evidence of the respondents’ regulatory experts went outside the pleading. The appellants have not challenged the primary judge’s finding at TJ [1360] nor explained why it was wrong.

686 Her Honour went on to say (at TJ [1363]):

Each of Dr Allman, Ms Holland and Dr Pence was well-qualified in the field. Each had extensive relevant experience and an in-depth understanding of the regulatory requirements. Each presented as a conscientious and careful witness exhibiting no hint of partisanship. Each easily withstood cross-examination. The respondents’ submissions largely ignored their evidence. Neither in writing nor orally did they engage with it. Indeed, their submissions did not even mention the witnesses’ criticisms of their conduct. Instead, as I observed earlier, they tried to marginalise the evidence. This strategy might have been a convenient way to sideline evidence that was potentially very damaging. But it was a risky one. And it did not succeed.

Her Honour concluded, in effect, that the appellants made a forensic choice not to adduce evidence in response to the respondents’ expert evidence regarding the appellants’ non-compliance with the requirements and standards to obtain and retain the CE Mark: TJ [1338].

687 In ***Banque Commerciale*** *SA en Liquidation v Akhil Holdings Ltd* [1990] HCA 11; (1990) 169 CLR 279 at 296, Dawson J said, as cited with approval in *Vale v Sutherland* [2009] HCA 26; (2009) 237 CLR 638 at [41]:

But modern pleadings have never imposed so rigid a framework that if evidence which raises fresh issues is admitted without objection at trial, the case is to be decided upon a basis which does not embrace the real controversy between the parties … cases are determined on the evidence, not the pleadings.

688 To similar effect, in *Betfair Pty Ltd v Racing New South Wales and Anor* [2010]FCAFC 133; (2010) 189 FCR 356 at [51]-[53], [55]-[58] the Full Court explained that at trial a party is entitled to have the opposing party confined to that party’s pleadings, but if the first party does not seek to so confine the opposing party but allows the other party to raise other material facts and issues for the determination of the Court, then the Court is permitted and possibly obliged to decide the proceeding on the further material facts and issues raised and addressed at trial. The Full Court said (at [52]-[53]):

Pleadings are a means to an end and not an end in themselves (*Banque Commerciale* per Dawson J at 292-3). As early as 1916 Isaacs and Rich JJ said, in *Gould and Birbeck and Bacon v Mount Oxide Mines Ltd (in Liquidation)* (1916) 22 CLR 490 (at 517):

Undoubtedly, as a general rule of fair play, and one resting on the fundamental principle that no man ought to be put to loss without having a proper opportunity of meeting the case against him, **pleadings should state with sufficient clearness the case of the party whose averments they are. That is their function**. **Their function is discharged when the case is presented with reasonable clearness.** Any want of clearness can be cured by amendment or particulars. **But pleadings are only a means to an end**, and if the parties in fighting their legal battles choose to restrict them, or to enlarge them, or to disregard them and meet each other on issues fairly fought out, it is impossible for either of them to hark back to the pleadings and treat them as governing the area of contest.

(Emphasis added).

Approached in these terms, the question is whether the respondents knew the nature of the case they had to meet.

689 Their Honours further explained (at [55]):

The course of proceedings is in the control of the Court. That control is to be exercised for the attainment of a just outcome. There will obviously be cases where a pleaded case does not raise an important fact for attention. If that remains the position at the end of the case, the case may be lost on that basis, so far as it depends on that fact. Sometimes it would be unfair to allow a party to amend a case, or a pleading, to raise a new matter which could have been, but was not, raised earlier. **On the other hand, mere infelicity of drafting will rarely be allowed to defeat a case on its merits if the merits of the case have been made apparent on the evidence without unfairness to the other party**.

(Emphasis added).

690 The evidence of the respondents’ regulatory experts formed part of the “real controversy” between the parties. The appellants knew that their devices carried the CE Mark and must have known that “the use of any mark in relation to” the goods is a mandatory relevant circumstance under s 75AC. They knew that the case they faced included a claim that they did not have adequate clinical evidence to support their application of the CE Mark to the devices, and thereby their obtaining Australian regulatory approval. They must have known that resolution of the question whether their certification that the devices met the requirements and standards for applying the CE Mark was reasonable or appropriate may be a relevant circumstance under s 75AC.

691 Fourth, in relation to the appellants’ other contentions, it is far from central that the primary judge had no evidence as to any Australian surgeon’s or patient’s understanding or appreciation of the CE Mark or as to what surgeons’ knew about the path to regulatory clearance for medical devices: TJ [3250].

692 This is a curious submission. The IFUs for the devices (using Gynemesh PS and TVT as examples) expressly stated:

CE Mark: Product conforms to the essential requirements of the Medical Device Directive 93/42/EEC.

The appellants thereby represented to treating surgeons that they had complied with a directive that required them to inform users of all residual risks associated with the device (that is, risks which cannot be eliminated or protected against). Having done so, however, they now argue that the primary judge should not have taken that into account as a relevant circumstance under s 75AC.

693 The statutory test is an objective one as to the safety that persons generally are entitled to expect, not what surgeons or patients actually expected. Irrespective of what surgeons or patients actually understood from the CE Mark, the fact that the appellants made this representation is plainly a relevant circumstance for consideration under s 75AC.

694 The primary judge was obliged to decide whether the safety of the devices was such as persons generally were entitled to expect having regard to the presence of the CE Mark in relation to the devices and the evidence of the respondents’ regulatory experts that, in fact, the appellants did not comply with the requirements and standards to apply CE Marks to the devices. It was mandatory for the Court to take that evidence into account.

695 We are not persuaded that the primary judge erred as alleged under appeal ground 2.

696 But even if we are wrong in that view, it is not material to the result in the appeal. The fundamental matter underpinning the primary judge’s finding of defect was the conclusion that at all material times implantation of the devices presented a risk of harm through the pleaded complications, against which risk the appellants failed to provide any or any adequate warning. That finding was challenged in the appeal but in in our view no error was established. Having regard to that and to the other relevant circumstances under s 75AC to which her Honour referred at TJ [3458], [3496], [3499], if her Honour’s findings based on the appellants’ non-compliance with the requirements for CE marking were erroneous, there nevertheless remains a strong and sufficient basis for concluding that each of the devices was defective.

##### 6. MERCHANTABLE/ACCEPTABLE QUALITY AND FITNESS FOR PURPOSE (GROUND 3)

697 Under this ground the appellants alleged that, as a consequence of grounds 1 and/or 2, the primary judge erred in finding that each of the devices was not of merchantable or acceptable quality under s 74D or s 54 of the ACL, and not reasonably fit for purpose under 74B of the TPA and s 55 of the ACL.

698 It was common ground before the primary judge that these causes of action turned on the same issues as the defect claims: TJ [3544]. The same was true before us, and the parties merely reiterated their submissions in relation to defect. For the reasons we explained in relation to defect, this ground must also be dismissed.

##### 7. NEGLIGENCE – FAILURE TO WARN (GROUND 5)

###### 7.1 Primary judge’s conclusions

699 As noted, the primary judge concluded that a reasonably prudent manufacturer and supplier in the position of the appellants would have warned prospective users of all of the pleaded complications except the risk of psychiatric injury and that the appellants were negligent in failing to do so. The appellants alleged that the primary judge erred by not properly considering the evidence of the pelvic surgeons, preferring the evidence of the non-clinical experts and not properly considering the differences between the different devices.

###### 7.2 Appellants’ submissions

700 The appellants contended that the primary judge erred in finding that they breached their duty of care to consumers by providing information that “fell well short of capturing all known, let alone reasonably foreseeable risks, and was liable to mislead the reader about the safety and efficacy of the various devices”: TJ [3878].

701 The appellants alleged that the primary judge departed from the test of whether reasonable steps had been taken: AS [42]. Instead of applying that approach, according to the appellants, the primary judge focused, retrospectively, on the list of complications developed by the respondents’ lawyers after the devices were on the market rather than asking what, prospectively, the exercise of reasonable care would require in response to the risk. This ignored the anterior question of the content of the duty to take reasonable care, an approach which invites error as demonstrated at TJ [3838] and [3844]: AS [45]. These paragraphs have been set out above. In these paragraphs the primary judge rejected the argument that because users of the devices either knew of the pleaded complications or could have acquired that knowledge, the appellants could not have been negligent in failing to warn those users about the pleaded complications.

702 The reasons the primary judge gave after TJ [3838] were that:

(1) it is not to be assumed that the physician or surgeon has other potential sources of information: TJ [3839];

(2) since the commencement of the Medical Devices Regulations on 4 October 2002, there has been an unqualified statutory obligation to provide certain information with any medical device including “[a]ny warnings, restrictions, or precautions that should be taken, in relation to use of the device” and IFUs were required to include “[a]ny contra-indications, warnings, restrictions, or precautions that may apply in relation to use of the device” and “[f]or an implantable medical device—information about any risks associated with its implantation”: TJ [3840] and [3841];

(3) the notion that the medical literature was sufficient to alert the medical profession of the true nature and extent of the risks associated with implantation of mesh was rebuffed by a number of witnesses: TJ [3843];

(4) the appellants had an obligation to warn of all reasonably foreseeable risks regardless of what they might presume to think surgeons already knew or could learn from their own research or upon inquiry or after further education: TJ [3844];

(5) the appellants pursued a marketing strategy that targeted both surgeons and patients. Having embarked upon that course, the respondents were bound to take reasonable care to ensure that the information they imparted was complete and sufficient to warn their target market of all reasonably foreseeable risks of harm: TJ [3845]; and

(6) consumers are in a vulnerable position and depend on the manufacturer and the doctor to provide enough information to enable them to make an informed decision about their treatment: TJ [3847].

703 According to the appellants, the primary judge’s analysis ignores the critical question whether, having regard to the nature of the devices as medical devices (including both their risks and benefits) and the knowledge of treating surgeons, the totality of the warnings and other information provided was reasonable. It substitutes the required multi-factorial approach with a single inquiry as to whether each complication in the pleading was foreseeable. In so doing the primary judge inverted the burden of proof so that it was the appellants which had to prove, in the primary judge’s language, that they had in some way an “excuse” from liability: AS [47].

704 The appellants alleged that the primary judge assessed whether they had taken reasonable steps without properly taking into account the critical role of the treating surgeon: AS [48]. The standard of reasonableness, they submitted, must be considered in light of the knowledge of those specialist surgeons. It follows that the finding at TJ [3839] (“[i]t is not to be assumed that the physician or surgeon has other potential sources of information”) is both analytically and factually flawed (see appellants’ Annexure D): AS [49].

705 The appellants alleged that the primary judge did not properly consider and failed properly to take account of the significance of the evidence as to the differences between each of the POP devices and the SUI devices and in particular the incidence and severity of complications. The primary judge was required to consider the reasonableness of the appellants’ actions in connection with each of the devices separately. Part of that inquiry required a consideration of the incidence and severity of complications for each device which did not occur: AS [50].

###### 7.3 Discussion

706 It should be noted at the outset that ground 5 does not involve any suggestion that the primary judge misapplied any provision of the CLA or the Wrongs Act which applied to the claims of the representative respondents (that is, the CLA which applied to Mrs Gill and Mrs Sanders and the Wrongs Act which applied to Mrs Gill).

707 It should also be noted that, as the respondents submitted, the appellants did not contend that the primary judge was wrong to conclude that patients should have been warned about the matters set out in the answer to common question 18 before they were implanted with any of the devices. As the respondents noted, the appellants submitted to the primary judge (SBM.020.002.0024 [108]):

It is uncontroversial that manufacturers of a product owe duties of care to consumers to take reasonable steps to safeguard consumers against foreseeable risks of injury, and that the duty extends to ensuring appropriate and necessary information about the product is communicated to persons who will use the product.

708 The appellants’ case, as ultimately formulated after Dr Hinoul’s concessions, was that the appellants did not need to provide that warning as pelvic surgeons were already aware of those matters or the respondents had not proved that pelvic surgeons did not know about the pleaded complications. We have rejected that contention above.

709 In oral submissions the appellants contended that the primary judge must be wrong at TJ [3883] and [3884] where this was said:

[3883] As the manufacturer of TVT, Ethicon Sàrl breached its duty of care to Mrs Sanders by failing to conduct adequate clinical evaluations of the device before her implant surgery on 12 March 2001. It also breached its duty of care to Mrs Gill by failing to conduct an adequate evaluation of Prolift, more particularly, Prolift Total, before her implant surgery on 12 January 2007. Equally, the company breached its duty of care to both these applicants by failing to issue adequate warnings about the risks to which they were exposed if they were to undergo surgery with the relevant device and about the shortcomings of their evaluations. As the manufacturer of Gynemesh PS, Ethicon Inc. breached its duty of care to Mrs Dawson by failing to conduct an adequate evaluation of its safety before her implant surgery on 8 May 2009 and by failing to provide adequate warnings of the risks to which she was exposed if she were to agree to implantation with the device and of the shortcomings of their evaluations.

[3884] JJM also breached its duty of care to the applicants. Like Ethicon Sàrl and Ethicon Inc., it failed to provide adequate warnings of the risks of the pleaded complications and of the limitations of the clinical evaluations.

710 The appellants submitted that it cannot be the case that they were bound to inform patients directly of the pleaded complications if pelvic surgeons knew about them. It may be accepted that it would have been sufficient for the appellants to have warned pelvic surgeons, rather than patients directly, about the pleaded complications. But, as discussed, the evidence shows that the appellants did not do so.

711 In oral submissions the appellants sought to identify other alleged errors by the primary judge. Reference was made to TJ [3646] where the primary judge said:

It is well established that the standard of care is determined by what a reasonable person in the position of the respondent or respondents would do in response to the reasonably foreseeable risk: *Graham Barclay Oysters (HC)* [*Graham Barclay Oysters Pty Ltd v Ryan* [2002] HCA 54; (2002) 211 CLR 540] at [192] (Gummow and Hayne JJ). The response will be affected, amongst other things, by the nature of the product, the gravity of the risk and the severity of the consequences should the risk eventuate. In the case of an inherently dangerous product or a product designed for human consumption or implantation, particularly permanent implantation, the level of caution required of a reasonable manufacturer (and of a supplier in the position of JJM) will necessarily be high.

712 The question of what a reasonable person would do in response to the reasonably foreseeable risk is relevant to the requirement of the standard of care (reasonableness) in the particular circumstances, and thus breach of the duty of care. Accordingly, in *Graham Barclay Oysters Pty Ltd v Ryan* [2002] HCA 54; (2002) 211 CLR 540 at [192], this was said:

A duty of care that is formulated retrospectively as an obligation purely to avoid the particular act or omission said to have caused loss, or to avert the particular harm that in fact eventuated, is of its nature likely to obscure the proper inquiry as to breach. That inquiry involves identifying, with some precision, what a reasonable person in the position of the defendant would do by way of response to the reasonably foreseeable risk.

713 On a fair reading of the primary judge’s reasons in context, we do not consider that she was applying a standard of care other than objective reasonableness in the particular circumstances, as is apparent for her reference in TJ [3646] to a “reasonable” manufacturer in the position of the appellants: see also, for example, TJ [3656]-[3669]. The primary judge’s reference to the level of caution which a reasonable manufacturer of a permanent implant would exercise being “high” is nothing more than a reflection of the fact that the objective standard of reasonableness which might be required in any particular case is related to the probability and nature of the risk involved. This reasoning is orthodox.

714 The appellants also took issue with the statement at TJ [3652] that the primary judge did not accept that the “standard of care expected of the manufacturer, or the supplier for that matter, is affected by the fact that the devices are supplied through surgeons or following consultation with surgeons.” If her Honour meant nothing more than that the relevant standard of care remains reasonableness, assessed objectively in the circumstances which includes the role of the treating pelvic surgeon as a learned intermediary, then it is unexceptionable. If her Honour meant that the role of the pelvic surgeon is irrelevant to the duty, its content, the standard of care, and breach then, as already noted, we would disagree. Whatever the meaning, the primary judge did not in fact resolve the issues on the basis that the intermediary function of pelvic surgeons was irrelevant.

715 The appellants said that the primary judge was wrong to apply the observation in ***McLean v Tedman***[1984] HCA 60; (1984)155 CLR 306 at 311 that the “standard of care expected of the reasonable man requires him to take account of the possibility of inadvertent and negligent conduct on the part of others”: TJ [3648]. It is true that *McLean v Tedman* involved an employer’s liability for a dangerous system of work. The point the primary judge was making, however, was limited. As she said at TJ [3648] reasonable care required the appellants to consider that a medical practitioner might not inform a patient about a risk of the devices which the appellants had not brought to the practitioner’s attention. We do not consider this observation involves error.

716 As the primary judge correctly identified at TJ [3620], the respondents’ claims were that the appellants were negligent in failing to warn of the risks of the devices of which they were (or ought to have been) aware and of the fact that they had not undertaken sufficient steps to evaluate their safety before launch. In concluding that the appellants were liable to each of the respondents for negligence in failing to warn of the risks of the devices of which the appellants were aware and of the fact that they had not undertaken sufficient steps to evaluate their safety before launch, the primary judge recorded that the appellants accepted that they owed a duty to exercise reasonable care to avoid injury to consumers: TJ [3624]. The appellants do not resile from that acceptance in the appeal. Nor do they directly challenge the primary judge’s conclusion at TJ [3627] that, insofar as this aspect of the respondents’ claims is concerned, the relevant duty of care included a duty to provide accurate information about the performance and safety of the devices, including warnings about potential complications and contraindications. Moreover, no challenge is made to the primary judge’s approach to the liability of JJM in negligence in its capacity as a supplier of the devices, consistent with the approach of the appellants below which the primary judge records at TJ [3642] (that the appellants never distinguished between the positions of the first and second appellants as manufacturers and JJM’s position as a supplier of the devices in Australia).

717 Contrary to the appellants’ submissions, TJ [3844] and [3838] do not disclose error. In particular, they do not suggest that the primary judge ignored the anterior question of the content of the relevant duty of care and failed to approach the issue by asking what, prospectively, the exercise of reasonable care involved. The primary judge defined the content of the relevant duty of care without regard to the pleaded complications. She concluded that the relevant duty of care was a duty to provide accurate information about the performance and safety of the devices, including warnings about potential complications and contraindications: TJ [3627]. At TJ [3844] and [3838] the primary judge explained why she rejected the appellants’ submissions that the existence of the independent duty of medical practitioners to warn or provide information to their patients did not obviate the duty of care owed by the appellants as identified by the primary judge. Neither these paragraphs nor any other aspect of the primary judge’s reasons indicate that she ignored the anterior question of the content of the relevant duty of care and failed to approach the issue by asking what, prospectively, the exercise of reasonable care involved. Nor do her reasons suggest that the primary judge assumed that anything more than reasonable care, assessed objectively in the particular circumstances, was required to be exercised by the appellants.

718 Further, it is inherently unlikely that the primary judge would have proceeded on the bases of the errors asserted by the appellants in circumstances where the primary judge identified the relevant principles to be applied in orthodox terms. In particular, at TJ [3653] the primary judge referred to Mason J’s statement in *Wyong Shire Council v Shirt* [1980] HCA 12; (1980) 146 CLR 40 at 47-48 that:

In deciding whether there has been a breach of the duty of care the tribunal of fact must first ask itself whether a reasonable man in the defendant’s position would have foreseen that his conduct involved a risk of injury to the plaintiff or to a class of persons including the plaintiff. If the answer be in the affirmative, it is then for the tribunal of fact to determine what a reasonable man would do by way of response to the risk. The perception of the reasonable man’s response calls for a consideration of the magnitude of the risk and the degree of the probability of its occurrence, along with the expense, difficulty and inconvenience of taking alleviating action and any other conflicting responsibilities which the defendant may have. It is only when these matters are balanced out that the tribunal of fact can confidently assert what is the standard of response to be ascribed to the reasonable man placed in the defendant’s position.

719 At TJ [3656] the primary judge stated that:

To determine whether or not the duty has been breached it is necessary to consider what a reasonable person in the position of the respondents would have done if confronted by a foreseeable risk. The inquiry is a prospective one. It cannot be confined by the circumstances in which the applicants were injured: *Vairy v Wyong Shire Council* [[2005] HCA 62] (2005) 223 CLR 422 at [125]–[129] (Hayne J); *Adeels Palace Pty Ltd v Moubarak* [[2009] HCA 48;] (2009) 239 CLR 420 at [31] (French CJ, Gummow, Hayne, Heydon and Crennan JJ).

720 In other words, the primary judge specifically referred to the reasoning in *Vairy v Wyong Shire Council* [2005] HCA 62; (2005) 223 CLR 422 at [125]-[129], which reasoning the appellants contend the primary judge failed to apply.

721 At TJ [3657] the primary judge also identified the cumulative statutory requirements for liability in negligence for any harm caused by a failure to take precautions against a risk of harm that the risk was foreseeable in the sense that it was a risk of which the appellants knew or ought to have known, the risk was not insignificant, and in the circumstances, a reasonable person in the appellants’ position would have taken those precautions.

722 As the primary judge also noted at TJ [3669], the appellants knew about all the relevant risks and conceded that each of the risks was clinically significant (that is, material). The issue in dispute was whether the appellants acted unreasonably in not taking the relevant precautions (that is, insofar as ground 5 is concerned, providing accurate information about the performance and safety of the devices, including warnings about potential complications and contraindications). The primary judge was satisfied that it was unreasonable for the appellants not to have provided accurate information about the performance and safety of the devices, including warnings about potential complications and contraindications for a number of reasons, namely:

(1) the relevant risks were not only foreseeable but known: TJ [3837];

(2) the relevant risks were at least “not insignificant”: TJ [3837];

(3) it is not to be assumed that the physician or surgeon has other potential sources of information apart from the appellants: TJ [3839];

(4) since the commencement of the Medical Device Regulations on 4 October 2002, there has been an unqualified statutory obligation to provide certain information with any medical device including any warnings, restrictions, or precautions that should be taken, in relation to use of the device: TJ [3840];

(5) the Medical Device Regulations also required IFUs to include any contraindications, warnings, restrictions, or precautions that may apply in relation to use of the device and for an implantable medical device—information about any risks associated with its implantation: TJ [3841];

(6) the notion that the medical literature was sufficient to alert the medical profession of the true nature and extent of the risks associated with implantation of mesh was rebuffed by a number of witnesses: TJ [3843];

(7) the existence of the duty of a medical practitioner to warn or provide information does not obviate the duty of care owed by a manufacturer; the duties are at least co-extensive: TJ [3844];

(8) the appellants directly communicated with patients through brochures and a website. The appellants pursued a marketing strategy that targeted both surgeons and patients. Having embarked upon that course, the appellants were bound to take reasonable care to ensure that the information they imparted was complete and sufficient to warn their target market of all reasonably foreseeable risks of harm: TJ [3845]; and

(9) consumers are in a vulnerable position and depend on the manufacturer and the doctor to provide enough information to enable them to make an informed decision about their treatment: TJ [3847].

723 Given these conclusions of the primary judge, the appellants’ complaint that the primary judge’s analysis ignores the critical question whether, having regard to the nature of the devices as medical devices (including both their risks and benefits) and the knowledge of treating surgeons, the totality of the warnings and other information provided was reasonable is unsustainable. The primary judge had regard to the nature of the devices as medical devices (including both their risks and benefits) and the knowledge of treating surgeons and evaluated the totality of the warnings and other information the appellants provided. It was on the basis of the consideration of all of these factors that the primary judge concluded at TJ [3878] that:

…the information about the potential risks in the IFUs and promotional material for all devices was below the standard required of a reasonably prudent manufacturer or supplier in the position of the [appellants]. It fell well short of capturing all known, let alone reasonably foreseeable risks, and was liable to mislead the reader about the safety and efficacy of the various devices. From the first of the IFUs to the last, the warnings they contained and the information they conveyed were insufficient to discharge the [appellants’] duty of care.

724 The appellants’ characterisation of the quality of the warning that the applicable duty of care required exposes the flaw in their case. The appellants said that the requisite warning was one that was sufficient to permit the recipient of the warning – the treating surgeons with the necessary clinical experience and expertise – properly to engage in the informed consent process with the particular patient. As discussed, however, pelvic surgeons in the present case could not properly engage in the informed consent process because they did not know about the pleaded complications.

725 The primary judge’s consideration of all relevant circumstances is reinforced by her subsequent observations that:

(1) there was no reason to believe that the burden of taking the relevant precautions was so great as to render the appellants’ conduct reasonable in the circumstances: TJ [3880];

(2) there was no evidence to suggest that it would have been oppressive for the appellants to include appropriate warnings or to conduct and complete suitable clinical studies to assess their efficacy and safety: TJ [3881]; and

(3) the utility of medical devices that would provide more effective long-term relief from SUI and POP than traditional surgical procedures offered does not excuse or justify the appellants’ conduct: TJ [3882].

726 It will be apparent from this discussion of the primary judge’s reasons that the appellants’ contention that the primary judge substituted the required multi-factorial approach with a single inquiry as to whether each complication in the pleading was foreseeable is devoid of merit. The primary judge applied the requisite multi-factorial approach, as her reasons for judgment disclose. She did not reach her conclusions of a negligent failure to warn on the part of the appellants merely because the pleaded complications were reasonably foreseeable. Nor did she reason on the basis that every foreseeable risk must be the subject of a warning. It also follows that the submission that the primary judge reversed the burden of proof is unsustainable. Nothing in the primary judge’s reasons supports that submission.

727 The appellants’ repeated references to the critical role of the treating surgeon do not support their contention that the primary judge failed to take that factor into account. As the preceding discussion discloses, the primary judge was cognisant of the role of the treating surgeon. The mere assertion that the finding at TJ [3839] (“[i]t is not to be assumed that the physician or surgeon has other potential sources of information”) is both analytically and factually flawed does not make it so. The primary judge was not referring to the information any pelvic surgeon has about the risks of pelvic surgery. She was concerned with the risks the devices involved separate and distinct from the risks of pelvic surgery. The finding does not indicate that the primary judge ignored the context in which the devices were in fact inserted. The generalisation in the appellants’ submissions that surgeons have a wealth of training, knowledge and other sources of information does not assist. They did not have a wealth of training, knowledge and other sources of information about the pleaded complications, which are risks specific to the devices. As the primary judge found at TJ [3843], the notion that the medical literature was sufficient to alert the medical profession of the true nature and extent of the risks associated with implantation of mesh was rebuffed by a number of witnesses. Consistently with this, the primary judge rejected the appellants’ contention that “there is no suggestion that there was a relevant knowledge gap between the [appellants] and the general surgical community”: TJ [3236]. The primary judge had also found that:

(1) it is absurd to think that average gynaecologists and urologists, acting reasonably, would attend every conference at which the POP and SUI devices were discussed or read every article in every journal in which their complications were canvassed: TJ [3248];

(2) an average, reasonably competent gynaecologist would expect the manufacturer to provide her or him with information about the use, surgical technique, risks of adverse events, and studies supporting safety and efficacy: TJ [3249]; and

(3) surgeons could not be expected to know that there is uncertainty about the long-term consequences of implantation of polypropylene mesh: TJ [3250].

728 The appellants’ case on appeal does not grapple with these findings which undermine their reliance on the role of the treating surgeon as obviating or reducing their duty of care to provide accurate information about the performance and safety of the devices, including warnings about potential complications and contraindications of the devices. These findings are part of the context within which the primary judge’s other observations at TJ [3215] and [3311] must be read. The appellants relied on TJ [3215] and [3311] to support a proposition, put in different ways to support various grounds of appeal including ground 5, that the treating surgeon would not have assumed that what was said about the adverse side effects of the devices reflected what the appellants in fact knew, as the primary judge concluded at TJ [3605]. But TJ [3215] and [3311] do not conflict with that conclusion. At TJ [3215], as already noted, the primary judge said:

Furthermore, it may be accepted that treating surgeons would be aware of the risks of pelvic surgery and that it is unlikely that the IFU would be the sole source of information for most, if not all, surgeons. And I am prepared to assume that some pelvic surgeons would have been aware of many, if not most, of the risks associated with the implantation of the various Ethicon devices as a result of their own experience or research.

729 At TJ [3311], as also already noted, the primary judge said:

I accept that the IFUs will not be the only source of information for surgeons. I also recognise that the IFUs were drafted for pelvic surgeons familiar with pelvic floor surgery. Moreover, I accept that none of the relevant witnesses gave evidence that he or she relied solely on the IFUs for information as to the risks associated with the devices. But that does not mean that surgeons are not entitled to rely on the IFUs or to depend on the manufacturer for accurate information about the risks posed by the devices and the precautions that should be taken to guard against or minimise them. Indeed, unless they had reason to know that an IFU was deficient in these respects, they might well consider that there was no need to look beyond it.

730 These conclusions are not inconsistent with the conclusion that pelvic surgeons would reasonably assume that what was said about the adverse side effects of the devices in the IFUs reflected what the appellants in fact knew. It is apparent that the primary judge was not saying that pelvic surgeons generally would have been aware of the pleaded complications irrespective of the IFUs. At best she was prepared to assume that *some* treating surgeons would have been aware of many, if not most, of the risks associated with implantation of the devices. As the respondents submitted, the appellants’ approach involves the latent and flawed proposition that pelvic surgeons in general at all relevant times were aware of the pleaded complications.

731 Annexure D to the appellants’ submissions does not support ground 5 of the appeal. The annexure fails to have regard to the primary judge’s unchallenged adverse credit findings against a number of the experts called by the appellants. Nor does the content of Annexure D gainsay the key findings of the primary judge about the knowledge gap between the appellants and the treating surgeons. The other problems with Annexure D, and the impermissible invitation it involves to re-hear this matter on the basis of only that part of the evidence which suits the appellants, have been discussed above.

732 Apart from these difficulties for the appellants, the respondents are right that the appellants’ underlying proposition is that pelvic surgeons were aware of the pleaded complications at all relevant times. This has been rejected above.

733 The fact that Mrs Gill, Mrs Dawson and Mrs Sanders were not told about every risk mentioned in the relevant IFUs does not prove that their treating pelvic surgeons were aware of all of the pleaded complications or that they would not have informed their patients of the pleaded complications had they been included in the IFUs. As noted, the pleaded complications involve risks of a kind materially different from those which were disclosed in the IFUs. They are risks of the devices themselves, in contrast to the risks generally of pelvic surgery. They are risks which could emerge in any woman at any time after implantation. As such, they are material risks in the sense they would be of obvious significance to a woman considering implantation with one of the devices.

734 A short answer to the appellants’ additional contention that the primary judge failed to account for the differences between the devices is that the appellants, through Dr Hinoul and their counsel, conceded that each of the devices could cause the pleaded complications and that each of the pleaded complications was (not merely could be) clinically significant: TJ [189]-[191]. The appellants’ additional contention cannot be accepted in the face of their concessions. The concessions meant that there was no difference between the devices and their rates of complication which was material to the resolution of the issues in dispute.

735 Further, and contrary to ground 5 of the appeal, the evidence on which the appellants relied did not establish that the warnings provided in connection with each device were reasonable and appropriate in the circumstances. As discussed, it is not permissible to resolve the appeal on the basis that only the selected parts of the evidence which suited the appellants are relevant. Further, the appellants do not explain how it is that the warnings which were provided were reasonable and appropriate in the circumstances even if the evidence could be confined to that which suited their case. Although the appellants’ Annexure E discusses the warnings that the appellants gave about the devices and related evidence, nothing in that annexure explains how it is that the warnings which were provided were reasonable and appropriate in the circumstances. The appellants’ Annexure E, as the revised version of that annexure prepared by the respondents discloses, is selective, incomplete and self-serving.

736 For example, the appellants took issue with the fact that the primary judge accepted the evidence of Dr Pence to the effect that the IFUs for the devices were inadequate and deficient and that it could not be assumed that every clinician understood all of the risks associated with a medical device. The primary judge referred to that evidence as follows:

(1) Dr Pence said that one cannot assume that every clinician understands all the risks or the extent of the risks. She pointed out that some of the clinicians were generalists. Moreover, she added, the company has “the most information” about its own products and groups of people dedicated to evaluating the scientific and medical literature about them”. Those resources, she observed, are beyond those of most clinicians: TJ [2577];

(2) I accept Dr Pence’s evidence (TJ [2622]-[2627]) that at the time of her report the IFUs for all the SUI devices were deficient. Having regard to the other evidence in this case, and Dr Hinoul’s testimony in particular, which indicated the extent of the respondents’ knowledge, however, I would place no limitation on the times the warnings should have been given. They should have been provided with the devices from the time each of them was made available for sale: TJ [2628]; and

(3) I accept Dr Pence’s evidence (TJ [2645]-[2654]) that the IFUs for all the POP devices were, and remained, incomplete at the time of her report. Once again, however, having regard to the other evidence in this case and Dr Hinoul’s testimony in particular, I would place no limitation on the times the warnings should have been given: TJ [2655].

737 The appellants said that Dr Pence was not an expert in SUI or POP surgery and did not did not undertake a systematic review of the published literature.

738 Contrary to the appellants’ submissions, however, the opinion of Dr Pence recorded at TJ [2577] is not contrary to the evidence of each of the pelvic surgeons. It is contrary only to the appellants’ selective and tendentious characterisation of the evidence of the pelvic surgeons.

739 Dr Pence’s expertise was not in SUI or POP surgery but in the regulatory approvals processes of the United States for medical devices and pharmaceuticals: TJ [1352]. Her evidence was supplemented by evidence from Dr Allman and Ms Holland who had expertise in relation to the regulatory approvals processes in Europe and Australia: TJ [1348]-[1351]. The appellants called no competing evidence. At TJ [1353] the primary judge said:

Although Dr Allman, Ms Holland, and Dr Pence were all required for cross-examination, none of them was shaken in his or her opinions. In these circumstances and, in the absence of any evidence to the contrary and, having regard to their qualifications and experience, unless otherwise indicated I accept their evidence.

740 Nor was it put by the appellants to Dr Pence that she was unqualified to give the evidence she gave.

741 In these circumstances it is not apparent how the appellants can sustain their contentions to the effect that the primary judge erred. They chose not to adduce evidence contrary to that of Dr Allman, Ms Holland, and Dr Pence. Moreover, and as the respondents submitted, Dr Hinoul’s oral evidence in fact supported their opinions. Dr Hinoul gave evidence that:

(1) the IFU accompanying the devices represented Ethicon’s official statement as to what it said were the adverse reactions associated with the products: TJ [2584];

(2) the IFU was an important document from Ethicon’s point of view to ensure that the user of its devices had the means to know exactly what Ethicon regarded as the risks associated with the device: TRA.500.041.0001\_3 at 0041\_3.25-39; and

(3) it was important for all risks associated with the implantation of the product to be included in the IFU: TRA.500.041.0001\_3 at 0042\_3.44-46.

742 Otherwise, the support for the appeal which the appellants seek to obtain from Annexure E is obscure. The annexure accuses the primary judge of a selective re-counting of the evidence, but does not explain why the primary judge was bound to refer to the specific aspects of the evidence they contend to be missing, nor why those aspects were material to the conclusions the primary judge reached. The annexure simply does not confront the requirement that an appeal ground needs to identify not merely disagreement with the primary judge’s conclusions, but error.

743 For these reasons none of the appellants’ submissions sustain a conclusion that the primary judge erred as specified in ground 5 of the appeal. Ground 5 should be dismissed.

##### 8. NEGLIGENCE – PRE-MARKET AND POST-MARKET TESTING (GROUNDS 6, 7 AND 8)

###### 8.1 Primary judge’s conclusions

744 As noted, the primary judge found that the first and second appellants breached their duty of care to consumers by failing adequately to conduct pre-market (TJ [3762]) and post-market testing of the devices (TJ [3785]-[3794]). The appellants alleged that the primary judge erred in so concluding where the respondents did not advance a case that the regulatory environment informs the appellants’ obligations and did not advance a case as to how any non-compliance with the regulatory environment has relevantly affected the appellants’ obligations (ground 6). Further, the appellants alleged that the evidence did not establish that the pre-market or post-market evaluations of the devices were deficient (grounds 7 and 8).

###### 8.2 Appellants’ submissions

745 The appellants contended that the primary judge erred in finding that the first and second appellants breached their duty of care to consumers by failing adequately to conduct pre-market (TJ [3762]) and post-market testing of the devices (TJ [3776]-[3778], [3784]-[3794]), which findings were based significantly on findings of non-compliance with the European regulatory regime (TJ [3762] (pre-market testing), [3786]-[3787] (post-market testing)).

746 The TGA did not “require that the manufacturer of a medical device undertake independent pre-market testing of the safety and efficacy of a medical device with a CE marking prior to the TGA listing the device on the ARTG”: Beech 1, pp.4-5 [EXP.010.063.0001 at .0006-.0007]. The appellants alleged that in these circumstances and given there was no evidence that the first and second appellants failed to satisfy any Australian regulatory requirements, the primary judge’s findings must be set aside. In particular, there was no evidence demonstrating that there was insufficient clinical or other evaluation of the safety and efficacy of the devices in the Australian regulatory context. Evidence was required to demonstrate how the pre-market and post-market testing was insufficient from a clinical perspective. The primary judge did not refer to any such evidence: AS [55].

747 The appellants alleged that the primary judge did not afford proper weight to the factual circumstances in which the devices were developed. It is said the error is demonstrated at TJ [1551] where the primary judge found it unnecessary to address the studies concerning Prolene sutures and hernia mesh because there are differences between sutures and the devices, including the forces in the female pelvis (TJ [1549]) and because the respondents did not take issue with the pre-market evaluation of Prolene sutures or hernia mesh: TJ [1550]. This, however, ignores the (undisputed) fact that the advancement of science and the development of medical devices is predicated on both the testing and the experience associated with precursor products. Here, that evidence and that experience is of sutures and hernia mesh. There is no doubt that the devices are different from sutures and hernia mesh, but that did not permit the primary judge to ignore the evidence concerning the extensive testing conducted on sutures and hernia mesh in assessing whether the first and second appellants had taken reasonable care: AS [56].

748 The appellants alleged that the primary judge did not properly consider and failed properly to take account of the significance of the evidence as to the differences in the pre-market and post-market testing conducted for each of the POP devices and the SUI devices. The primary judge was required to be satisfied that the evidence demonstrated the pre-market and post-market testing for each device was inadequate. The primary judge did not do so: AS [57].

###### 8.3 Discussion

749 Contrary to the submissions for the appellants, the fact that the TGA did not require that the manufacturer of a medical device undertake independent pre-market testing of the safety and efficacy of a medical device with a CE marking prior to the TGA registering the device on the ARTG does not mean that:

(1) there was no evidence demonstrating that there was insufficient clinical or other evaluation of the safety and efficacy of the devices in the Australian regulatory context; or

(2) the primary judge’s findings that the appellants breached their duty of care to consumers by failing adequately to conduct pre-market evaluations (TJ [3762]) must be set aside.

The evidence which was before the primary judge, and which she accepted, exposes the fallacies which these contentions involve.

750 First, and as the respondents submitted, the unchallenged evidence of Dr Beech concerned the procedure for applying for registration of a medical device in Australia where CE marking had already been obtained: TJ [1390].

751 Second, and as the respondents also pointed out, the effect of Dr Beech’s evidence was not as the appellants represent it. In particular, his evidence, which the primary judge accepted was that:

(1) apart from class III medical devices, at the time the devices were registered on the ARTG, products that had received a CE marking were accepted 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: TJ [1391];

(2) the presence of a CE Mark on a medical device constitutes a representation that the device conforms to the requirements of the particular European directive which applied to that type of product at the time of certification and thereafter and is an indication to the world at large that it may lawfully be sold in all member states of the European Union. In effect, a CE Mark, evidenced by a CE certificate, is a declaration by a manufacturer that its product conforms to the requirements of that directive. For medical devices, the applicable directive is the European Directive: TJ [1392];

(3) the manufacturer must have information to demonstrate compliance with the “essential requirements” listed in the European Directive, but the TGA does not require that information to be produced before including a device bearing the CE Mark in the ARTG: TJ [1397];

(4) although “legally not binding”, the guideline documents for the European Directive (MEDDEV 2.7.1 or the Guidelines) are considered authoritative since they are the result of intensive consultation between the European Commission, competent authorities (that is, the national regulatory authorities), industry, and other interested parties. Ethicon’s internal documents referred to them and it is reasonable to infer that it considered it should apply them. Certainly, in the absence of good reason to the contrary, such as national legislation which required a different course, any reasonably prudent manufacturer would follow them: TJ [1396];

(5) when a manufacturer of a medical device makes a declaration of conformity with the European Directive, it must ensure that the device has complied with each of the “essential requirements” contained in Annex 1 to the Directive, see European Directive, articles 3 and 17: TJ [1403];

(6) the essential requirements are a set of 14 requirements, set out in Annex 1 to the European Directive, designed to ensure that the benefits of the device outweigh the risks: TJ [1404];

(7) provided that the medical device complies with the essential requirements, as assessed by the notified body, and the quality management system is certified to ISO 13485, the notified body will issue CE notification: TJ [1407];

(8) in substance the system is self-regulating. As Dr Beech emphasised, the obligation to establish and maintain compliance with the regulatory requirements rests exclusively with the manufacturer, as does the obligation to take all possible steps to ensure that its medical devices are safe and efficacious: TJ [1408]; and

(9) the CER for the device is “a key element in the work to be performed to ensure compliance with the Essential Requirements”. “[I]t must contain a comprehensive literature review and details of the outcomes of clinical studies on the device itself, which provide a reasoned, clinically-valid basis to confirm that the benefit of the device exceeds the risk, as assessed by a clinician who is expert in the field”: TJ [1406].

752 Each of the devices carries a CE Mark and was listed on the ARTG on this basis: TJ [1398]-[1402].

753 As the respondents submitted:

(1) the essential principles in Australia were harmonised with international standards established by the GHTF**:** TJ [1371]. The European Essential Requirements are substantially identical to the Australian Essential Principles: TJ [1404]-[1405]. Once a manufacturer has declared – by CE Mark – that their product complies with the Essential Requirements, the product is permitted to be recorded on the ARTG. The system is largely self-regulating: TJ [1408] (RS [108]); and

(2) in opening, the appellants’ senior counsel informed the Court that registration of the devices in Australia “piggybacks off the CE authorisation” and accepted her Honour’s observation that if a device “is good enough for the European community, it’s good enough” for Australian regulatory purposes. The result, the Court was informed, was that “there’s nothing specific about the Australian [regulatory] atmosphere” which differentiates it from the position as it applies in Europe: TRA.500.006.0101\_2.1-11 (RS [109]).

754 In these circumstances, the fact that the TGA did not impose separate requirements for registration of the devices on the ARTG does not mean that the pre-marketing evaluations of the first and second appellants could not involve breach of a duty of care to Australian consumers to ensure that there had been adequate pre-market testing of the devices before they were sold into the Australian market. Nor can it be said that there was no evidence capable of establishing breach of such a duty of care merely because there were not separate Australian regulatory requirements. Failure to comply with the European Directive and associated guidelines, as the primary judge said at TJ [1396], could evidence breach of a duty of care to Australian consumers.

755 The primary judge summarised the Essential Requirements at TJ [1409] as follows:

(1) the devices must be designed and manufactured in such a way that, when used under the conditions and for the intended purposes, they will not compromise the health or safety of patients; any risks which may be associated with their intended use must be “acceptable” “when weighed against the benefits to the patient”, and “compatible with a high level of protection of health and safety”: European Directive, Annex I § 1;

(2) the design and construction of the medical device must conform to safety principles, “taking account of the generally acknowledged state of the art”, paying particular attention to the compatibility between the materials used and biological tissues, cells and body fluids: European Directive, Annex I § 2 and §7;

(3) in selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order:

(a) eliminate or reduce risks as far as possible;

(b) where appropriate take adequate protection measures in relation to risks that cannot be eliminated;

(c) inform users of residual risks: European Directive, Annex I § 2;

(4) the device must achieve the performances intended by the manufacturer: European Directive, Annex I § 3;

(5) the characteristics and performances mentioned above must not be adversely affected “to such a degree that the clinical conditions and safety of the patients are compromised during the lifetime of the device when the device is subjected to the stresses which can occur during normal conditions of use”: European Directive, Annex I § 4;

(6) the devices must be designed, manufactured and packed in such a way so that transport and storage will not adversely affect their characteristics and performances during their intended use: European Directive, Annex I § 5;

(7) any undesirable side-effect must constitute an acceptable risk when weighed against the intended performance: European Directive, Annex I § 6; and

(8) (added in 2007) demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X: European Directive, Annex I § 6a.

756 For all of the devices, the path the appellants chose to rely on was a critical evaluation of the relevant scientific literature relating to the safety and performance of the devices. This was referred to in the evidence as the “literature route” (as distinct from the path of undertaking clinical studies, or a combination of clinical studies and evaluating literature): TJ [1413]-[1415]. However, this route was only available if the device the manufacturer was evaluating was demonstrated to be equivalent to the device to which the data relates and data adequately demonstrates compliance with the Essential Requirements: TJ [1413]. The Guidelines provide that for one device to be considered “equivalent” to another it must be similar with respect to three parameters: clinical, technical and biological performance: TJ [1422]. If differences are identified, the significance of the differences to the safety and performance of the devices must be described. Where, for example, the new device has a new principle of operation from the device or devices the subject of the published studies, the clinical benefit of the new device has to be generated by data resulting from specifically designed clinical investigations. Otherwise, the two devices cannot be considered equivalent: TJ [1423].

757 The primary judge dealt extensively with the evidence of Dr Allman, Ms Holland and Dr Pence about the inadequacies in the appellants’ processes and documents relating to the obtaining of the CE markings for its devices: TJ [1480]-[1547], all of which evidence the primary judge accepted. The primary judge dealt with the process by which each device obtained its CE marking and described the inadequacies in the process at length, including numerous admissions of Dr Hinoul: TJ [1548]-[1955]. The primary judge undertook the same exercise in relation to the appellants’ post-market evaluation of the devices: TJ [1956]-[2444]. She also gave detailed consideration to the process by which a number of the devices were removed from the market: TJ [2445]-[2559]. The primary judge then considered the information which Ethicon had provided in relation to the devices: TJ [2560]-[3035]. It was only after this extensive analysis of the evidence, and the making of the associated findings (discussed above), that the primary judge considered and upheld the statutory and common law claims. It is also clear that the primary judge did not equate non-compliance with regulatory requirements as determinative of the question of statutory defect or negligence, but she was right to consider it relevant to those matters: TJ [1342]-[1343].

758 As the respondents submitted, the regulatory evidence of Dr Allman, Ms Holland and Dr Pence was relevant to the issue of the steps that a reasonable medical device manufacturer should and does take in evaluating its products before and after releasing them for use by the medical community. Their evidence, which the primary judge accepted, was that the appellants’ conduct fell far short of those steps: for example, TJ [1480]-[1481], [1500]-[1503], [1507]-[1533], [1540]-[1547]. Their evidence was not contradicted by any expert called by the appellants and was unshaken by cross-examination: TJ [1344] and [1353]. In these circumstances, it cannot be accepted that the primary judge was in error in concluding that the pre-market and post-market evaluations of the first and second appellants involved a breach of their duty of care to Australian consumers.

759 Nor can it be accepted that the primary judge failed to give appropriate weight to the factual circumstances in which the devices were developed. Contrary to the appellants’ submissions, TJ [1551] does not disclose error. The primary judge there said that it was unnecessary to deal with the respondents’ lengthy submissions on the studies of Prolene sutures and hernia mesh because, as Ms Holland said:

[T]here is no disagreement that any clinical experience with PROLENE sutures and mesh [should] be considered when evaluating future devices of the same material. However, the evaluation should not have solely relied on prior history of similar devices for safety and effectiveness due to the new indication and use in pelvic floor repair versus the abdominal wall (hernia). What was not considered in these risk assessments was the impact of polypropylene mesh on anatomical location with respect to differing biomechanical properties (erosion/adhesion risk), microbiological flora (infection risk), as well as inflammatory response.

760 It must be recognised that the primary judge reached this conclusion in the context of numerous other findings including the “very significant differences between the sutures and the devices and between the environment of, and the mechanical forces at work in, the female pelvis and the abdomen” (TJ [1549]) and the unchallenged evidence of Professor Klinge that “the Ethicon companies did not conduct their own studies on mesh for specific use in the pelvic floor, and failed to define the physiological forces at work in the pelvis and incorporate this research into the development of the Ethicon devices”: TJ [1552]. As to the former proposition, the primary judge said that:

(1) I was impressed by the evidence of Professors Klosterhalfen and Klinge. They both struck me as honest and trustworthy. Their knowledge of, and experience with, the use of polypropylene implants, in general, and the POP devices, in particular, was far superior to that of any other witness. Their evidence was informed by their extensive and profound experience: TJ [302];

(2) I was not impressed with a number of the respondents’ witnesses including Professor Wright, Professor Santerre, Professor Deprest and Dr MacLean: TJ [303]-[325];

(3) given the lack of relevant evidence, it is difficult to understand howthe devices could have been considered biocompatible or suitable for release to the market without first testing their performance in vaginal tissue in a wide selection of patients and over a sufficient period of time: TJ [340];

(4) Professors Klosterhalfen and Klinge expressed strong views about the unsuitability of the devices for the purpose for which they were supplied and the deficiencies in the IFUs accompanying them: TJ [390];

(5) Professors Klosterhalfen and Klinge referred to the different forces at work in the abdomen and the pelvic floor and the unique nature of the vaginal environment: TJ [397];

(6) Professor Wright’s experience is inconsequential in comparison with the experience of Professors Klosterhalfen and Klinge: TJ [467];

(7) in February 2011 Ethicon acknowledged that “[t]he development of knowledge to understand the mechanics of pelvic floor disorders is imperative; yet, we are only just beginning to determine the necessary criteria on which to base design for pelvic floor implants”: TJ [487];

(8) bridging fibrosis has been documented to occur with Prolene, Prolene Soft, and UltraPro, which means that it can occur following implantation of all the devices: TJ [533];

(9) bridging fibrosis is of clinical significance: TJ [537];

(10) there is a wealth of evidence that contraction, often called shrinkage and “retraction” by the French, is a complication of the use of polypropylene meshes: TJ [538];

(11) mesh contraction has clinical significance: TJ [564] and [610];

(12) Professor Klosterhalfen’s evidence was that polypropylene mesh products are incompatible with the female pelvis because, while the meshes are flexible, they are not elastic. He said that flexible structures like polypropylene meshes are only able to elongate in one direction but an elastic structure like the vagina can stretch in all directions. He explained that the mesh acts as an inelastic material in an area needing elasticity and motion. He referred to this as a “mechanical mismatch”: He said that the mechanical mismatch is responsible for the main complications of polypropylene meshes in the pelvic floor: TJ [611];

(13) Professor Deprest said that the main reasons for post-surgery complications and with complications associated with erosion included the biomechanical properties of the mesh, especially “mesh stiffness”: TJ [616];

(14) Professor Wright’s opinion that the vaginal/pelvic host tissues response should be the same as for sutures and hernia mesh was problematic for numerous reasons: TJ [619]-[644];

(15) hernia repair meshes are only in direct contact with the abdominal fascia. Pelvic meshes, on the other hand, are placed in an environment with a wide range of soft tissues, including smooth and striated muscle, various kinds of connective tissue, and specialised organs: TJ [647];

(16) the vagina is regarded as a “clean-contaminated” field. When polypropylene is implanted transvaginally, it is seeded with bacteria which contribute to infection and inflammation in the tissues: TJ [648];

(17) one of the major causes of mesh-related infections in patients who have been implanted with pelvic floor meshes transvaginally is the formation of a biofilm which protects the harmful bacteria: TJ [650] and [651];

(18) in numerous other respects the environment of the pelvic floor is very different from the wall of the abdomen or, for that matter, the groin: TJ [653];

(19) the soft tissues of the pelvic floor are “metabolically active, with compositions that have been shown to change dramatically with normal aging and in response to hormone-driven events such as pregnancy, menstrual cycle, and menopause”: TJ [654];

(20) pelvic meshes are subjected to “predominantly uniaxial tensile loading conditions”, an environment which is “quite different” from the loading conditions to which abdominal hernia mesh is subjected: TJ [655];

(21) the female genital area has a much higher nerve density in comparison with the anterior abdominal wall and the groin so that placement of mesh implants in the female pelvis carries a higher risk of chronic pain than the placement of mesh for hernia repair, whether ventral or in the groin: TJ [660];

(22) erosion through the vaginal mucosa is one of the most common complications of implantation with polypropylene mesh but it is rare to encounter mesh erosion through abdominal skin or into internal organs with hernia mesh: TJ [664];

(23) since the arms of the POP devices and the ends of the SUI devices cross many structures in the pelvis, “pain distribution can involve areas from suprapubic to vaginal, introital, deep pelvic/vaginal, obturator/hip/groin, and into the buttock”. Pain can also radiate into the medial thigh: TJ [665];

(24) with hernia mesh, pain on intercourse can occur in cases of mesh migration into the spermatic cord, but dyspareunia is more prevalent as a complication of vaginal mesh: TJ [666];

(25) urinary obstruction is a complication “almost unique to vaginal implants”: TJ [667];

(26) other *de novo* urinary symptoms, such as overactive bladder and urge incontinence, are much more frequent for vaginal mesh implants: TJ [668];

(27) mesh excision is much more problematic in the case of vaginal implants as it is difficult to readily access the obturator and other “deep parts”. In addition, removal of mesh that has migrated into the bladder or rectum poses a risk of fistulas: TJ [669];

(28) “the vagina is not the abdominal wall” – “[t]he physical angles of support are different. The shape is different. The bacterial flora is different. The anatomic function is different. The pathophysiology of the problems is different. The reparative procedures are different. The volume, quality, and physiologic composition of the tissue coverage overlying the mesh is different. The surgical alternatives and options to treat the underlying problem are different. This list goes on and on. The only significant similarity between abdominal wall hernias and POP is that something is protruding where it should not”: TJ [670];

(29) the vaginal tissue to be augmented by the mesh is often structurally compromised, atrophic, and devascularised: TJ [671]; and

(30) there are several sensory nerves in the female pelvis, including the pudendal nerve. The chance of mesh coming into contact with sensory nerves is high, particularly if it moves or erodes: TJ [681].

761 It cannot be doubted that the overwhelming weight of the evidence before the primary judge amply supported the opinions of Ms Holland as referred to at TJ [1551]. The primary judge did not there err in concluding that the history of the development of the materials from which the devices were made for use in sutures and hernia meshes did not make it reasonable for the appellants to merely assume that the devices were suitable for use in repairing SUI and POP given the unique characteristics of the female pelvic area. It is not right to characterise the primary judge’s approach as ignoring the development of the materials for sutures and hernia mesh. The primary judge did not ignore that material. She found that the development of the precursor products could not justify the apparent assumption that the materials could be used in the devices which were to be used in the area of the female pelvis because of the unique characteristics of that area. The evidence in support of that conclusion, as noted, was overwhelming. The want of reasonable care the primary judge found was a result of the profound lack of scientific justification for the use of the devices for the purposes of POP and SUI because of the unique characteristics of the female pelvis.

762 Nor can it be accepted that the primary judge failed to satisfy herself that the evidence demonstrated the pre-market and post-market testing for each device was inadequate. The primary judge considered each device at length in terms of both pre-market and post-market testing: TJ [1554]-[1955] and [1956]-[2444]. The contention also disregards the overarching findings the primary judge made, including that:

(1) the conclusions in the CERs as to safety and performance were based on a comparison of a new device to Ethicon’s older devices, in circumstances where the new device had design changes that were intended to change clinical performance. Dr Allman (whose evidence the primary judge accepted) considered this approach unjustifiable. Indeed, he described the claims of equivalence as “spurious” in the circumstances: TJ [1484];

(2) for each device Ethicon should have conducted “proper clinical investigations” (involving clinical trials designed to test the performance and safety of the new device), that is to say, studies addressing the essential requirements of the European Directive: TJ [1488];

(3) Dr Allman (whose evidence the primary judge accepted) analysed the clinical evaluation reports that were contained in the technical files for each of the devices and concluded that none of the devices was clinically evaluated to the standard necessary to satisfy European regulatory requirements and therefore to justify CE marking: TJ [1494];

(4) Ms Holland (whose evidence the primary judge accepted) considered all nine devices, five of which she subjected to a comprehensive analysis and concluded that there was a clear pattern of deficiencies in testing which applied to all devices: TJ [1499]-[1500]; and

(5) Dr Pence identified deficiencies in the IFUs for all devices: TJ [1540].

763 Contrary to the contentions of the appellants, there was ample evidence from which the primary judge could be (and was) satisfied as to the manifest inadequacy of the pre-market and post-market testing of the devices as summarised at TJ [1554]-[1955] and [1956]-[2444]. In addition to the matters discussed above which are of primary relevance to pre-market testing, the primary judge’s analysis of the failure in post-market testing was compelling. As the primary judge recorded:

(1) the respondents argued that the post-market evaluation of all the devices was inadequate, and in some cases totally lacking, and failed to conform to the regulatory requirements. Their submissions on this question were detailed and the response to them largely superficial: TJ [1963];

(2) CERs were indeed produced, but not as often as the respondents submitted or at the intervals they asserted. For the most part, these reports could scarcely be described as evaluations at all: TJ [1970];

(3) the CERs were deficient in numerous respects, review of complaints and adverse events was unsatisfactory, and the conclusions drawn from them largely unjustified: TJ [1971];

(4) the appellants received numerous complaints about the devices: TJ [1973];

(5) if Ethicon had effectively monitored the MAUDE database, it would have encountered “some clear signposts as to issues upon which effective post-market evaluation” of the products should have been focused: TJ [1979] and [1981];

(6) Ethicon had a practice of dismissing (and determining not to report) complaints on the basis that they were the subject of adequate warnings in the IFUs, even though that was not the case. Ethicon would then proceed to feed back into its clinical evaluation process low adverse event rates as evidence of the safety of its products: TJ [1980] and [1981];

(7) complaints about the SUI and POP devices should have been reported but were not: TJ [1984]-[2003];

(8) Ethicon’s approach to complaints reporting limited the capacity of the regulatory authorities to adequately determine the safety of the devices: TJ [2004];

(9) the appellants’ internal documents showed that they recognised that inadequate reporting was an issue: TJ [2005];

(10) had sufficient post-market evaluation been undertaken it would quickly have become apparent that the adverse events, the impact of those events on patients, and the warnings accompanying the devices were “all unacceptable”: TJ [3777] and [3778];

(11) post-market clinical evaluation was haphazard and for years the requirement for clinical evaluation reports was overlooked, if not ignored: TJ [3785];

(12) the BSI audits indicated that Ethicon’s procedures for risk management and clinical evaluation did not conform to the European regulatory requirements in serious respects: TJ [3786];

(13) no proper consideration was given to post-market clinical follow-up of the necessary kind, despite the requirement to do it or justify not doing it, included in the European Directive and the indication in the MEDDEV 2.12.2 that post-market clinical follow-up should always be considered where identification of possible emerging risks and the evaluation of long term safety are critical: TJ [3787];

(14) Ethicon had no coherent plan for generating post-market clinical evidence: TJ [3789];

(15) there was no system of formal review of complaints before March 2006: TJ [3791];

(16) Ethicon tended to minimise the significance of complaints and to avoid responsibility for adverse events: TJ [3792];

(17) Ethicon failed to take heed of the likelihood that adverse events were under-reported and failed to comply with their reporting obligations, a course of conduct which was liable to mislead both the regulators and the notified body (BSI) about the number and extent of the complaints and therefore the safety of their devices: TJ [3793];

(18) post-market CERs were not routinely or regularly prepared until 2010, by which time several of the devices had been on the market for years: TJ [3794];

(19) like the pre-market CERs, the post-market CERs were deficient in numerous respects: TJ [3795]; and

(20) since it was well aware of the problem of under-reporting, Ethicon’s reliance on complaints data to demonstrate a low incidence of adverse events in comparison to sales of the devices was disingenuous: TJ [3796].

764 As to the appellants’ responses to enquiries of regulators, the appellants have not explained why the primary judge’s findings in this regard involve any error. The primary judge considered the evidence relating to this matter at TJ [2445]-[2559] and [2656]-[2681]. The fact is that the concerns raised by the regulators were never answered by the appellants because when they were informed that their responses were deficient and not accepted, they elected to withdraw the products from the market.

765 The appellants’ case to the effect that the primary judge erred in her conclusions about the adequacy of the post-market testing for the devices does not confront these findings, nor how they provided compelling evidence (along with findings about the lack of post-market surveillance of individual devices at TJ [3797]-[3825]) for her ultimate conclusions as follows:

[3826] No post-market evaluation of any Ethicon device complied with the regulatory requirements. Evaluation was not undertaken actively or regularly. Neither was it appropriately updated. Post-market surveillance did not include clinical follow-up studies and the failure to do so was not documented or justified. Ethicon did not have adequate clinical evidence to support continued CE marking of any the Ethicon devices.

[3827] I find that Ethicon supplied and marketed the Ethicon devices without conducting sufficient post-market evaluations. The evaluations that were undertaken were haphazard, often perfunctory, and passive. For all the reasons canvassed above, they did not conform to the standard of care expected of a reasonable person in the position of Ethicon in response to the foreseeable risks of injury and having regard to the gravity of the potential consequences.

766 For these reasons, none of the submissions for the first and second appellants in support of grounds 6, 7 and 8 of the appeal are persuasive.

767 As to ground 6, it may be accepted that the respondents did not plead that the regulatory environment informs the appellants’ obligations, and if so, how non-compliance bears on the pleaded allegations of breach. The primary judge acknowledged this at TJ [3695] and [3699]. But as she also said (at TJ [3699]) no objection was taken to the evidence of the regulatory experts and the appellants had ample opportunity to meet the case which the respondents put that the regulatory evidence was relevant to the evaluation of breach of the duty of care owed to Australian consumers in respect of the conduct of adequate pre-market and post-market testing of the devices. It is also relevant in this regard that:

(1) the appellants had indicated an intention to lead evidence from JJM’s Director of Regulatory Affairs, Rebecca Gaudin, and an affidavit from her was filed, but was not read. Further, the appellants obtained a report from Elaine Duncan, a biomedical engineer and regulatory consultant, but elected not to tender it: TJ [1338]. If such evidence had been irrelevant to the case then it is not apparent why the appellants prepared that evidence;

(2) the appellants themselves had pleaded in their defence that the fact that they had obtained regulatory approval in Australia meant that they did not owe the respondents and group members a duty of care, or, in the alternative, that they had discharged that duty and as the primary judge said, the evidence of the regulatory experts went to the heart of this claim and to the rebuttal of this aspect of the defence: TJ [1343];

(3) the appellants also did not submit to the primary judge that the respondents had not put the case that the regulatory evidence was relevant to breach of the duty that the first and second appellants owed to Australian consumers to carry out adequate pre-market and post-market testing in relation to the devices. Rather, the appellants contended that the regulatory evidence was “of peripheral relevance”, “of limited assistance”, or “not relevant” altogether: TJ [1339]. If the respondents had not put a case about the relevance of the regulatory evidence then these contentions would have been meaningless; and

(4) the appellants submitted also that the regulatory evidence could not be used in circumstances where the regulators themselves did not assert any inadequacy in the regulatory process under which the devices were registered on the ARTG: TJ [1354]. Again, if the respondents had not put a case that the regulatory evidence was relevant to breach of the duty of care in relation to pre-market and post-market testing this submission would have been meaningless.

768 The primary judge accepted that evidence of non-compliance with some regulatory requirements may be irrelevant and evidence of non-compliance with regulatory requirements alone may not be determinative: TJ [3699]. But the identified non-compliances with the regulatory requirements were not isolated or irrelevant: TJ [3701].

769 It follows that ground 6 of the appeal, to the effect that the respondents did not advance a case that the regulatory environment informs the first appellant’s and second appellant’s obligations and did not advance a case as to how any non-compliance with the regulatory environment has relevantly affected the appellants’ obligations, is unsustainable.

770 Ground 7 is also unsustainable. Consistent with the discussion above and contrary to ground 7, the evidence did establish that:

(1) the first and second appellants’ engagement with the relevant regulators was insufficient;

(2) the first and second appellants’ risk analyses and design validation studies were insufficient;

(3) the first and second appellants did not satisfy the European Directive; and

(4) the first and second appellants did not have enough evidence to obtain CE marking for each of the devices.

771 Further, the evidence did not establish that the first and second appellants appropriately and reasonably relied on studies conducted on, and experience associated with, the use of polypropylene and polypropylene-based meshes in the body, as well as the surgical technique and benefit-risk profile of earlier devices before each relevant device was supplied in Australia. Given the unique characteristics of the female pelvis, the evidence established to the contrary as discussed above and as found by the primary judge.

772 For the same reasons, ground 8 is unsustainable. The primary judge did not err in finding that the first and second appellants breached their duty to take reasonable care to avoid injury to patients by finding that their post-market evaluation of each of the devices was deficient. Consistent with the discussion above and contrary to ground 8, the evidence did establish that:

(1) the appellants’ post-market evaluation of the devices, both in terms of clinical studies and ongoing review of the scientific literature was deficient;

(2) the appellants’ complaint handling and event reporting to regulatory authorities was deficient; and

(3) the appellants’ responses to enquiries raised by regulators was deficient.

773 Further, and again contrary to ground 8, for the reasons given above and in relation to ground 5, the evidence did not establish that the warnings provided by the appellants were reasonable and appropriate in the circumstances.

##### 9. MISLEADING OR DECEPTIVE CONDUCT – BEYOND THE PLEADED CASE (GROUND 12)

###### 9.1 Appellants’ submissions

774 The 5FASOC did not, it was said, comply with the cardinal requirement that it state the material facts necessary to give the appellants fair notice of the case to be made at trial: see r 16.02(1)(d) of the *Federal Court Rules 2011* (Cth). When allegations of misleading or deceptive conduct are made, they must be distinctly stated so that the defending party has a proper opportunity of meeting them: ***Forrest*** *v Australian Securities and Investments Commission* [2012] HCA 39; (2012) 247 CLR 486 at [21]-[26]. Insistence on this requirement is not mere pedantry or, as the plurality in *Forrest* put it, a “pleader’s quibble”.

775 According to the appellants, the case pleaded, particularised and advanced concerned the effectiveness and ease of use of the devices and certain statements about specifically identified complications. The primary judge found, however, that the appellants engaged in misleading or deceptive conduct because the information provided with the devices did not include warnings of all the risks that could arise with the use of the devices, and because it made false representations as to the safety and efficacy of the devices: TJ [3604]-[3607]. The appellants were not permitted to meet this case because it arose from the primary judge’s own “trawl” through the evidence: AS [60] and [61].

776 The appellants said this had significance for the answering of the common questions. A finding was made that Ethicon’s conduct was misleading or deceptive because it “falsely represented that the inflammatory reaction generated by implantation was transitory rather than permanent and possible rather than certain, and exaggerated the benefits of the devices and minimised the risks associated with implantation”: common question and answer 22. Not only is this not the case pleaded, particularised or advanced, it is also not the conduct found to be misleading at TJ [3604]-[3607]. It follows that the primary judge erred by making findings of misconduct beyond the issues fairly fought out: AS [62].

###### 9.2 Discussion

777 Although not described as such in the written submissions, this was a complaint as to a want of procedural fairness.

778 A pleading performs a dual role in a class action. It is to identify the case of group members at a relatively high level of generality such as to reveal the nature of their claims, and also to plead, with specificity and with adequate particularisation, the claims to be determined at an initial trial. This makes sense when one bears in mind the fundamental notion that pleadings are all about procedural fairness. That is, the dialectic of pleadings serves to ensure the basic requirement that a party should have the opportunity of meeting the individual case or cases being determined at a hearing and, incidentally, define the issue for decision: *Banque Commerciale* at 286-287.

779 It was this underlying purpose of a pleading to which the primary judge was referring when her Honour remarked she was alive to deficiencies in the pleading but observed that the case was “not, however, a judgment on the pleading”: TJ [3573]-[3575].

780 Her Honour was, with respect, rightly critical of the pleading. It adopted the at best, irritating, and at worst, confusing, technique of incorporating whole paragraphs of earlier averments (advanced in relation to other parts of the case) without discrimination, and leaving out others that might be thought to be relevant. Despite its infelicities, the nature of the case pleaded can be seen by the following summary as to the so-called Mesh case (with defined terms as they appear in the 5FASOC):

(1) the appellants engaged in trade and commerce: 5FASOC [5], [14] (although not incorporated in the cross referencing), [15]-[17];

(2) the Mesh Implants were designed and manufactured for the Mesh Purpose, this was known to the appellants and the Mesh Implants were marketed, promoted, distributed and supplied by the appellants as being medical devices that were reasonably fit for the Mesh Purpose: 5FASOC [18]-[20];

(3) but because of the Mesh Complications and Mesh Removal Complications, they did not fulfil the Mesh Purpose (although including an irrelevant reference to Native Tissue Repair): 5FASOC [23]-[23B];

(4) the appellants did not undertake sufficient evaluation of the risks associated with the use of the Mesh Implants, including the risk of occurrence of the Mesh Complications and Mesh Removal Complications and failed to give any, or any sufficient, information or warning of the Mesh Complications and Mesh Removal Complications: 5FASOC [23BA]-[23C];

(5) the appellants marketed, promoted and supplied the Mesh Implants notwithstanding the above and JJM failed to inform “any of the Mesh Sub-Group Members” or Treating Hospitals or Treating Doctors of the risk of the Mesh Complications and Mesh Removal Complications: 5FASOC [31A]-[36C]; and

(6) by reason of engaging in the above conduct, each of the appellants engaged in contravening conduct which caused loss: 5FASOC [39B]-[39C].

781 A similar case relating to the SUI devices took essentially the same form at 5FASOC [82]-[85]. These statutory claims had been refined and described in summary in the opening submissions below as being that the appellants’ conduct, in marketing the devices and continuing to market them, without proper disclosure or warning as to their complications and the gravity of them, was misleading or deceptive or likely to mislead or deceive.

782 Despite written complaint about the vagueness of the pleading below, there is no doubt that the appellants understood the nature of the complaint being made as it was opened. The appellants raised, in opening, the same argument they seek to make on appeal: that whether statements were misleading should be assessed by reference to the surgical population who would be the users of its products: TRA.500.007.0048.5-30 cf AS [65]. The appellants stated in closing submissions below that a “headline issue” for the Court to consider was the failure to warn allegations, which it recognised comprised the misleading or deceptive conduct claim put against it: TRA.500.076.0005.45 0006.5.

783 Further, and importantly, senior counsel for the appellants below informed the Court:

Without being too precious about it and wasting your Honour’s time with angels on the head of a pin about pleading, **the failure to warn case can be understood as – again these are broad strokes but enough to understand the shape of the issues your Honour has to grapple with – the failure to warn about matters the subject of the definitions of the mesh and tape complications, including the removal complications.** And we can look at section 23C of the fourth further amended statement of claim to see that. (TRA.500.076.0006.20-26): RS [130].

(Emphasis added).

784 Although written complaint was made that the 5FASOC did not identify what the impugned statements allegedly conveyed and closing submissions did not address what was misleading about certain statements (arguments her Honour accepted at TJ [3574] and [3579]-[3580]), what experienced senior counsel correctly understood was being alleged was a course of conduct contended to be misleading or deceptive by reason of the “failure to warn about matters the subject of the definitions of the mesh and tape complications, including the removal complications”.

785 It was to this case that the primary judge directed herself at TJ [3581] when a finding was made that the information in the IFUs and the brochures omitted warnings of the pleaded complications and the gravity of the risks. Her Honour called in aid earlier findings and pointed (at TJ [3584]) to ten aspects of conduct by which the appellants “neglected to warn of certain risks, gave incomplete warnings about other risks, and made inaccurate or false representations about a variety of matters” relating to the: (1) nature of the inflammatory reaction: TJ [3586]-[3589]; (2) risk of chronic pain until 2015: TJ [3591]; (3) risk of erosion: TJ [3592]; (4) risk of infection: TJ [3593]-[3595]; (5) risk of dyspareunia or apareunia – until 2007 for the POP devices and 2015 for the SUI devices: TJ [3596]; (6) increased risk of a heightened inflammatory response in immunosuppressed patients: TJ [3597]; (7) risk of revision surgery or multiple surgical procedures that might be necessary or about the potential effects of that surgery and the difficulties of removing the mesh: TJ [3598]; (8) the limitations of clinical evaluations of the devices and the shortcomings of any available studies: TJ [3599]; (9) the fact that the Gynemesh PS was not specially designed for transvaginal placement in prolapse repair or engineered for pelvic support: TJ [3600]-[3601]; and (10) the fact that the meshes used in the devices were not inert: TJ [3602].

786 The appellants’ submission that it was fatal to the misleading and deceptive conduct claim for her Honour to have found that the statement of claim was deficient and the closing submissions were incomplete (TJ, [3574], [3579] and [3580]) should be rejected. Although the pleading was substandard and her Honour did not receive as much assistance as she was entitled to expect in final submissions, the central allegation that the misstatement and non-statement of the accurate risks, which amounted to failure to warn about matters the subject of the definitions of the Mesh and Tape Complications, including the Mesh Removal Complications, was clearly understood by the appellants. The emphasis in the written submissions on the failure to identify particular “statements” relied upon as constituting contravening conduct is not to the point. To focus on the failure to identify particular statements or representations distracts from whether the *conduct* of the appellants which was sufficiently identified contravened the relevant statutory norm.

787 Further, the fastening on the primary judge’s description of having to undertake a “trawl through the material” as evincing error should also be rejected. The submission elides the distinction between: (a) pleadings, particulars and openings which define the issues, and (b) the evidence which enables a tribunal to decide where the truth lies: *Pilato v Metropolitan Water Sewerage & Drainage Board* (1959) 76 WN (NSW) 364 at 366. Her Honour’s trawl was identifying the evidence which demonstrated why the allegations as to the contravening nature of the conduct were made out. It was not the primary judge constructing a new case, but her Honour’s comments were a lament that she had been insufficiently assisted by the respondents in wading through voluminous evidence that was relevant to characterisation of the impugned conduct.

788 Any procedural fairness ground of appeal must fail when it is evident that the appellants, through their senior counsel, understood the nature of the misleading and deceptive conduct case that was being made and correctly appreciated that given the way the case was run below, any factual matters necessary to resolve in determining whether contravening conduct existed were necessary to resolve, in any event, in the defect and negligence aspects of the case.

##### 10. MISLEADING OR DECEPTIVE CONDUCT – FURTHER ALLEGED ERRORS (GROUND 13)

###### 10.1 Appellants’ submissions

789 The more substantive point is the contention of the appellants that the primary judge’s findings that they engaged in misleading or deceptive conduct (TJ [3604]-[3607]) ought to be set aside: AS [63].

790 The appellants alleged that the primary judge misapplied the statutory test as disclosed at TJ [3604]-[3605], and erred in finding that the conduct was misleading in circumstances where the primary judge did not have evidence of the surrounding facts and circumstances of the supply of each device in Australia: AS [64]. Consistently with other arguments, the appellants asserted that no evidence was adduced from any treating doctor or individual patient, let alone evidence to the effect that they made the inferences or assumptions suggested by the primary judge: AS [65]. The evidence was in fact to the contrary and the primary judge herself found it is unlikely the IFU would be the sole source of information for most surgeons: TJ [3215] and [3311]; AS [65].

791 The appellants further alleged that the primary judge did not properly consider and failed properly to take into account the significance of the evidence about the differences between each of the POP devices and the SUI devices. Proof was required that the appellants engaged in misleading or deceptive conduct for each device. Given the case that was pleaded, particularised and advanced, no such evidence was before the Court: AS [66].

792 In reply the appellants contended that the suggestion at RS [134] that there was proof of misleading or deceptive conduct because patient and surgeon brochures were in evidence must be dismissed. Implicit in this assertion is that it was for the appellants to show that no-one read those documents or that anyone who did read them were not misled. The suggestion (at RS [141] and RS Annexure E [1]-[7]) that it was, in some way, incumbent on the appellants to call witnesses from its regulatory affairs, marketing, or sales teams to give evidence concerning whether those patient and surgeon brochures were disseminated assumes, incorrectly, that the appellants bore the onus of disproving the allegations.

###### 10.2 Discussion

793 The only claim for statutory compensation arising from misleading and deceptive conduct at the initial trial was that of Mrs Sanders. Contrary to the respondents’ submissions, this ground of appeal does not involve consideration of the sufficiency or otherwise of the evidence adduced to prove that Mrs Sanders suffered loss by reason of the appellants’ misleading or deceptive conduct: RS [133]. Rather this ground (unlike ground 14 considered below), is directed to answers given by the primary judge to the relevant common questions.

794 As explained above, if the parties had assisted in ensuring that this class action was run as it ought to have been run, there would have been clarity as to the relevant common questions the primary judge was to consider at the initial trial. Any uncertainties and ambiguities in the questions would have been resolved well in advance of the hearing. But here the relevant questions and the answers were considered separately and after the delivery of the primary judgment. In March 2020, for the reasons set out in the RJ, the primary judge made an order which was relevantly in the following terms:

**Common questions**

1. The common questions raised in the proceedings be answered in the terms set out in Schedule A to these orders…

**Schedule A**

…

**MISLEADING OR DECEPTIVE CONDUCT**

**Q21: Between the first supply in Australia of the Ethicon devices and 4 July 2017 was the respondents’ conduct in marketing the Ethicon devices misleading or deceptive or likely to mislead within the meaning of s**[**52**](https://jade.io/article/224884/section/608)**of the Trade Practices Act or s**[**18**](https://jade.io/article/224884/section/72)**of the Australian Consumer Law?**

A:  Yes.

**Q22: Why was the respondents’ conduct misleading or deceptive or likely to mislead or deceive?**

Throughout the period from the first supply in Australia of the Ethicon devices to 4 July 2017, the respondents falsely represented that the inflammatory reaction generated by implantation was transitory rather than permanent and possible rather than certain, and exaggerated the benefits of the devices and minimised the risks associated with implantation.

795 We have rejected above the allegations of error by the primary judge in not giving proper consideration to the evidence of the pelvic surgeons and preferring the evidence of the non-clinical experts. Our reasoning in that regard applies equally to the complaints in this ground of the appeal.

796 We will come back to the form of both the order and answer to common question 22 below, but it is useful initially to deal with the submission that no evidence was adduced from any treating doctor or individual patient, thus preventing a finding that contravening conduct had been established.

797 In explaining why this complaint is misconceived, it is necessary to emphasise some bedrock notions which inform the assessment as to whether contravening conduct is established. Whether particular conduct is misleading or deceptive is a question of fact to be determined in the context of the evidence about the alleged conduct and all relevant surrounding facts and circumstances: *Taco Company of Australia Inc v Taco Bell Pty Ltd* [1982] FCA 170; (1982) 42 ALR 177 at 199 per Deane and Fitzgerald JJ. The relevant inquiry is whether, in the circumstances, the impugned conduct induces or is capable of inducing error: ***Parkdale****Custom Built Furniture Pty Ltd v Puxu Pty Ltd* [1982] HCA 44; (1982) 149 CLR 191 at 198 per Gibbs CJ.

798 It is correct, as Gibbs CJ observed in *Parkdale* at 198, that this means that consideration must be given to the class of persons likely to be affected by the conduct. But in this regard, the characterisation exercise involves consideration of a *notional* cause and effect relationship between the conduct and the state of mind of the relevant person or class of persons. The test is necessarily objective: see ***Campbell*** *v Backoffice Investments Pty Ltd* [2009] HCA 25; (2009) 238 CLR 304 at [25] per French CJ.

799 In considering the appellants’ submissions it is important to be alive to the distinction between the characterisation task (whether conduct is misleading or deceptive or likely to mislead or deceive) and the causation inquiry (whether any person has suffered loss or damage by reason of that conduct). The first task is logically anterior to the second. In a case such as the present, as the primary judge accepted (at [4357]), the issue of causation could not be a common issue. The common questions answered by her Honour were directed to the first of these inquiries and while similar contextual factors relevant to characterisation may play a role in determining causation for any individual group member, no issue as to causation has been determined for any claimant beyond Mrs Sanders.

800 An answer to a common question directed to whether contravening conduct took place is possible because determining whether any particular conduct is misleading or deceptive is a question of fact to be determined objectively. In *Campbell* at [102], Gummow, Hayne, Heydon and Kiefel JJ approved the following statements of McHugh J in *Butcher v Lachlan Elder Realty Pty Ltd* [2004] HCA 60; (2004) 218 CLR 592 at [109]:

The question whether conduct is misleading or deceptive or is likely to mislead or deceive is a question of fact. In determining whether a contravention of s 52 has occurred, the task of the court is to examine the relevant course of conduct as a whole. It is determined by reference to the alleged conduct in the light of the relevant surrounding facts and circumstances. It is an objective question that the court must determine for itself. It invites error to look at isolated parts of the [alleged contravener’s] conduct...

(Emphasis added, citation omitted).

801 The primary judge correctly identified and applied these principles: see TJ [3547], [3552], [3553] and [3555].

802 Contrary to the appellants’ submissions, in resolving the objective characterisation task, it was not necessary for any doctors to be called to state that they had read, received and relied on Ethicon’s marketing materials. The characterisation issue was whether the appellants’ conduct, in marketing the products and continuing to market them without proper disclosure or warning as to their complications and the gravity of them, in the light of all relevant surrounding facts and circumstances including the class of persons to which the conduct was directed and the applicable regulatory regime, was conduct capable of inducing error. Given the primary judge’s findings about the deficiencies in the conduct of the appellants as it related (as senior counsel for the appellants described it below) to “the failure to warn about…the mesh and tape complications, including the removal complications” (TRA.500.076.0006.20–26), the result of the characterisation exercise was obvious.

803 Two further points should be made. The first relates to the complaint that the primary judge did not properly take into account the significance of the evidence as to the differences between each of the POP devices and the SUI devices. This complaint has no substance. Evidence as to the impugned conduct in relation to every device was before her Honour. Every IFU issued by Ethicon for each device at all material times was tendered and was, on her Honour’s findings, deficient at all times: TJ [2627]-[2628] and [2654]-[2655].

804 The second point has more significance. It arises peripherally in relation to a debate as to the significance of surgeon and patient brochures, and goes to the nature and form of the s 33ZB order made recording the answer to common question 22.

805 The respondents relied on the patient and surgeon brochures being in evidence to support the conclusion that there was proof of misleading or deceptive conduct: RS [134]. This suggestion was attacked by the appellants as they contended that implicit in this assertion is that it was for the appellants to show that no-one read those documents or that anyone who did read them were not misled. The appellants further asserted that the respondents (at RS [141] and RS Annexure E [1]-[7]) suggested wrongly that it was, in some way, incumbent on the appellants to call witnesses from its regulatory affairs, marketing, or sales teams to give evidence concerning whether those patient and surgeon brochures were disseminated in Australia.

806 In Part XI her Honour dealt with all the information provided by the appellants about the devices. This included canvassing the IFUs (at TJ [2561]-[2681]), professional training (at TJ [2682]-[2705]), patient and surgeon brochures for both the SUI and POP devices (at TJ [2717]-[2797]), and other marketing activities.

807 As noted above, the misleading and deceptive conduct case as it was opened and understood was resolved by her Honour finding (at TJ [3581]) that the conduct in providing the information in the IFUs and the brochures (which omitted warnings of the pleaded complications and the gravity of the risks) was misleading and deceptive. At TJ [3261] the primary judge found that both kinds of brochures were integral to Ethicon’s marketing strategy.

808 As recorded at TJ [3262], the appellants argued below that the brochures were of no consequence because: (a) as to the surgeon brochures, the relevant audience had access to a range of information as to treatment options and the efficacy and risks of those options; and (b) as to the patient brochures, they were only provided to patients once a treating surgeon had formed the view that surgery was appropriate and suitable for the patient, and as part of the provision of information generally concerning treatment options and the potential complications associated with medical intervention. But these submissions were beside the point. As explained above, the objective characterisation question was whether the conduct in providing the material, with its deficiencies as to warnings of risks, was apt to mislead contrary to the statutory norm.

809 The appellants went on to point to the absence of evidence that any of the representative respondents or their pelvic surgeons relied on any of the brochures, that any treating surgeon or patient was provided with them, or that any surgeons provided such materials to their patients. The appellants invited the Court to infer that evidence of the influence of these marketing materials on patients or treating surgeons would not have assisted the representative respondents: TJ [3265]. This invitation was rejected by the primary judge. Her Honour reasoned that given that brochures were produced, this meant it could “safely be inferred that this material was deployed on the Australian market” and there was no reasonable prospect that the brochures were left in storage and not distributed to their intended audience and there was some evidence (from Associate Professor Lam) indicating otherwise: TJ [3267]. In the absence of any evidence to the contrary, the primary judge found it was reasonable to infer that brochures were supplied around the time the devices came on the market or shortly thereafter: TJ [3267]. We have rejected above the alleged error by her Honour in dealing with the evidence of Associate Professor Lam. There was nothing erroneous about this process of inferential reasoning, and contrary to the appellants’ submissions, it does not amount to a finding that any particular brochure was disseminated to any representative respondent or to any particular group member or their surgeon.

810 Again, this was an example of the tendency in the written submissions of the appellants to elide issues of characterisation and causation. It was no part of the individual misleading and deceptive conduct case of Mrs Sanders that she was given or relied upon a particular patient brochure. Nor was it her case that her surgeon relied upon an identified surgeon brochure. Her (necessarily individual) causation case was that the misleading and deceptive conduct (being the conduct of marketing the devices and continuing to market them, without proper disclosure or warning as to their complications and the gravity of them) materially contributed to her loss. Needless to say, calling other persons as to whether group members or their surgeons read the brochures in individual cases had nothing to do whether the impugned conduct could be characterised as likely to mislead or deceive.

811 There was no error in her Honour’s findings as to the conduct engaged in by the appellants. In particular, no error has been demonstrated in the way the primary judge analysed and identified that conduct in Part XI of the reasons. Nor is there error in the way that her Honour characterised the respondents’ conduct in marketing the devices as contrary to s [52](https://jade.io/article/224884/section/608) of the TPA or s [18](https://jade.io/article/224884/section/72) of the ACL.

812 The question as to whether the s 33ZB order incorporating the answer to common question 22 was appropriate is more problematical. We have reached the conclusion that it cannot stand in its current form. This is for two reasons.

813 The first is that s 33ZB(a) of the FCA Act provides that such an order *must* describe or otherwise identify the [group members](http://www.austlii.edu.au/cgi-bin/viewdoc/au/legis/cth/consol_act/fcoaa1976249/s33a.html#group_member) who will be affected by it. Precision in this regard is always important but is of especial importance in cases such as the present. There has already been significant confusion between the parties as to precisely who was, and was not, a group member at various times in the proceeding: see *Ethicon Sàrl* *v Gill* [2018] FCAFC 137; (2018) 264 FCR 394 at [6]-[32]. The persons who are bound by the statutory estoppel must be identified, which we presume will be all persons who were group members pursuant to the group definition extant at the end of the initial trial, save for any persons who opted-out.

814 The second is the nature of the answer to common question 22 (reproduced above). Given the purpose to which this answer will be put at any secondary or individual hearings, it is necessary that there be greater precision in the answer. To the extent necessary, in a misleading and deceptive conduct case of a group member, this answer will become a starting point from which an individual case of causation can be assessed.

815 When one considers its purpose of creating a statutory estoppel, it can be seen that an answer to a common question is, in effect, a form a declaration. Like a declaration it says something about something and is a formal statement which may be of fact or law or mixed fact and law. The Court is not providing a mere advisory opinion: see Young PW, *Declaratory Orders* (Butterworths, 2nd ed, 1984) [203] and [602]-[603].

816 The form of answers to common questions embodied in a s 33ZB order, like a declaration, should not speak in generalities or merely in the terms used in a statute, without giving any content to those expressions and without indicating the gist of the findings made: *Rural Press Ltd v Australian Competition and Consumer Commission* [2003] HCA 75; (2003) 216 CLR 53 at [[89]-[90]](https://jade.io/article/68449/section/3696). The answers should contain sufficient indication about how and why the relevant conduct contravened the applicable statutory norm: *BMW Australia Ltd v Australian Competition and Consumer Commission* [2004] FCAFC 167; (2004) 207 ALR 452 at [35], quoting *Rural Press* at [90].

817 There are a number of questions and answers to common questions which are expressed in general terms. But it is no part of our function, in the absence of a relevant ground of appeal, to re-work the form of the s 33ZB orders generally. The answer to common question 22, however, falls into a different category because it was referred to in two grounds of appeal (12 and 13(b)) and is of some importance for the future conduct of the class action. The answer should, in express terms and in detail, identify the conduct engaged in that was found to have been contrary to the statutory norm, and identify, in detail and with precision, the complications (and the gravity of them) that were not the subject of proper disclosure or warnings.

818 The reasons of the primary judge are clear in this regard. If her Honour had received the assistance she should have received concerning the formulation of common questions and submissions at the initial trial on appropriate answers, no doubt this problem would have been avoided. But in the circumstances, the appropriate course now, as was foreshadowed during oral argument on the appeal, is to require the parties to confer about a proper form of s 33ZB order and answer to common question 22 and provide that proposed order (in an agreed or competing form) together with any short submissions within 14 days so that an order can be made pursuant to s 28 of the FCA Act.

##### 11. CAUSATION – NEGLIGENCE (GROUNDS 9, 10 AND 11)

###### 11.1 Overview

819 In ground 9 the appellants challenge the primary judge’s conclusion that, but for the appellants’ negligent pre-market and post-market evaluations, the devices would not have been on the market and thus Mrs Gill, Mrs Dawson and Mrs Sanders would not have suffered their injuries.

820 In ground 10 the appellants challenge the primary judge’s approach to the application of the relevant statutory provisions (ss 5C and 5D of the CLA and ss 51 and 52 of the Wrongs Act) to the appellants’ negligent pre-market and post-market evaluations and allege that the primary judge reversed the onus of proof in relation to causation in this regard.

821 In ground 11 the appellants challenge the primary judge’s approach to the application of the relevant statutory provisions (ss 5C and 5D of the CLA and ss 51 and 52 of the Wrongs Act) to the appellants’ negligent failures to warn about the pleaded complications and allege that the primary judge reversed the onus of proof in relation to causation in this regard.

###### 11.2 Appellants’ submissions

822 The appellants contended that the primary judge erred in finding that, but for the inadequate testing, none of the devices would have been on the Australian market at any time (common question and answer 19(a)), no group member would have received a device and suffered damage (common question and answer 19(b)), and that Mrs Gill (TJ [4445]-[4446]), Mrs Dawson (TJ [4502]), and Mrs Sanders (TJ [4521]) would not have suffered their injuries: AS[85]. The appellants contended that these findings were not based on any evidence, were contrary to common-sense (cf *March v Stramare*, recognised by the primary judge at TJ [4363]), and were inconsistent with the (limited) evidence before the Court: AS [96].

823 The appellants alleged that the primary judge’s “no transaction” findings should be set aside as the findings were contrary to the evidence. The evidence did not establish that registration of the devices on the ARTG in Australia would have been withheld had the first and second appellants disclosed additional facts about the testing process for each device or that withholding or withdrawing each device from the market was the only course reasonably open to the appellants or any regulator. The error is demonstrated by TJ [4440]-[4446] in which the primary judge reasoned from a series of criticisms concerning the first and second appellants’ testing regime and literature review and a finding that the evaluations conducted did not justify CE marking (TJ [4440]-[4445]) to the proposition that Prolift would not have been sold in Australia (TJ [4446]). However:

(1) this begs the question as there was no evidence of any causal link between these two propositions;

(2) the respondents did not call representatives from any regulator (or any expert on the Australian regulatory regime) who said or could have said that registration would have been withheld had the first and second appellants disclosed certain facts about the testing process; and

(3) as such, there was no evidence to support this proposition for any of the devices let alone each of the devices: AS [88].

824 Further, the appellants alleged that:

(1) the respondents did not adduce evidence from Dr Hinoul that the appellants would not have placed each of the devices on the Australian market had they had an appreciation of the asserted problems with the testing regime: AS [88]; and

(2) the evidence was to the contrary:

(a) the SUI devices have been demonstrated to be the operation of choice, the gold standard of care, and the most extensively researched surgical treatment for SUI with a good safety profile;

(b) Professor Blavias said “I mean, I think – I’m – it’s not my position that sling should be taken off the market, it’s not – they’re not the enemy of the people” (T723.15-17 [TRA.500.008.0001\_2 at .0112\_2]); and

(c) as to the POP devices, Professor Korda indicated that abdominal sacrocolpopexy (which involves the use of mesh) is the gold standard for treating vault and apical prolapse, and accepted that mesh can be used when the natural tissues are so compromised that they cannot be used to effect a repair. Implicit in this evidence is the rejection of the proposition that the POP devices should never have been launched: AS [89].

825 The appellants alleged that the same analysis applies to the post-market testing and the assumption that further testing would have resulted in the withdrawal of each of the devices from the market. Specifically:

(1) there was no evidence from any regulator or witness that more testing would have resulted in each device being withdrawn from the market: AS [90];

(2) the evidence was to the contrary:

(a) at no point did the FDA indicate that it would require the appellants to remove any or all of the devices from the market in the United States. Rather, the evidence was that failure to satisfy the FDA would result in regulatory action which might include revoking regulatory clearance or taking steps to prevent the continuation of supply (TJ [2470]);

(b) the same is true for the TGA’s review (beginning in October 2012) of the IFUs (TJ [2676]-[2681]). Although the TGA required amendments to the IFU, at no point did the TGA indicate it would require the removal of any or all of the devices from the market in Australia; and

(c) this evidence is a powerful demonstration why the finding by the primary judge that inadequate testing would more likely than not lead to the removal of the devices from the market was wrong: AS [91].

826 Further, the appellants alleged that the primary judge reversed the onus of proof in relation to causation (which was always on the respondents – s 5D of the CLA (Mrs Gill and Mrs Sanders) and s 52 of the Wrongs Act (Mrs Dawson)). The respondents did not prove the facts relevant to the issue of causation because there was no evidence (and the evidence, such that it was, suggested otherwise) that had the breach of duty not occurred, Prolift, Gynemesh PS and TVT-Classic would not have been on the market or would have been removed from the market: AS [92]-[94].

827 The appellants alleged that the respondents also did not demonstrate that Mrs Gill, Mrs Dawson and Mrs Sanders would not have suffered their respective injuries in light of the incidence and severity of complications associated with alternative treatments, and their respective pre-existing conditions. In particular:

(1) Mrs Gill, Mrs Dawson and Mrs Sanders each suffered from pre-existing conditions (see Annexures G1 to G3 to the appellants’ submissions);

(2) any alternative treatment (see Annexure B to the appellants’ submissions) was associated with risks and complications; and

(3) accordingly, it cannot be assumed that, but for the implantation of Prolift, Gynemesh PS or TVT-Classic, Mrs Gill, Mrs Dawson, and Mrs Sanders would not have had any surgery, that alternative treatments would have led to no complications, fewer complications, or that not having surgery would have meant that Mrs Gill, Mrs Dawson and Mrs Sanders would not have had any medical issues: AS [95].

828 For the same reasons as set out above the appellants submitted that, as contended for in ground 11, the primary judge erred in finding that Mrs Gill (TJ [4492], [4496]-[4497]), Mrs Dawson (TJ [4508], [4514]-[4515]), and Mrs Sanders (TJ [4530], [4556], [4558]) suffered injuries caused, respectively, by deficiencies in warnings accompanying Prolift, Gynemesh PS, and TVT-Classic: AS [97].

###### 11.3 Discussion

829 The appellants’ arguments relating to causation must be rejected.

830 The appellants could not import into or supply within Australia the devices unless they were registered on the ARTG: Pt 4-11 Div 3 of the TG Act, TJ [1366]. Apart from TVT (which was supplied at an earlier time) JJM, as the Australian sponsor of the devices, had to apply for registration on the ARTG and certify certain matters including that the device complied with the essential principles as set out in the Medical Devices Regulations: s 41FC of the TG Act, TJ [1378]. The primary judge identified the essential principles at TJ [1380]-[1388]. If the device had a CE marking the TGA did not conduct an independent assessment but allowed the device to be registered on the basis of the CE marking: TJ [1391]. The devices were registered on the ARTG on the basis of the CE marking (other than TVT Secur): TJ [1398]-[1399]. On the primary judge’s findings the CE marking could not have been placed on any of the devices other than because of the appellants’ negligence: TJ [1480], [3689]. The proper inference to be drawn from these circumstances, which the primary judge drew, is that but for the appellants’ negligence the devices would not have been supplied in Australia in the way they were in fact supplied. The appellants maintained that, nevertheless, the respondents had not proved that the devices would not have been supplied in Australia by some other method. As the appellants put it in oral submissions, why would it not be inferred that the devices would have been otherwise registered on the ARTG and thus supplied in Australia?

831 There are three alternative answers to this proposition.

832 First, given the way in which the case was run before the primary judge (as described above) it was not a matter for the respondents to negative every potential pathway to registration of the devices on the ARTG. The devices had been registered on the ARTG on the basis of the appellants applying a CE Mark to the devices in circumstances where the appellants could only do so as a result of their negligent evaluation of the safety and effectiveness of the devices. Having proved that fact on the balance of probabilities, there was no further burden of proof on the respondents to prove that the appellants could not otherwise have obtained registration of the devices on the ARTG unless evidence was adduced by the appellants to support that proposition. But merely to complain after the event that the respondents had not negatived a possibility never seriously advanced below is impermissible: see, by analogy in the context of negligent failure to warn, *Bennett v Minister of Community Welfare* [1992] HCA 27; (1992) 176 CLR 408 at 420-421, *Chappel v Hart* [1998] HCA 55; (1998) 195 CLR 232 at [34], [93.8], *Naxakis v Western General Hospital* [1999] HCA 22; (1999) 197 CLR 269 at [31], [76], [127], *Rosenberg v Percival* [2001] HCA 18; (2001) 205 CLR 434 at [88]. See also *Scope Machinery Pty Ltd v Ross* [2009] WASCA 100 at [25], *Amaca Pty Ltd v Hannell* [2007] WASCA 158; (2007) 34 WAR 109 at [395].

833 Second, to obtain registration without the CE marking, as is apparent from the primary judge’s reasons, the TGA would have carried out an independent assessment of the safety and efficacy of the devices and the appellants would have needed to demonstrate that independent pre-market testing of their safety and efficacy had been carried out: TJ [1391]. There was no basis to assume or infer that the appellants would have obtained registration of the devices on the ARTG on some basis alternative to their application of the CE Mark to the devices. The appellants have not explained how it might be that, if the TGA had done an independent assessment of the safety and efficacy of the devices, the TGA might have been satisfied that the devices should be registered on the ARTG as they were in fact registered. That possibility, on the unchallenged findings of the primary judge about the material risk of clinically significant complications which each device carries, is inconceivable. The devices were only on the Australian market because the appellants’ negligent pre-market evaluations enabled the appellants to apply a CE Mark to the devices. It cannot be assumed or inferred that the TGA, in conducting an independent assessment of the safety and efficacy of the devices, would have been satisfied with the seriously deficient pre-market evaluations which the appellants had conducted.

834 To the contrary, if the primary judge had been called upon to consider this issue, we are satisfied that the proper answer on the evidence is that it must be inferred that the TGA would not have permitted the POP devices or TVT Secur to be registered on the ARTG at all. Any non-negligent evaluation of the POP devices would have caused the appellants to realise that they could not persuade regulatory authorities or pelvic surgeons that the benefits of these devices outweighed the risks: TJ [2491]. Further, any non-negligent evaluation of the POP devices would have caused the TGA to conclude, as the primary judge did, that the POP devices 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: TJ [3498]. There was persuasive evidence supporting this conclusion: TJ [1026], [1036], [1791], [1951], [2942]. It must also be inferred that if the appellants had conducted a non-negligent evaluation of the SUI devices excluding TVT Secur (which also should never have been on the market at all, as to which see below) then, if the appellants had sought registration of those devices on the ARTG (see the third issue below), the TGA would not have permitted registration unless the risks of those devices were fully disclosed.

835 As to TVT Secur, which was a Class III medical device, it is a single incision sling: TJ [1656]. The pre-market evaluation of TVT Secur was inadequate, including the lack of any clinical trials: TJ [1656]-[1700]. Evidence of problems emerged quickly: TJ [2168]-[2201], [3075]-[3092]. It was only on the market in Australia between April 2007 and March 2008. By 2017 it was apparent that surgery with single-incision slings should only occur in the context of a clinical trial or where arrangements are in place for clinical governance such as a long-term prospective audit: TJ [3092]. It follows that a non-negligent evaluation of TVT Secur would have disclosed that its risks outweighed its benefits for any patient. It is not to the point that the TGA assessed the TVT Secur on the basis of examination of the full design dossier. The information which should have accompanied any application to the TGA as a result of a non-negligent evaluation of the TVT Secur (if such an application would have been made at all which is unlikely, as discussed below) would have included the outcomes of clinical trials which would have disclosed what ultimately became clear about the device: it should not have been on the market and was only suitable for use in the context of a clinical trial or long-term audit.

836 Third, in any hypothesised circumstances of a non-negligent pre-market evaluation of the safety and efficacy of the devices there are some necessary considerations. One, the hypothesis cannot involve any other negligence or legal wrong on the part of the appellants (such as dishonesty, fraud or misleading and deceptive conduct). Two, on the evidence, any non-negligent evaluation of the devices would have resulted in the appellants’ recognition of the fact that they could not persuade regulatory authorities or pelvic surgeons that the benefits of the POP devices or TV Secur outweighed the risks and that the other SUI devices could not be supplied without disclosure of the risks of those devices (in effect, the pleaded complications). Three, it is the appellants which remain relevant, not some hypothesised other entities. In this regard, the appellants consistently demonstrated that they were unwilling to disclose any risk of the devices that might adversely affect their marketing of the devices as minimally invasive, with no long-term side effects, accompanied only by ordinary surgical risks: see, for example, TJ [2732]-[2736], [2739]-[2741], [2742]-[2746], [2810]-[2939], [2940]-[3028], [4539]. The appellants were companies that the primary judge found:

(1) did not consider it was in their commercial interests to be full and frank with the public about the risks associated with their products: TJ [3318];

(2) knew that doctors were very interested in the incidence of complications: TJ [3321];

(3) were concerned not to give “overinformation” (that is, information about the risks of the devices): TJ [3323]; and

(4) in public documents, minimised or avoided mentioning the risks of the devices: TJ [3322], [3328]-[3344], [3346].

837 It is these same companies which must be posited to exist in any hypothetical non-negligent pre-market evaluation of the devices. On the basis of the evidence, it is impossible to infer that the appellants would have been willing to take the devices to the market on the basis of a proper disclosure of the risks they involved. Disclosure of the risks effectively destroyed the market for the POP devices: TJ [2491]. Nor could it be inferred that the appellants would have taken the Gynemesh PS device to the market based on only a limited indication for abdominal sacrocolpopexy and excluding transvaginal indication (noting that in 2013 the indication for this device, before its withdrawal from the market in 2017, was narrowed to non-transvaginal surgery): TJ [140], [2547], [2553], [2559]. While there is no evidence about the marketing consequences of proper disclosure of the risks for the SUI devices (as required by the Injunction), the idea that the appellants would have wanted to bring such devices to the market on that basis seems far-fetched. The contrary inferences are compelling.

838 Further, we do not accept that the course of events which occurred with the regulators including the TGA once the risks of the devices began to emerge is good evidence of what would have occurred if the appellants had conducted a non-negligent pre-market evaluation of the devices and sought registration on that basis. There is a material difference between a case where a company and a regulator are dealing with a new product not yet on the market and a case where a company and a regulator are dealing with a product that has been on the market for a number of years. It is not surprising that in the latter case the regulators did not require immediate removal of the devices from the market. If there had been a non-negligent pre-market evaluation of the devices all of the material risks would have been known and would had to have been disclosed. As it was, however, the risks emerged over years and in a piecemeal fashion. Compliance with the regulators’ ultimate requirements for the POP devices, as noted, destroyed the market for the POP devices. If there had been a non-negligent pre-market evaluation, however, the position would have been different. There would have been a new product with accompanying proper disclosure of the new product’s material risks. It is not difficult to infer that in such an event the appellants would not have proceeded to market the devices at all or that, if they did, the POP devices and TVT Secur would never have been approved by a regulator for supply and the other SUI devices would have been approved only with proper disclosure of the risks.

839 It is thus misconceived for the appellants to complain that the evidence did not establish that registration in Australia would have been withheld had the appellants disclosed additional facts about the testing process for each device or that withholding or withdrawing each device from the market was not the only course reasonably open to the appellants or any regulator. Had they conducted a non-negligent pre-market evaluation of the devices the appellants and the regulators would have been faced with a new device carrying material risks such that the POP devices and TVT Secur should not be on the market at all and the other SUI devices either should not be on the market or should only be on the market with warnings about the risks commensurate with the terms of the Injunction.

840 Contrary to the appellants’ contentions, and consistent with the reasoning above, TJ [4440]-[4446] do not involve any error by the primary judge. The primary judge rejected the appellants’ contentions about proof of causation in the case of Mrs Gill. Mrs Gill was implanted with a Prolift in January 2007: TJ [3919]. Prolift is a POP device which the primary judge found was 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: TJ [3498]. The primary judge said:

(1) while it is true that clinical testing is not the only regulatory avenue to market, a manufacturer has to satisfy the essential requirements for CE marking. The appellants did not do so for Prolift: TJ [4440];

(2) the fact that (some surgeons) considered TVT the gold standard treatment for SUI says nothing about the negligent evaluation of Prolift: TJ [4441];

(3) it was Ethicon which applied the CE marking: TJ [4442];

(4) the person at Ethicon who made that decision did not give evidence and nor did any member of the regulatory team. It may be inferred that their evidence would not have assisted the appellants: TJ [4443];

(5) the proposition that the devices were “extensively evaluated” does not hold good for Prolift in general, let alone Prolift Total, which was the device Mrs Gill received: TJ [4444];

(6) a reasonably prudent manufacturer would not have affixed the mark or taken the device to market until or unless its safety had been demonstrated in adequately powered randomised controlled trials: TJ [4445]; and

(7) there is no evidence to indicate, and the respondents did not submit that, without CE marking, Prolift would have been sold in Australia: TJ [4446].

841 This reasoning process involves no error. It is both sound and persuasive.

842 For these same reasons, it is not to the point that the respondents did not adduce evidence from Dr Hinoul that the appellants would not have placed each of the devices on the Australian market had they had an appreciation of the asserted problems with the testing regime. It was not for the respondents to adduce evidence from Dr Hinoul as to this hypothetical possibility. The evidence referred to by the appellants, properly understood, is also not to the contrary in any event. The fact is Dr Hinoul never suggested that the devices would have been supplied in Australia by some means other than reliance on the CE marking. Further, it is simply not open to infer or assume that if the appellants appreciated that their pre-market evaluations of the devices were inadequate and did not permit the CE Mark to be applied to them, the appellants would nevertheless have proceeded to apply the CE Mark and on that basis obtain registration for the devices on the ARTG. To so infer or assume would involve another assumption that the appellants were willing to falsely represent that they had complied with the requirements to enable CE marking to be applied to the devices. This is impermissible.

843 It is also misconceived for the appellants to focus on the issue whether but for the negligent post-market evaluation of the safety and efficacy of the devices, the devices would not have remained on the market. The fact is that, but for the negligent pre-market evaluation of the devices, they would not have been on the market at all and, if the SUI devices had been on the market at all (excluding TVT Secur which would not have been), then they would not have been on the market without proper disclosure of the pleaded complications. The post-market evaluation of the devices was also negligent. The primary judge did not find that but for the negligent post-market evaluation of the devices the devices would have been withdrawn from the market, presumably because she did not need to do so. But it could not have been inferred that, had adequate post-market evaluations been carried out, the appellants would have knowingly continued to supply the devices in circumstances where to do so would involve knowingly exposing consumers to a reasonably foreseeable risk of clinically significant complications which had never been the subject of any warning to consumers. Nor could it be inferred or assumed that the TGA would have permitted this to occur had it been notified of the hypothesised non-negligent post-market evaluations (which it necessarily would have been on this counter-factual hypothesis). The contrary inference would have been necessary.

844 For the same reasons, the appellants’ contention that the primary judge reversed the onus of proof of causation, which was on the respondents, cannot be accepted. The reasoning above does not involve any reversal of the onus of proof.

845 The appellants said:

Given the [respondents] did not allege any of the treating surgeons of Mrs Gill, Mrs Dawson or Mrs Sanders was negligent and that the information and warnings provided by those treating surgeons was different to those in the relevant IFU, this must mean that their respective treating surgeons applied their clinical expertise and decided not to discuss all the potential risks of which they were aware.

846 However, given the evidence, it could not be inferred or assumed that the treating surgeons of Mrs Gill, Mrs Dawson or Mrs Sanders were aware of the pleaded complications. It could not be inferred or assumed that their treating surgeons decided not to discuss with their respective patients all of the potential risks of which they were aware. It could not be inferred or assumed that had the appellants made them aware of the pleaded complications, the treating surgeons would not have informed their patients to that effect or recommended an alternative treatment not involving implantation of the devices. The weight of the evidence in each respect was to the contrary and the primary judge so found: TJ [4421], [4491], [4492], [4494], [4508], [4558]. In so doing, the primary judge did not reverse the onus of proof. As the respondents submitted, the lack of evidence from the treating surgeons was not a necessary bar to the respondents’ success. The primary judge accepted the representative respondents’ evidence that, if warned of the pleaded complications, they would not have had the implant surgery. The central issue in this case was whether each representative respondent would have had the device implanted had she been appropriately warned about the risk of the pleaded complications, not what the treating surgeons might have done.

847 Further, and as the respondents submitted orally, it is difficult to accept that any inference of the kind identified in *Jones v Dunkel* or *Ferrcom* should be drawn against the representative respondents to the effect that the evidence of the treating surgeons would not have assisted them. The circumstances of the present case weigh against any such inference. First, the appellants had denied the existence of the pleaded complications. Secondly, if the treating surgeons had acted consistently with their professional obligations then it should be inferred that they would have communicated the pleaded complications to the representative respondents had they been aware of them. This is an appropriate inference given the nature and severity of the pleaded complications. As noted, most of the pleaded complications are different in kind from the adverse reactions disclosed in the IFUs before 2015. The fact that the treating surgeons did not communicate to the respective respondents every adverse reaction in the IFUs (a point the appellants repeatedly made) may be accepted. But that is not powerful evidence that the treating surgeons would not have communicated the pleaded complications to their patients had they known about them, given the nature and severity of the pleaded complications compared to the transient, surgical, and limited risks of the devices disclosed in the IFUs which never included, for example, chronic inflammation, chronic pain, reoperation or revision surgery associated with complications, difficulty or impossibility of complete removal of the devices, and associated risks of aggravation or new complications caused by revision surgery. Further, the kind of evidence the treating surgeons could have given would have involved a hypothetical reconstruction of a kind which is of doubtful value: see, for example, *Australian Executor Trustees (SA) Ltd v Kerr* [2021] NSWCA 5 at [285].

848 Nor can it be accepted that if the implantation of the devices was not contraindicated for any individual patient then it may be inferred that no pelvic surgeon would have communicated any warning about the pleaded complications to their patient. The problem with this submission is the concept of contraindication. It assumes that the pleaded complications are a risk only for specific patients. The evidence established, however, that the pleaded complications are a material, clinically significant, risk for every woman implanted with any of the devices. The risks are increased for those suffering from an auto-immune disorder but, on the evidence, they exist for every woman. Accordingly, had there been an adequate warning by the appellants of the pleaded complications (see the answer to common question 18 and the Injunction) then the appropriate inference is that a pelvic surgeon, acting in accordance with their professional obligations, would have communicated the risk of those complications to every woman considering implantation of any of the devices. The primary judge did not err in drawing that inference in the case of each of the representative respondents.

849 It is also misconceived for the appellants to contend that the respondents did not demonstrate that Mrs Gill, Mrs Dawson and Mrs Sanders would not have suffered their respective injuries in light of the incidence and severity of complications associated with alternative treatments, and their respective pre-existing conditions. The primary judge rejected this argument at [5673] referring to the observations in ***Commonwealth v McLean*** [1996] NSWSC 657; (1996) 41 NSWLR 389 at 411 that:

Causation in fact of an actual event is an all or nothing issue. The plaintiff was not entitled to recover anything for his throat cancer unless he established, on the balance of probabilities, that it had been caused by the tort. Once the plaintiff succeeded on that issue the defendant was not entitled to any deduction for the chance that the plaintiff might have contracted throat cancer in any event…

850 In *Commonwealth v McLean* reference was also made at 410 to ***Purkess*** *v Crittenden* (1965) 114 CLR 164; [1965] HCA 34 at 168 where Barwick CJ, Kitto and Taylor JJ said:

…where a plaintiff has…made out a prima facie case that incapacity has resulted from the defendant’s negligence, the onus of adducing evidence that his incapacity is wholly or partly the result of some pre-existing condition or that incapacity, either total or partial, would, in any event, have resulted from a pre-existing condition, rests upon the defendant.

851 At TJ [4906] the primary judge said:

The third area of dispute relates to the correct approach to other contingencies and two contingencies in particular. The first is the chance that, had the applicants undergone a different form of surgery, they might have developed some of the same complications. The second is the significance of pre-existing conditions, that is, conditions which preceded the implantation of the respondents’ devices. The first is to be dealt with according to the principles in *Malec* [*Malec v J C Hutton Pty Ltd* (1990) 169 CLR 638[[1990] HCA 20],the second according to the principles in ***Watts v Rake***(1960) 108 CLR 158 [[1960] HCA 58] and *Purkess*….

852 The appellants did not submit that the primary judge’s analysis in this regard was in error.

853 In any event, the appellants failed on the facts for each representative respondent.

854 As to Mrs Gill, the appellants accepted that the device caused some of Mrs Gill’s injuries, including the four episodes of mesh exposure, the consequential surgical procedures, and some of her pelvic pain: TJ [4428]. Otherwise, the evidence included that:

(1) Dr Leake said that it was tightness of the mesh around the cervix that caused the erosions Mrs Gill had experienced but the excessive tension was not due to incompetence on the part of Dr Chapple or faulty operating technique: TJ [3962];

(2) Dr Leake stated that, with the benefit of hindsight, it was clear that all of Mrs Gill’s gynaecological symptoms for which she consulted her were secondary to the use of Prolift mesh to repair her prolapse: TJ [3977];

(3) Dr Jeffrey reported that Mrs Gill’s pain radiating from the rectum to the pelvic side wall and down the right leg was typical of a mesh arm too tight through the sacrospinous ligament: TJ [4013];

(4) Dr Tsokos said that “[a]s always mesh and its complications provide a difficult issue, particularly in a relatively young woman in whom the inability to have satisfactory intercourse is creating a marital problem”: TJ [4014];

(5) Professor Korda expressed the view that all her current symptoms and disabilities resulted from the insertion of the Prolift device, the resultant erosion and the multiple surgical procedures required to correct and manage her symptoms, although he retreated a little from this in cross-examination: TJ [4035];

(6) Dr Meagher reported that he did not think there was any real doubt that the Prolift implant did more likely than not cause physical damage to Mrs Gill’s body: TJ [4042];

(7) Dr Meagher’s unequivocal view was that if Mrs Gill had not been implanted with the Prolift, more likely than not she would avoided the physical damage to her body that led to the revision surgery and he had no doubt that the complications of the Prolift implant had had “a very substantial effect” on Mrs Gill’s life: TJ [4043];

(8) Dr Kriel, a specialist pain management physician, considered all Mrs Gill’s pain to be “consistent with the mesh”: TJ [4050]-[4051];

(9) Professor Vancaillie diagnosed Mrs Gill with chronic pain syndrome (pudendal neuropathy) secondary to mesh insertion and removal surgery: TJ [4055]; and

(10) Dr Brown reported Mrs Gill was “tender +++on [right] anterior wall/apex where mesh fibres are exposed”: TJ [4060].

855 The primary judge also found, after a detailed evaluation of the evidence, that for Mrs Gill the device caused:

(1) Mrs Gill’s recurrent prolapse: TJ [4927]-[4931];

(2) the pain Mrs Gill experienced after her Prolift surgery in her pelvis, coccyx, her groin, her lower back, her vagina and her rectum was caused by the implantation of Prolift Total, mesh infection, mesh erosions or exposure, and the surgery undertaken to treat the exposures: TJ [4981];

(3) a multitude of Mrs Gill’s colorectal problems, including chronic pain, pain on large bowel movements, pain when straining to defecate, pain with orgasms, and faecal and flatal incontinence: TJ [5002]; and

(4) aggravation of Mrs Gill’s depression and generalised anxiety disorder: TJ [5027].

856 As to Mrs Dawson, the appellants accepted that the device caused the mesh exposure requiring surgery on 14 October 2009 and the surgery itself, the mesh exposure requiring surgery on 31 January 2014 and the surgery itself, the mesh exposure requiring surgery on 30 October 2015 and the surgery itself, and the scarring on the left side of the vagina and the operation on 17 May 2017 to remove it: TJ [5337]. Otherwise, the evidence included:

(1) Professor Dwyer advised her that the best option was surgical removal of as much of the mesh as possible to relieve her symptoms: TJ [4137];

(2) it is clear from the discharge summary, signed by Dr Schierlitz, that she was of the view that the mesh was the or at least a cause of Mrs Dawson’s pain: TJ [4151];

(3) Dr Schierlitz reported that she had managed to remove most of the mesh that was palpable and painful on prior examination: TJ [4154];

(4) Professor Korda concluded that Mrs Dawson had detrusor overactivity and chronic pain syndrome as a result of mesh insertion. More specifically, he concluded that the Gynemesh implant resulted in dyspareunia and chronic pain syndrome. Apart from the constipation, the need to digitate, the prolapse symptoms, lower back pain and dragging pain that preceded the implant surgery, he attributed all the symptoms she described to him at the time of the consultation to the Gynemesh implant. In his report he also attributed her urinary dysfunction to the implant but in cross-examination, when reminded of the pre-existing urinary symptoms, revised his opinion, stating that the mesh repair worsened her urinary dysfunction: TJ [4173];

(5) Professor Eyers considered the abnormalities in Mrs Dawson’s pelvic floor were consistent with her previous mesh prolapse surgery and the subsequent procedures to remove the mesh: TJ [4176]. He added that the insertion and later removal of the mesh had caused what he referred to as “collateral damage” to the normal tissues alongside and around the mesh. He said that this explains the abnormalities he was able to palpate in the parametrial and pararectal tissues and the irregularities he could feel in the pelvic floor. He said that these palpable abnormalities were “indicative of residual mesh and/or the secondary effects of surgery performed [in an attempt] to remove the mesh”: TJ [4177];

(6) Professor Korda expressed the view that it was more likely than not that Mrs Dawson had pudendal neuropathy because of mesh placement near the sacrospinous ligaments which are near the pudendal nerve: TJ [4181];

(7) Professor Korda’s opinion was that, but for the mesh implant, it is more likely than not that Mrs Dawson “would have avoided vaginal pain, pain in her buttocks which radiates down her legs, a prickly feeling inside her pelvis, a burning feeling when she extends both legs, mesh erosions and repeated revision surgery”: TJ [4182]; and

(8) Professor Korda expressed the opinion that the formation of the vaginal band, scarring and the ongoing pain involving Mrs Dawson’s vagina, rectum and buttock more likely than not resulted from the mesh implant surgery performed on 8 May 2009. Further, Professor Korda opined that it was more likely than not that the surgery Mrs Dawson underwent on 17 March 2017 was necessary because of the mesh implant surgery that was performed on her on 8 May 2009. His opinion was based on the fact that the scar tissue was related to the initial mesh insertion and subsequent revision surgeries and was most unlikely to have developed from any other procedure she had had. This opinion was not challenged in cross-examination: TJ [4193].

857 The primary judge also found, after a detailed evaluation of the evidence, that for Mrs Dawson the device caused:

(1) Mrs Dawson’s pudendal neuropathy which was contributing to her pelvic pain: TJ [5354];

(2) Mrs Dawson’s chronic pain syndrome: TJ [5365]-[5371];

(3) Mrs Dawson’s coccyx pain: TJ [5404]-[5423];

(4) Mrs Dawson’s apareunia: TJ [5431];

(5) aggravation of Mrs Dawson’s pre-existing defecation disorder: TJ [5442]; and

(6) Mrs Dawson’s severe and chronic pelvic pain: TJ [5456].

858 As to Mrs Sanders, the appellants accepted that the device had caused some of her injuries including the exposure requiring surgery on 8 August 2011 and the surgery itself and the adjustment disorder with mixed anxiety and depressed mood, though only to the extent that her reduction in mobility is causally related to the implant rather than her co-morbidities, particularly the osteoarthritis of her hip: TJ [4516].

859 The primary judge also found, after a detailed evaluation of the evidence, that for Mrs Sanders the device caused:

(1) the formation of scar tissue: TJ [5616];

(2) the urinary symptoms (incontinence) of which Mrs Sanders’ complained in and from 2011, as the insertion of the TVT, the subsequent erosion, and the necessity for excision damaged the integrity of the urethra, causing urethral instability: TJ [5644]-[5645];

(3) Mrs Sanders’ overactive bladder symptoms of urgency and frequency, but some allowance must be made for the chance that they would have persisted or recurred even if she had not undergone TVT surgery: TJ [5652];

(4) Mrs Sanders’ dyspareunia, apareunia, and chronic pelvic pain, with the exception of the hip pain which was cured by the hip replacement: TJ [5669]; and

(5) Mrs Sanders’ adjustment disorder with mixed anxiety and depression: TJ [5674]-[5675].

860 The primary judge also considered potential alternative sources of the injuries and made allowance for them where appropriate: for example, see TJ [4981]-[4982], [5002], [5018], [5442], [5652]. Where the evidence was inadequate to prove that the devices caused the injury the primary judge rejected the claim. Accordingly, the following claims were rejected:

(1) Mrs Gill – development of a bulky, fibroid, acutely anterverted uterus: TJ [4932]-[4937]; vaginal bleeding and spotting: TJ [4983]; urinary symptoms: TJ [5032];

(2) Mrs Dawson – rigid vagina: TJ [5355]; detrusor instability or overactivity and lower urinary tract dysfunction: TJ [5364]; psychiatric disorder: TJ [5403]; and

(3) Mrs Sanders – erosion into the bladder and urethra: TJ [5617]; squamous metaplasia of the trigone: TJ [5624]; flatal incontinence and constipation: TJ [5653].

861 This reasoning by the primary judge is orthodox and consistent with the principle that the legal onus in relation to causation was for the respondents to discharge.

862 Further, the appellants’ contention that the primary judge erred in finding that Mrs Gill, Mrs Dawson and Mrs Sanders would not have suffered their injuries but for the negligent lack of warnings also cannot be sustained. The primary judge found that had non-negligent warnings about the pleaded complications been given, none of them would have consented to implantation of the device that was implanted in them. The primary judge also found that it was the devices that caused the compensable injuries. That was sufficient for the conclusion that the requirement of causation was satisfied. That conclusion is not undermined by the submissions of the appellants to the contrary.

863 First, and as already noted, the fact that Mrs Gill was told that mesh was probably not for her given that she did not wish at that time to exclude the possibility of further children says nothing about what she would have done had she been warned of the pleaded complications. Her evidence that she would not have had the implant surgery was clear and was accepted by the primary judge: TJ [4465]-[4496].

864 Second, there can be no meaningful comparison drawn between the information which the primary judge found should have been provided by the appellants (see the answer to common question 18) and the information in the Prolift IFU which would have been available to Mrs Gill’s treating surgeon. It cannot be inferred that Dr Chapple would not have passed on a warning about the pleaded complications (had such information been known) merely because Dr Chapple apparently did not pass on all of the information in the Prolift IFU. The Prolift IFU said nothing about the device causing chronic inflammation which may then cause any of the other pleaded complications including such matters as chronic pain. Accordingly, the information given to Ms Gill is not “powerful evidence” that pelvic surgeons generally (or Dr Chapple in particular) would not have passed on warnings about the pleaded complications to Mrs Gill.

865 Third, it is one thing to be told about a risk of erosion of the mesh for a small percentage of women if their body rejected the mesh implant (as Mrs Gill was according to her evidence). It is another to be told that the devices cause chronic inflammation, which can result in the extrusion or erosion of the mesh into surrounding organs, including the vaginal wall, bladder or urethra, along with accompanying infection, chronic pain, dyspareunia and offensive vaginal discharge, for example. Mrs Gill also has psoriasis which is an autoimmune disorder: TJ [2986], [3888], [3962], [4462], [4465], [4486], [4494]. The pleaded complications include 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. It is difficult to imagine that Dr Chapple would not have communicated this information to Mrs Gill had he known it. On the evidence, the contrary inference was properly drawn by the primary judge. It is equally difficult to reject Mrs Gill’s evidence that she would not have had the implant surgery had she known of some of the complications caused by the devices: TJ [4465]. On her evidence Mrs Gill was not concerned about the communicated risk of erosion of the mesh in a small percentage of women whose bodies rejected the mesh because she assumed that she was unlikely to fall into that small percentage. Had she been informed of the matters in the answer to common question 18, it is unlikely that she could have made that assumption. The primary judge was right to accept her evidence that she would not have had the surgery if she had known about some of the pleaded complications.

866 Fourth, and for the same reasons, it cannot be accepted that Dr Lim, had she known about the pleaded complications, would not have communicated that information to Mrs Dawson. The primary judge was correct to so infer: TJ [4508]. There is also a material difference between the information contained in the Gynemesh PS IFU (“potential adverse reactions… including infection potentiation, inflammation, adhesion formation, fistula formation, erosion and scarring that results in implant contraction”), the risks which the records show that Dr Lim communicated to Mrs Dawson (“bleeding, infection, anaesthetic risk, erosion, recurrence of prolapse, visceral injury, *de novo* stress incontinence, dyspareunia, and an increase in vaginal discharge”, TJ [4504]) and the pleaded complications. As such, this is not “powerful evidence” that Dr Lim would not have communicated the pleaded complications to Mrs Dawson had Dr Lim known about them. Mrs Dawson’s evidence was that she was not told that the “mesh could erode into my vagina or cause pain, pain with intercourse or the need for multiple operations to alleviate the problem”, that if “these complications arose, it may not be possible to remove the entire implant, or substantial parts of the implant, in order to alleviate the problem”, that the “implant surgery could lead to me experiencing chronic and severe pain, which could significantly affect my quality of life”, amongst other things: TJ [4505]. Apart from the fact of possible erosion, the primary judge accepted this evidence: TJ [4507]. The primary judge’s reasons for accepting that Mrs Dawson would not have had the implant surgery had she known of these risks are cogent and compelling: TJ [4509]-[4515].

867 Fifth, the same analysis applies to Mrs Sanders. Again, it should be inferred that Dr Taylor would have communicated these to Mrs Sanders given their nature and seriousness. As the primary judge noted, the IFU for TVT mentioned only transitory and surgical risks or (at best) additional risks of extrusion, erosion, fistula formation and inflammation. These are materially different risks from the pleaded complications: TJ [4531]. The primary judge was also right to infer that Dr Taylor would have been in no better position than Dr O’Neill about the risks of the devices: TJ [4551]-[4552]. Mrs Sanders gave evidence that she would not have had the surgical implant had she known some of the pleaded complications: TJ [4554]. The primary judge’s inference that had Ms Dawson been informed of these matters she would not have had the implant surgery is cogent and persuasive: TJ [4555]-[4556].

868 Accordingly, it cannot be accepted that the primary judge erred in finding that the appellants’ negligence in not providing the necessary warnings with the devices caused the injuries to the representative respondents.

869 For these reasons grounds 9, 10 and 11 of the appeal are unsustainable.

##### 12. CAUSATION – CONSUMER LAW CLAIMS (GROUNDS 4 AND 14)

###### 12.1 Appellants’ submissions

870 The appellants contended that the primary judge erred in relation to causation for each representative respondent because, first, there was insufficient evidence to make findings of causation and, second, insofar as there was evidence, the evidence was inconsistent with the findings made by the primary judge: AS [68]. The result is that the primary judge erred in finding the defect caused the injuries to Mrs Gill, Mrs Dawson, and Mrs Sanders. The findings were not based on any evidence and were inconsistent with the (limited) evidence before the Court: AS [84].

12.1.1 Mrs Gill

871 The appellants alleged that there was no evidence that the defect found by the primary judge (that Prolift had a propensity to cause harm that persons generally would not expect) caused Mrs Gill’s injuries. Specifically:

(1) Mrs Gill did not adduce evidence from Dr Chapple (despite the fact that he was the treating surgeon who implanted the Prolift device) or Dr Natalwala (as one of the surgeons who discussed treatment options with Mrs Gill); and

(2) as a consequence, it was not possible to know whether Dr Chapple (or Dr Natalwala) was aware of the risks associated with Prolift device (noting that the primary judge found that it is unlikely the IFU would be the sole source of information for most surgeons (TJ [3215] and [3311])), or that a different or additional warning would have prompted Dr Chapple (and, as a consequence, Mrs Gill) to act differently: AS [70].

872 The appellants alleged that the evidence (such that it was) tended to show that different or additional warnings would not, on the balance of probabilities, have resulted in a different outcome: AS [71]. In particular:

(1) the Prolift IFU for that period outlined a number of potential adverse reactions, warnings and precautions: see Annexure 4B to Ethicon’s written submissions below [SBM.020.008.0001];

(2) Mrs Gill’s evidence, however, was that she did not remember any warnings from Dr Natalwala (affidavit of Kathryn Gill affirmed 27 July 2016, [51] [LAY.010.001.0001 at .0011]), and the matters discussed with Dr Chapple did not include a number of the matters in the IFU (affidavit of Kathryn Gill affirmed 27 July 2016, [63]-[81] [LAY.010.001.0001 at .0013-.0018]);

(3) equally, the contemporaneous records of Dr Natalwala and Dr Chapple do not record that these matters were discussed with Mrs Gill. This is powerful evidence, consistent with the evidence that each informed consent discussion is tailored by the individual treating surgeon (applying their medical expertise to the individual patient) to the circumstances of the individual patient, that not every warning in an IFU will more likely than not be passed on or repeated to each patient; and

(4) it follows that different or additional warnings would not more likely than not have changed the actions by Dr Chapple (or Dr Natalwala) and Mrs Gill.

873 Further, in support of the claim that the evidence of Mrs Gill suggests that different or additional warnings would not have resulted in a different outcome, the appellants pointed to the fact that Mrs Gill was told by Dr Natalwala that mesh was “probably not for her” and by Dr Chapple that he would “lean away from a Prolift procedure”: see TJ [3906], the appellants’ Annexure G). They also relied on the fact that Mrs Gill indicated that she, despite being told that erosion was a potential consequence of mesh surgery, “assumed I was unlikely to fall into that small percentage”: affidavit of Kathryn Gill affirmed 27 July 2016, [70(a)] [LAY.010.001.0001 at .0014]. It follows it cannot be said that, on the balance of probabilities, Mrs Gill would have decided on a different treatment option, particularly in light of the matters discussed above: AS [74].

12.1.2 Mrs Dawson

874 The complaint about the causation findings in relation to Mrs Dawson is substantially the same.

875 Mrs Dawson was first diagnosed with a prolapse in 1999, and underwent a hysterectomy and anterior and posterior colporrhaphy: TJ [4081]-[4083]. In 2008, Mrs Dawson was diagnosed with vaginal wall prolapse (TJ [4093]-[4095]), and was referred to Dr Lim: TJ [4094]. Dr Lim recommended physiotherapy, which Mrs Dawson declined because she had had “enough physiotherapy”: TJ [4095]. However, the appellants relied on the fact that:

(1) Mrs Dawson did not adduce evidence from Dr Lim and, as such, it is not possible to know whether Dr Lim was aware of the risks associated with Gynemesh PS, or whether a different or additional warning would have prompted Dr Lim (and, as a consequence, Mrs Dawson) to act differently; and

(2) it follows that it cannot be said, on the balance of probabilities, that the defect found by the primary judge (that Gynemesh PS had a propensity to cause harm that persons generally would not expect) caused Mrs Dawson’s injuries.

876 The appellants alleged that the evidence (such that it was) again tends to show that different or additional warnings would not, on the balance of probabilities, have resulted in a different outcome. Specifically:

(1) the primary judge’s findings in relation to Mrs Dawson’s consultations with Dr Lim are recorded at TJ [4094]-[4096]. The findings were based on the records of Dr Lim;

(2) the relevant Gynemesh PS IFU outlined a number of potential adverse reactions, warnings and precautions: see Annexure 4B to Ethicon’s written submissions below [SBM.020.008.0001];

(3) Mrs Dawson’s evidence, however, was that she did not recall any of the risks mentioned by Dr Lim and, notably, that she did not recall and did not believe she was advised that the mesh could erode into her vagina: affidavit of Dianne Rosemary Dawson affirmed 28 July 2016, [22] [LAY.010.007.0001 at .0008-.0009];

(4) the contemporaneous records of Dr Lim record that Mrs Dawson was made aware of the risks of “bleeding, infection, anaesthetic risk, erosion, recurrence of prolapse, visceral injury, de novo stress incontinence, dyspareunia, and an increase in vaginal discharge”: TJ [4504];

(5) as such, the warnings and information with which Mrs Dawson was provided do not mirror the information in the IFU; and

(6) accordingly, this is powerful evidence, consistent with the evidence that each informed consent discussion is tailored by the individual treating surgeon (applying their medical expertise to the individual patient) to the circumstances of the individual patient, that not every warning in an IFU will more likely than not be passed on or repeated to each patient and, as such, different or additional warnings would not more likely than not have changed Dr Lim’s or Mrs Dawson’s actions: AS [78].

12.1.3 Mrs Sanders

877 Again, the same complaint is made as to Mrs Sanders who, as noted above, was the only claimant to have made a misleading and deceptive conduct claim.

878 In October 2000, Mrs Sanders consulted Dr Taylor, who diagnosed her with SUI and told her that “he would ‘make things better’ and ‘fix the incontinence’ and put her on a waiting list for a TVT implant”: TJ [4234]. Dr Giele obtained Mrs Sanders’ written consent to the procedure, and the surgery was performed by Dr McNeill in March 2001: TJ [4235] and [4530]. However, the appellants relied on the fact that:

(1) Mrs Sanders did not adduce evidence from Dr Taylor (who was the treating surgeon who conducted the informed consent process with Mrs Sanders);

(2) as such, it is not possible to know whether Dr Taylor was aware of the risks associated with TVT-Classic, or whether a different or additional warning would have prompted Dr Taylor (and, as a consequence, Mrs Sanders) to act differently; and

(3) it follows that it was not open, on the balance of probabilities, for the primary judge to find that the defect caused Mrs Sanders’ injuries: AS [80].

879 The appellants alleged that the evidence (such that it was) again tends to show that different or additional warnings would not, on the balance of probabilities, have resulted in a different outcome. Specifically:

(1) there were limited findings (due to the limited evidence) in relation to Mrs Sanders’ consultations with Dr Taylor and Dr Giele which are recorded at TJ [4235] and [4530];

(2) regardless of which iteration of the TVT-Classic IFU (there was some dispute as to whether it was the Medscand IFU or the IFU used between September 2000 and November 2003), the IFU outlined a number of potential adverse reactions, warnings and precautions, including reference to (transitory) local irritation, potentiation of infections, and (in the case of the later IFU) extrusion, erosion, fistula formation and inflammation: see Annexure 4A to Ethicon’s written submissions below [SBM.020.007.0001];

(3) Mrs Sanders’ evidence, however, was that Dr Taylor did not advise her of any risks, and that she had never heard of the word erosion: affidavit of Ann Sanders affirmed 28 July 2016, [35] [LAY.010.005.0001 at .0007]. Dr Giele only mentioned intraoperative risks and did not mention erosion or exposure: TJ [4530]; and

(4) accordingly, this is powerful evidence, consistent with the evidence that each informed consent discussion is tailored by the individual treating surgeon (applying their medical expertise to the individual patient) to the circumstances of the individual patient, that not every warning in an IFU will more likely than not be passed on or repeated to each patient and, as such, different or additional warnings would not more likely than not have changed the actions of Dr Taylor and Mrs Sanders: AS [82].

880 Further, with respect to the primary judge’s finding that Mrs Sanders suffered damage caused by any misleading or deceptive conduct in connection with the TVT-Classic (TJ [4560]), the appellants alleged that there is no evidence that any treating surgeon would have provided different advice, including a different or additional warning, or that Mrs Sanders would not have undergone surgery to implant her TVT: AS [83].

###### 12.2 Discussion

881 The appellants’ contention that there was an insufficiency of evidence to make out causation for the consumer law claims for the representative respondents ought to be rejected.

882 As can been seen from the above, there are two types of statutory causation issues that need to considered: first, the issue of causation for the misleading and deceptive conduct claim of Mrs Sanders (ground 14); and secondly, the issue of causation for the statutory consumer claims as to defect, fitness for purpose and merchantability which relate to the individual claims of all three representative respondents (ground 4). Given what we have already said about causation in the context of the negligence claims, each of these grounds can be dealt with relatively shortly.

12.2.1 Misleading and deceptive conduct

883 The fact that Mrs Sanders did not call her treating surgeon, Dr Taylor, to give evidence that he would have provided different advice, goes nowhere for reasons we have explained above. The primary judge considered in some detail the material that would have been available to Mrs Sanders’ treating doctors, including Dr Taylor, and inferred, by an orthodox process of reasoning, that medical practitioners involved in Mrs Sanders’ treatment, including Dr Taylor, did not in fact know about the pleaded complications: TJ [4551]-[4552].

884 As to any suggested deficiency in the evidence of Mrs Sanders, the primary judge heard evidence from Mrs Sanders as to the matters which she regarded as important and would have regarded as important in determining whether to undergo mesh surgery. At TJ [4554] this evidence was summarised, which was that she would not have agreed to proceed if she had been told that: (a) the operation had a risk of the tape eroding into the bladder or vagina or urethra, which might require numerous operations to treat or that may not be able to be permanently fixed, (b) the operation had a risk of the tape causing pain with intercourse that might require a further operation to treat and that the operation may not be able to fix the problem, (c) if an erosion occurred, the tape may have to be cut, which might lead to a return of her urinary problems, (d) the tape could be difficult to remove if complications developed that required its removal, (e) the long-term effectiveness of the tape in treating urinary incontinence had not been proved because it had only been on the market for a few years, and (f) it was unknown whether the tape was safe to be left inside her for the rest of her life.

885 This evidence was unchallenged below: TJ [4555]. It is trite to remark that if a witness gives evidence that is not inherently incredible and it is unchallenged, then ordinarily a tribunal of fact will accept it: see *Precision Plastics Pty Limited v Demir* (1975) 132 CLR 362 (at 370-371 per Gibbs J, Stephen J agreeing and Murphy J generally agreeing). But the primary judge was alive to the fact that Mrs Sanders was reflecting on events that had taken place more than 15 years earlier and she had had no reason to reflect on the matter until, at the earliest, she was told that her symptoms were attributable to TVT: TJ [4555]. Her Honour cautioned herself not to place much too much weight on what Mrs Sanders said but nevertheless, found her account consistent with such contemporaneous documents as existed (TJ [4529]) and considered it more likely than not that Mrs Sanders would not have agreed to TVT surgery if she had been informed of the pleaded complications, in particular, the matters in respect of which she gave evidence: TJ [4556]. Hence, but for the absence of a suitable warning (conduct found to amount to a contravention of the statutory norm), the finding was made that it was more likely than not that Mrs Sanders would have undergone some other form of incontinence surgery which did not involve the use of polypropylene mesh.

886 Given the absence of error in these factual findings of the primary judge and her characterisation of the appellants’ conduct as contravening the statutory norm, there can be no sensible suggestion that it was erroneous for the primary judge to conclude that the found misleading and deceptive conduct materially contributed to the damage suffered by Mrs Saunders. There was no error in the causation finding.

12.2.2 The other statutory claims and causation

887 We now turn to the issue of causation for the defect, fitness for purpose and merchantability claims of the three representative respondents (ground 4).

888 It will be recalled that a fundamental matter underpinning the findings of defect was that the devices could cause the pleaded complications in any woman implanted with one of the devices, against which the appellants provided no or no adequate warning. As noted above, the respondents submitted that the primary judge was correct to reason that in the case of such a defect, causation is determined by an inquiry as to whether that harm came to pass: see RS [136]. However, the respondents’ proposition that causation is simply determined by whether the harm came to pass and that proof of what would have occurred had a warning been given is unnecessary (RS [136]) must be rejected. The relevance of the knowledge of the treating surgeon for each of the representative respondents was a question of fact which had to be answered in the circumstances of each individual case and not at the level of abstraction suggested by the respondents and as is evident in some part of her Honour’s reasons: TJ [4415], [4428], [4498] and [4517].

889 But on her Honour’s factual findings in the case of each representative respondent, our disagreement with the primary judge’s statement of principle goes nowhere.

890 It is unnecessary to repeat what we have noted above about the evidence of Mrs Sanders. As to Mrs Gill and Mrs Dawson, the position is relevantly the same as Mrs Sanders, and while each of these other representative respondents was cross-examined, their evidence in relation to causation was not the subject of direct challenge.

891 As we have explained above in the context of the causation in the negligence grounds (grounds 9, 10 and 11):

(1) as to Mrs Gill, there can be no meaningful comparison drawn between the information which the primary judge found should have been provided by the appellants and that available to Mrs Gill’s treating surgeon, Dr Chapple, and Mrs Gill’s evidence that she would not have had the implant surgery had she known of some of the complications caused by the devices (TJ [4465]) was compelling and was appropriate to be accepted; and

(2) as to Mrs Dawson, it was not in error for her Honour to conclude at TJ [4508] that if Dr Lim had known about the pleaded complications, she would have communicated that information to Mrs Dawson. The primary judge’s reasons for accepting that Mrs Dawson would not have had the implant surgery had she known of these risks are also compelling: TJ [4509]-[4515].

892 The primary judge’s factual findings in relation to the cases of each of the representative respondents are not attended by error. The representative respondents’ claims (other than under s 75AD of the TPA which makes a corporate manufacturer liable to compensate the individual who suffered injuries “because of” a defect of its goods and to recover compensation for “the amount of the individual’s loss suffered as a result of the injuries”) all fell within Pt V of the TPA which, in familiar terms, allowed for a person who suffers loss or damage “by” contravening conduct to obtain statutory compensation. In the light of her Honour’s findings as to the contravening conduct, it necessarily followed causation was established.

##### 13. LIMITATION PERIODS (GROUNDS 15 AND 16)

893 The primary judge found that Mrs Gill’s (TJ [4806] and [4832]) and Mrs Sanders’ (TJ [4854] and [4861]-[4863]) causes of action in negligence were statute barred, but that both were entitled to an extension of time.

###### 13.1 Mrs Sanders – extension of time (ground 16(a))

894 Although not elaborated upon orally, this ground of appeal involved a complaint that the applicable limitation statute was the 1935 Limitation Actrather than the 2005 Limitation Act. This wascontrary to the finding of the primary judge, who had found the 2005 Limitation Act applied because Mrs Sanders’ cause of action in negligence accrued no earlier than January 2007: TJ [4854]. There were some immediate difficulties with this argument. First, Mrs Sanders’ evidence necessarily demonstrated the 2005 Limitation Act applied: TJ [4854]. Secondly, even if it was accepted (on the basis of the contemporaneous medical records in evidence) that Mrs Sanders noticed symptoms at an earlier date, her Honour found that the symptoms described were so vague that they could not ground a determination that Mrs Sanders had sustained a “not insignificant injury” (TJ [4845], [4848]) prior to 15 November 2005, such as to result in the application, by reason of ss 6(1) and 55 of the 2005 Limitation Act, of the period of limitation set by the 1935 Limitation Act.

895 It is evident that the primary judge’s acceptance of Mrs Sanders’ evidence turned on her finding that Mrs Sanders did not present as a dishonest person, it was not suggested that she was dishonest, and it was not put to Mrs Sanders that she was reconstructing her conversations with her treating doctors: TJ [4845]. This finding was far from “glaringly improbable” or “contrary to compelling inferences”: *Lee v Lee* [2019] HCA 28; (2019) 266 CLR 129 at [55] per Bell, Gageler, Nettle and Edelman JJ; RS [147]. Moreover, the appellants do not challenge the findings that the file notes of Mrs Sanders’ treating doctors erroneously recorded her medical history (stating that Mrs Sanders had undergone a prolapse repair) (TJ [4847]) and, as between treating doctors, were inconsistent: TJ [4840], [4843] and [4847]. As such, these records are a very insecure foundation for any argument that it was not open to accept Mrs Sanders’ evidence. In any event, her Honour’s treatment of the file notes discloses no error.

896 As was accepted in oral submissions, however, the real complaint was as to the “absence of evidence” to base the finding of the “jurisdictional fact necessary for the court to have the power exceptionally to permit cases to be prosecuted after the law generally says they can’t be”: T97.45-T98.14. It is to this topic we now turn with regard to both Mrs Sanders and Mrs Gill.

###### 13.2 Mrs Gill and Mrs Sanders – extensions of time (grounds 15 and 16(b))

897 The appellants contended that the primary judge erred in granting Mrs Gill and Mrs Sanders an extension of time: AS [106].

898 The appellants noted that the concise demonstration of the error is seen at TJ [4831] (Mrs Gill) and [4861]-[4862] (Mrs Sanders), where the primary judge said that “[Ethicon] adduced no evidence of prejudice” and concluded that there was therefore no reason not to exercise the discretion to extend time: AS [108]. The appellants submitted that it is:

…well established that “an applicant for an extension of time must prove the facts which enliven the discretion to grant the extension and also show good reason for exercising the discretion in his or her favour. An extension of time is not a presumptive entitlement which arises upon satisfaction of the pre-conditions that enliven the extension. The onus of persuasion is upon the applicant for an extension of time” (Emphasis added) (*Prince Alfred College Inc v ADC* (2016) 258 CLR 134, [99] (French CJ, Kiefel, Bell, Keane and Nettle JJ, applying *Brisbane South Regional Health Authority v Taylor* (1996) 186 CLR 541, 544 (Dawson J), 547 (Toohey and Gummow JJ), 553-554 (McHugh J), 573 (Kirby J)).

899 According to the appellants at AS [109]:

…it is not to the point that Ethicon did not adduce evidence of prejudice. Rather, it is for Mrs Gill and Mrs Sanders – as the parties seeking the extension – to demonstrate why the extension ought to have been granted. By placing the onus on Ethicon to demonstrate prejudice (and in the case of Mrs Gill, to demonstrate significant prejudice: see TJ, [4832]) should time be extended, the discretion miscarried because the primary judge reversed the onus of proof, failed to find that Mrs Gill and Mrs Sanders had not shown good reason for the Court to exercise the discretion and, as such, failed properly to apply ss 39(3), (4) of the *Limitation Act 2005* (WA).

900 These submissions do not do justice to the way the primary judge approached the question of extensions of time, given the way the applications were presented to her Honour.

901 Turning first to Mrs Sanders, as her Honour recorded (TJ [4857]-[4858]), Mrs Sanders argued that an extension of time should be granted because: (a) she did not become aware that there was a problem with her TVT implant until January 2011 and was not aware her injuries could be permanent until August 2011 (until then, she believed her symptoms would be resolved by revision surgery), and (b) there is no evidence of actual or significant presumptive prejudice and the delay was not such as to diminish unacceptably the conduct of a fair trial. These submissions were engaged with briefly and at a high level of generality. This framed the scope of the debate below. It was asserted below that Mrs Sanders had failed to show that, when the limitation period expired, she was not aware of the physical cause of her symptoms, that the physical cause was attributable to the conduct of a person, or that she was unable to establish the identity of the party responsible after reasonable inquiry.

902 This response of the appellants was rejected by the primary judge on the facts. The following findings by her Honour (TJ [4859]-[4860]) have not been shown to be the result of error: (a) the physical cause of Mrs Sanders’ personal injury was the erosion of the TVT tape, (b) Mrs Sanders was not aware that the tape had eroded until she was told by doctors in 2011 and there is no reason why she ought reasonably to have become aware of these matters at an earlier time, and (c) Mrs Sanders was not aware that her injury was attributable to the acts and omissions of the appellants said to have constituted negligence before she consulted her lawyers which the primary judge found was more likely to have been after the erosion was detected.

903 Although it may be accepted that it was for Mrs Sanders to not only prove the facts which enliven the discretion, but also good reason for exercising the discretion in her favour, we are not convinced the primary judge made the elementary error in simply assuming an extension of time was a presumptive entitlement, which arose upon satisfaction of the pre-conditions that enlivened its exercise. Reference was made to the absence of any prejudice to the appellants because this fact was plainly relevant, but the focus of such argument as there was on the extension application, was directed to the awareness of Mrs Sanders of relevant matters at the material time. This is shown in the course of oral submissions below, where senior counsel for the appellants was asked by the primary judge:

…on the question of whether or not an extension of time should be granted, correct me if I’m wrong, but there’s nothing in your written submissions to suggest that if the applicants [the respondents] manage to overcome the various hurdles, that the discretion should be exercised otherwise than in the applicants’ [the respondents’] favour?

The primary judge was told by senior counsel:

No, there’s no issue about that, your Honour. And – no. There’s no prejudice. The respondents [the appellants] aren’t alleging any prejudice (TRA.500.087.0017 – 0018).

904 Although this was said in the context of a discussion about the case of Mrs Gill, it is notable her Honour used the term “applicants”.

905 Implicit in the way the cases for extension were run below was the notion that given the nature of the injuries suffered by her, if Mrs Sanders proved what she needed to prove to enliven the discretion then the proper exercise of the discretion, in the absence of any countervailing considerations of substance, was to provide an extension. This involved no reversal of onus, but rather reflected the way the case for and against the grant of an extension was run below.

906 As to Mrs Gill, the way the case was argued below and on appeal related to when Mrs Gill first had reason to think that the relevant acts or omissions of the appellants might have been responsible for her injuries. Her Honour found (TJ [4828]) that this was “after 2013” when she “promptly set about investigating her rights”. It also appears her Honour found that this occurred when “the action was already on foot”, that is, the class action. There is no basis to conclude that this factual finding was not open to her Honour.

907 The primary judge correctly noted that “the burden of proof lies with the person applying for the extension: 2005 [Limitation] Act, s 79(3)”: TJ [4809]. Her Honour also noted the Court has power to extend time to enable Mrs Gill to sue after she had commenced proceedings: TJ [4828]. Her Honour recorded that the appellants “made no submissions about the exercise of the discretion” but, in any event, her Honour proceeded (TJ [4830]-[4831]) to direct herself to considering its exercise which, by reason of s 44 of the 2005 Limitation Act, required the Court take into account: (a) whether the delay in commencing the action, whatever the merits of the reasons for it, would unacceptably diminish the prospects of a fair trial, and (b) whether extending the time would significantly prejudice the defendant (other than by reason only of the commencement of the proposed action). The primary judge found (at TJ [4831]) there is no reason to think that the delay would unacceptably diminish the prospects of a fair trial, and her Honour also noted she was told that if the Court was satisfied that it had the power to grant an extension (which her Honour did), the appellants did not dispute that it should exercise its discretion in Mrs Gill’s favour. An extension granted in these circumstances does not reveal any error.

##### 14. INJUNCTION (GROUND 17)

###### 14.1 Appellants’ submissions

908 The appellants contended that the primary judge erred in enjoining them from supplying, distributing, marketing or promoting any of the SUI devices (other than TVT Secur) anywhere in Australia without including a warning or advice in the terms set out in orders 2 and 3 of the RJ (amended in *Gill v Ethicon Sàrl (No 8)* [2020] FCA 771) (ie, the Injunction)) and the Injunction ought to be set aside. It was contended the error in granting the Injunction was twofold: (a) a want of evidence point, that is, there was no evidence as to the knowledge of treating surgeons or persons generally as at 21 November 2019 (the date reasons were published in the TJ) or 6 March 2020 (the date reasons were published in the RJ and the Injunction ordered), and/or (b) a want of party point, that is, the Injunction was ordered in the absence of hearing from the TGA.

909 As to the want of evidence point, according to the appellants at AS [111]:

…there was no evidence before the Court as to the knowledge of treating surgeons or persons generally as at 21 November 2019 or 6 March 2020 (the dates the TJ and RJ were respectively handed down). It is the treating surgeons who read the mandated warning and who tailor the information to their individual patients as part of the informed consent process. The vice with the mandated warning is not because it has been crafted by lawyers per se (contrary to the finding at TJ, [5817]), but because there was no evidence which could satisfy the primary judge that the terms of the mandated warning could and would be effective.

910 Further, the appellants submitted at AS [112] that:

…the primary judge’s basis for granting the Injunction were the findings that the Ethicon Devices were defective (because they had “a propensity to cause harm that persons generally would not reasonably expect” (TJ, [4401])) and that Ethicon had failed to warn of the pleaded complications. These findings were based on the evidence, at the very latest, as at 4 July 2017 (when the oral hearing commenced). Whatever the knowledge of the treating surgeons may have been before 4 July 2017 (noting the lacuna of evidence as to that knowledge), the state of that knowledge had necessarily changed by the time the Injunction was ordered (6 March 2020, nearly three years after 4 July 2017). It follows that the primary judge’s discretion (including determining the necessity and utility of the Injunction) was exercised on an incorrect factual basis and ought be set aside.

911 Further again, the appellants said at AS [113]:

…the terms of the Injunction include medical issues which were not among the pleaded issues until the 5FASOC which was filed after the oral hearing and closing addresses: see Annexure A. As such, they were not issues upon which the proceedings were conducted (and Ethicon could not have adduced evidence). Consequently, the terms of the Injunction enjoin Ethicon in respect of their conduct as and from 2020, but based on the relevant knowledge as at 4 July 2017.

912 As to the want of party point, according to the appellants at AS [114]:

…the injunction was ordered in the absence of information about the position of the TGA. The TGA is the regulatory authority with responsibility for administering the TG Act and, as such, is charged by Parliament to oversee and manage a national regime “relating to the quality, safety, efficacy and timely availability of therapeutic goods” that are used in Australia (s 4(1)(a)). It follows that the attitude of the TGA, having regard to its expertise and responsibility, is necessarily a relevant consideration in determining the necessity and utility of a proposed warning, as well as the contents of that warning. The approach of the primary judge, however, was to accept that the TGA may be better placed to supervise the contents of the warnings (see TJ, [5816]), but ultimately to ignore the basis of that finding (that it is because of the TGA’s expertise and responsibility that they are better placed) and the logical consequence of that finding (that it is appropriate to hear from the TGA before warnings are to be mandated) by proceeding to make the Injunction.

###### 14.2 Discussion

913 In order to deal with these two points, it is necessary to pay regard to the nature of the power that was exercised by the primary judge in granting the Injunction. Section 232 of the ACL provides (as did s 80 of the TPA) that a statutory injunction may be granted whether or not it appears to the Court that the person enjoined intends to engage again, or to continue to engage, in contravening conduct: see ss 232(1) and (4) of the ACL and ss 80(1) and (4) of the TPA.

914 The inaptness of uncritically relying upon principles attending the grant of final injunctive relief in equity is evident from the Full Court’s reasons in *ICI Australia Operations Pty Ltd v Trade Practices Commission* [1992] FCA 707; (1992) 38 FCR 248 per Lockhart, Gummow and French JJ. As Lockhart J (with whom French J generally agreed) explained at 256, the statutory power is novel in that if the condition precedent to the exercise of the power to grant injunctive relief was satisfied, the Court would be given “the widest possible injunctive powers, devoid of traditional constraints, though the power must be exercised judicially and sensibly”. His Honour continued at 256-257:

Injunctions are traditionally employed to restrain repetition of conduct. A statutory provision that enables an injunction to be granted to prevent the commission of conduct that has never been done before and is not likely to be done again is a statutory enlargement of traditional equitable principles. But this is because traditional doctrine surrounding the grant of injunctive relief was developed primarily for the protection of private proprietary rights. Public interest injunctions are different... These are legislative enactments of matters vital to the presence of free competition and enterprise and a just society. This does not mean that the traditional equitable doctrines are irrelevant. For example, it must be relevant to consider questions of repetition of conduct or whether it has ever occurred before or whether imminent substantial damage is likely: but the absence of any one or more of these elements is not fatal to the grant of an injunction...

915 Further, the width of the power was noted by Gummow J at 267:

[The relevant statutory provisions] provide that the power of the court to grant prohibitory and mandatory injunctions may be exercised in circumstances where, under the general law, there ordinarily would be a good answer to an application for injunctive relief. There may have been no previous infraction of the law, there may be no threat of any infraction or further infraction of the law, and there may be no imminent danger of substantial damage by the act or omission of the defendant.

916 Although the discretion must be exercised judicially and for a proper purpose, it is clear that such a proper purpose may extend to marking the court’s disapproval of the conduct of the contravenor: see *Trade Practices Commission v Mobil Oil Australia Ltd* [1984] FCA 403; (1984) 4 FCR 296 at [300](https://jade.io/article/149096/section/1495) per Toohey J and *Australian Competition and Consumer Commission v 4WD Systems Pty Ltd* [2003] FCA 850; (2003) 200 ALR 491 at [212] per Selway J.

917 Both in writing and at the oral hearing of the appeal, the submissions made by the appellants as to utility tended to range more broadly than the relevant ground of appeal as to a want of evidence as to knowledge of surgeons or others at particular dates. For completeness it is necessary to deal with these submissions.

918 The wide power to grant relief below was enlivened by the findings that the appellants had contravened chapters 2 and 3 of the ACL. The assertion of the appellants that the primary judge erred because there was no evidence that the proposed warnings “could and would be effective” sits unhappily with reality of the width of the statutory power being exercised. To accept, like on an application for final injunctive relief in equity, that the moving party must demonstrate a particular level of utility in granting relief, would have the effect of attenuating the width of the power. More particularly, the supposed added hurdle of a demonstrated level of practical utility or effectiveness is in tension with the express terms of s 232(4)(a) and (c) which provide that an injunction can be granted whether or not it appears that the person intends to engage in the contravening conduct again and whether or not there is an imminent danger of substantial damage. This is not to say effectiveness or utility were not proper discretionary considerations in determining whether relief should be granted – they clearly were. But an absence of particular evidence that the proposed warnings gave a level of satisfaction of “effectiveness” or of knowledge of particular matters at particular dates was not in itself fatal to relief being granted.

919 What must be recalled is that prior to the Injunction being made, the parties had an opportunity of putting on any evidence they wished to adduce as to effectiveness and her Honour obviously considered the relief she granted to be utile. In this regard, the primary judge received and considered evidence after the initial trial as to new, amended IFUs which were issued for the relevant devices: RJ [31]. After having found that contrary to applicable statutory norms information, including information “which ultimately proved to be uncontroversial” had not been disclosed (RJ [29]), the new, amended IFUs were found to contain the vice of not “go[ing] far enough” in not disclosing “all of the previously undisclosed complications”: RJ [31] and [43]. The primary judge emphasised that injunctive relief for a contravention of the TPA or the ACL serves a public purpose, including “the prevention and deterrence of undesirable, indeed, unlawful trade practices”: RJ [42]. She further considered and dismissed the submission that the Injunction would interfere with the work of the TGA: RJ [44].

920 Specifically, contrary to the appellants’ suggestion that the Injunction was issued by the primary judge based on her Honour’s finding of a failure to warn as at 4 July 2017 (AS [112]), as noted above, the Injunction was issued after the appellants were given the opportunity of adducing further evidence as to the content of the IFUs which were proposed to accompany those of the devices which remained on the market in Australia as at December 2019, and those IFUs were found to be deficient: RJ [30]-[31]. Indeed, the appellants had two attempts at resisting the relief and there was no fetter on them adducing such evidence as they wished to rely upon going to the exercise of her Honour’s broad discretion. The primary judge was satisfied on the basis of all the evidence adduced and her findings as to contravening conduct that the Injunction served a proper purpose, was in the public interest, and was an appropriate remedial response to the contravening conduct. No error in granting the Injunction because of a want of particular evidence or as to an absence of utility is established.

921 It should be noted further that the suggestion (at AS [113]), which again went beyond the grounds of appeal, that the mandated warning ought not to include the complications associated with use of the devices in women with autoimmune conditions must be rejected. This is because, as the respondents correctly submitted, this matter was put in issue prior to judgment and the appellants accepted that such patients are at heightened risk.

922 It was the want of party point that received most focus at the hearing of the appeal. The appellants put this in writing as a contention that the Injunction could not issue *absent evidence* from the TGA (AS [114]), but the ground of appeal was somewhat different: it was contended the error was that the Injunction “was ordered *in the absence of hearing* from the TGA” (emphasis added). The only way of the TGA being heard was if it was made a party or allowed to intervene. No application was made for intervention (nor was it suggested) and the notion it was a necessary party does not withstand analysis. Section 232(2) of the ACL expressly provides that an injunction may be obtained on application by a regulator “or any other person”. If the argument that the Court was required to hear from the TGA was correct, it would seem the relevant regulator of activity governed by norms found to be breached would need to be heard before relief by way of a statutory injunction regulating the conduct of a contravenor could be made. That proposition only need be stated to be rejected in circumstances where persons other than the regulator are expressly given standing to seek relief in non-regulatory proceedings. In some cases it may be appropriate to hear from a regulator as an intervener, but it is a different matter entirely to accept that the discretion to grant statutory relief by way of an injunction would miscarry if such a course was not taken.

923 Assuming, despite the way ground 17 was expressed, the argument encompassed an allegation of error relating to a want of *evidence* from the TGA, the argument still has fundamental difficulties. As noted above, given each party was able to adduce evidence from the TGA, why should the failure of the moving party to adduce evidence from persons within the TGA be fatal in circumstances where the primary judge was affirmatively satisfied that the Injunction would not interfere with the work of the TGA? The appellants did not explain why it was the case that the Injunction could not be granted unless the moving party adduced evidence that the TGA was somehow content with the proposed order.

924 The appellants submitted that the attitude of the TGA, having regard to its expertise and responsibility, “is necessarily a relevant consideration in determining the necessity and utility of a proposed warning, as well as the contents of that warning”: AS [114]. But as explained above, her Honour did consider the position of the TGA. As the primary judge explained (TJ [5815]-[5816]):

I maintain what I said [in an earlier interlocutory judgment]:

The contentions that the job of regulating the sale of the products should be left to the regulator and that any such order could not be made without adding the regulator as a party are spurious. The TGA does not have an exclusive role in protecting the safety of consumers. As Selway J observed in *Australian Competition and Consumer Commission v 4WD Systems Pty Ltd* [2003] FCA 850; (2003) 200 ALR 491; (2003) 59 IPR 435 at [217], “[t]he purpose of an appropriately drafted injunction may be merely to reinforce to the market place that the restrained behaviour is unacceptable”…

[T]he TGA might well be better placed to supervise the content of warnings, but the evidence indicates that it did nothing about them until after Ethicon stopped manufacturing and selling the POP devices and TVT Secur was no longer sold in Australia. Not even the FDA alerts were sufficient to prompt an investigation before then. Besides, I have found that not even the most recent IFUs are adequate to protect women from the risks to which the SUI devices still on the ARTG expose them.

925 Although it again travelled beyond the grounds of appeal, for completeness, reference should also be made to the oral submission made by the appellants on appeal at T99.15-19:

Our point simply is that her Honour has given plainly insufficient weight to the fact that these orders have a judge who is not, with respect, a regulator of the kind that the Parliament intends, to lay down a regime which, presumably, could only be adjusted by indefinite possibilities of liberty to apply, which in itself is a mark of an invidious exercise of a discretion.

926 This submission ought to be rejected. Parliament provided the remedial response of a statutory injunction for the public purpose of preventing and deterring contravening conduct in trade and commerce. If there is a need for adjustment of the Injunction because of any regulatory imperatives or other change of circumstances (including that the Injunction became, for some reason, unworkable), the Parliament also provided a mechanism, by s 235 of the ACL, by which a private party or a regulator can seek to vary or discharge an injunction granted under s 232.

927 No error has been demonstrated in the exercise of the primary judge’s discretion to order the Injunction.

##### 15. CONCLUSION

928 For the reasons given the appeal should be dismissed save and except for the requirement to provide a proper answer to common question 22. The parties will be given the opportunity to make further submissions in that regard.

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| I certify that the preceding nine hundred and twenty-eight (928) numbered paragraphs are a true copy of the Reasons for Judgment of the Honourable Justices Jagot, Murphy and Lee. |

Associate:

Dated: 5 March 2021

**SCHEDULE A**

**Definitions**

*Australian Consumer Law* means Schedule 2 of the *Competition and Consumer Act.*

*CE mark means* Conformité Européenne mark applied as a declaration by a manufacturer that its *product conforms to the requirements of the European Council Directive 93/42/EEC issued on 14 June* 1993 as amended from time to time.

*Competition and Consumer Act* means the *Competition and Consumer Act 2010* (Cth).

*Ethicon devices* means the SUI devices and the POP devices.

*Group members* means the group members as defined in para 1(b) of the Fifth Further Amended Statement of Claim.

*JJM* means Johnson & Johnson Medical Pty Limited.

*Manufacturers* means the first and second respondents, Ethicon Sàrl and Ethicon, Inc.

*POP* means pelvic organ prolapse.

*POP devices* means the medical devices used for the treatment of pelvic organ prolapse known by the trade names Gynecare Gynemesh Prolene Soft (**Gynemesh PS**), Gynecare Prolift Pelvic Floor Repair System (**Prolift**), Gynecare Prolift+M Pelvic Floor Repair System (**Prolift+M**) and Gynecare Prosima Pelvic Floor Repair System (**Prosima**).

*SUI* means stress urinary incontinence.

*SUI devices* means the medical devices used for the treatment of stress urinary incontinence known by the trade names Gynecare Tension-free Vaginal Tape System (**TVT**), Gynecare TVT Obturator System (**TVT-O**), Gynecare TVT Secur System (**TVT Secur**), Gynecare TVT Exact Continence System (**TVT Exact**) and Gynecare TVT Abbrevo Continence System (**TVT Abbrevo**).

*Trade Practices Act* means the *Trade Practices Act 1974* (Cth).

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**The purpose for which the Ethicon devices were acquired**

**Q1: What was the purpose for which the POP devices were acquired?**

A: The POP devices were acquired for the purpose of treating pelvic organ prolapse in women and, more particularly, for the purpose of treating the condition more effectively, or at least as effectively as other surgical interventions, and with fewer risks to safety.

**Q2: What was the purpose for which the SUI devices were acquired?**

A: The SUI devices were acquired for the purpose of treating stress urinary incontinence in women and, more particularly, for the purpose of treating the condition more effectively, or at least as effectively as other surgical interventions, and with fewer risks to safety.

**Complications that can be caused by the Ethicon devices?**

**Q3: Can the Ethicon devices cause the following complications**

**(a)** **a chronic inflammatory reaction of the tissues surrounding the implanted device, also known as a foreign body response, which is affected by conditions which affect the immune response and healing, including autoimmune and connective tissue disorders;**

**(b) extrusion or erosion of the mesh into surrounding organs, including the vaginal wall, bladder or urethra;**

**(c) infection;**

**(d) chronic pain;**

**(e) dyspareunia and/or apareunia;**

**(f) difficulty voiding;**

**(g) offensive vaginal discharge;**

**(h) *de novo* or recurrent urinary incontinence;**

**(i) damage to surrounding organs, nerves, ligaments, tissue and/or blood vessels;**

**(j) haemorrhage;**

**(k) leg weakness;**

**(l) psychiatric injury;**

**(m) the need for reoperation or revision surgery associated with complications;**

**(n) the need to remove the implanted device or part of the implanted device; and**

**(o) complications associated with the removal of the implanted device or part of the implanted device, which might prove difficult or impossible, including aggravation of existing complications?**

A: Yes.

**Q4: Can the POP devices also cause the following complications:**

**(a) difficulty defecating; and**

**(b) recurrence of prolapse?**

A: Yes.

**Q5: Are each of the complications referred to in questions 3 and 4 clinically significant?**

A: Yes.

**Q6: Are the complications confined to the transvaginal use of mesh?**

A: No, they extend to mesh implanted transabdominally.

**Q7: Can the complications occur many years after implantation?**

A: Yes.

**Q8: Is it necessary for group members to prove the mechanism by which the Ethicon devices caused the complications they suffered as a result of implantation of those devices?**

A: No.

**Biocompatibility issues**

**Q9: Can the pores of the mesh used in the Ethicon devices deform and collapse under mechanical load?**

A: Yes.

**Q10: Does deformation and collapse of the pores of the mesh used in the Ethicon devices cause bridging fibrosis or fibrotic bridging?**

A: Yes.

**Q11: Is bridging fibrosis of clinical significance?**

A: Yes. It can cause or contribute to contraction of the mesh which, in turn, can cause complications such as mesh exposure, erosion, chronic pain and dyspareunia.

**Negligence**

**Q12: Did the respondents owe a duty of care to group members?**

A: Yes. The respondents owed a duty to take reasonable care to avoid injury to consumers.

**Q13: Did the manufacturers owe the group members a duty to take reasonable care in the design, testing, evaluation, supply, and marketing of the Ethicon devices?**

A: Yes.

**Q14: Did JJM owe the group members a duty to take reasonable care in the supply and marketing of the Ethicon devices?**

A: Yes.

**Q15: Did the manufacturers breach their duty of care to the group members by failing to undertake adequate pre-market evaluations of the safety and efficacy of the Ethicon devices?**

A: Yes.

**Q16: Did the manufacturers breach their duty of care to the group members by failing to undertake adequate post-market evaluations of the safety and efficacy of the Ethicon devices?**

A: Yes.

**Q17: During the period from the time of first supply in Australia of each of the Ethicon devices until 4 July 2017, did the respondents breach their duty of care to group members by failing to provide any adequate information, advice or warnings about the above-mentioned complications and the absence of any adequate clinical or other evaluation of the risks?**

A: Yes, throughout the period, except that they did not breach their duty of care by failing to warn of the risk of psychiatric injury.

**Q18: In what respects was the information, advice or warnings provided by the respondents about the complications inadequate?**

A: Save as indicated below, the respondents failed to disclose or make adequate disclosure of the following matters:

(a) that the mesh used in the Ethicon devices was designed to, and would invariably elicit in patients, an acute inflammatory reaction followed by a chronic inflammatory response;

(b) that in some patients the chronic inflammatory response will have adverse effects;

(c) that it is not possible to predict which patients will be adversely affected but they include healthy patients;

(d) that the severity of a patient’s chronic inflammatory response can be affected by conditions which affect the immune response and healing, such as autoimmune and connective tissue disorders;

(e) that the severity of a patient’s chronic inflammatory response can be affected by physical activity and mechanical loading of the pelvic floor;

(f) that the mechanical forces in the pelvic floor may influence the compatibility and function of the implant;

(g) that the adverse effects of the chronic inflammatory response in some patients include:

(i) infection, rather than merely the potentiation of infection;

(ii) that erosion of the mesh into the vaginal canal could cause infection which might be difficult to treat and cause offensive vaginal discharge and pain;

(iii) that erosion of the mesh into surrounding organs, such as the bladder, urethra or rectum, could cause pain and damage those organs;

(iv) damage to nerves in the scar tissue surrounding the implant or elsewhere (except for Gynemesh PS from 16 March 2013, Prolift from 1 October 2009, and Prolift+M from 12 December 2008);

(v) chronic pain, which may be severe;

(vi) dyspareunia, which may be severe and become chronic;

(vii) apareunia;

(viii) leg weakness;

(ix) *de novo* or recurrent incontinence (except TVT from 7 October 2015, TVT-O from 22 September 2015, TVT Abbrevo from 24 September 2015, TVT Exact from 18 September 2015, Gynemesh PS from 16 March 2013, Prolift from 1 October 2009, Prolift+M from 12 December 2008);

(x) difficulty voiding (except for TVT from 7 October 2015, TVT-O from 22 September 2015, TVT Abbrevo from 24 September 2015, TVT Exact from 18 September 2015, Gynemesh PS from 16 March 2013, Prolift from 1 October 2009, Prolift+M from 12 December 2008);

(xii) vaginal discharge (except TVT from 7 October 2015, TVT-O from 22 September 2015, TVT Abbrevo from 24 September 2015, TVT Exact from 18 September 2015, Gynemesh PS from 3 April 2015); and

(xiii) (in the case of the POP devices only) recurrent prolapse (except for Gynemesh PS from 16 March 2013, Prolift from 1 October 2009, and Prolift+M from 12 December 2008) and pain on defaecation;

(h) that the adverse events may occur years after implantation and the risk will endure for as long as the implant remains in the body;

(i) that the adverse events may occur regardless of the skill of the surgeon;

(j) that the true incidence of the adverse events is unknown but they are not rare;

(k) that removal of the implant in whole or in part will not necessarily alleviate the patient’s symptoms;

(l) that removal of part of an implant can be difficult and removal of the whole may be practically impossible;

(m) that mesh removal surgery can result in further scarring and tissue damage which, in turn, may have adverse outcomes, including severe chronic pain which may not be able to be satisfactorily treated;

(n) that surgery to remove the whole or part of an implanted SUI device can result in recurrence of stress urinary incontinence;

(o) that surgery to remove the whole or part of an implanted POP device can result in recurrence of pelvic organ prolapse; and

(p) that removal of eroded mesh will not necessarily prevent further erosions or other adverse events.

**Q19: But for the respondents’ negligent pre-market evaluations:**

**(a) would any of the Ethicon devices have been on the Australian market at any time?**

A: No.

**(b) would any group member have received an Ethicon device and suffered damage from its implantation?**

A: No.

**The statutory causes of action**

**Q20: Do the causes of action under the Trade Practices Act or the Australian Consumer Law apply to Ethicon Sàrl and Ethicon, Inc. even though they are incorporated overseas and neither has a place of business in Australia?**

A: Yes.

**Misleading or deceptive conduct**

**Q21: Between the first supply in Australia of the Ethicon devices and 4 July 2017 was the respondents’ conduct in marketing the Ethicon devices misleading or deceptive or likely to mislead within the meaning of s 52 of the Trade Practices Act or s 18 of the Australian Consumer Law?**

A: Yes.

**Q22: Why was the respondents’ conduct misleading or deceptive or likely to mislead or deceive?**

Throughout the period from the first supply in Australia of the Ethicon devices to 4 July 2017, the respondents falsely represented that the inflammatory reaction generated by implantation was transitory rather than permanent and possible rather than certain, and exaggerated the benefits of the devices and minimised the risks associated with implantation.

**Defective goods**

**Q23: Did the POP devices or any of them have a defect within the meaning of s 75AC of the Trade Practices Act and a safety defect within the meaning of s 9 of the Australian Consumer Law in that their safety was not such as persons generally are entitled to expect?**

A: Yes, all of them. The safety of those devices was not such as persons generally are entitled to expect because they exposed women to significant risks of injury against which inadequate precautions were taken and in respect of which misleading representations were made. The mesh 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 complications.

**Q24: Did the SUI devices or any of them have a defect within the meaning of s 75AC of the Trade Practices Act and a safety defect within the meaning of s 9 of the Australian Consumer Law in that their safety was not such as persons generally are entitled to expect?**

A: Yes, all of them because, taking into account all the relevant circumstances, including the way in which and the purposes for which they were marketed, the use of the CE mark in relation to them, the deficiencies in the warnings and other information supplied by the respondents they exposed women to significant risks of injury against which inadequate precautions were taken and in respect of which misleading representations were made.

**Q25: Which of the respondents is liable to compensate a group member who can prove she suffered an injury because of a defect, or safety defect, in a POP device?**

A: Ethicon Sàrl and JJM are jointly and severally liable to compensate group members who suffered an injury because of a defect, or safety defect, in Prolift, Prolift+M or Prosima. Ethicon, Inc and JJM are jointly and severally liable to compensate group members who suffered an injury because of a defect, or safety defect, in Gynemesh PS.

**Q26: Which of the respondents is liable to compensate a group member who can prove she suffered an injury because of a defect, or safety defect, in a SUI device?**

A: Ethicon Sàrl and JJM are jointly and severally liable to compensate group members who suffered an injury because of a defect, or safety defect, in any of the SUI devices.

**Q27: Did the respondents establish a state of the art defence within s 75AK(1)(c) of the Trade Practices Act or s 142(c) of the Australian Consumer Law?**

A: No.

**Unfitness for purpose and unmerchantable quality**

**Q28: Were the POP devices reasonably fit for the purpose for which they were acquired?**

A: No.

**Q29: Were the SUI devices reasonably fit for the purpose for which they were acquired?**

A: No.

**Q30: Were the POP devices not as fit for the purpose for which goods of that kind are commonly bought as it is reasonable to expect having regard to all relevant circumstances?**

A: No.

**Q31: Were the SUI devices not as fit for the purpose for which goods of that kind are commonly bought as it is reasonable to expect having regard to all relevant circumstances?**

A: No.

**SCHEDULE B**

2 Pursuant to s 232 of the Australian Consumer Law, being Schedule 2 to the *Competition and Consumer Act 2010* (Cth), after 20 March 2020 the respondents may not supply, distribute, market or promote any of the medical devices identified in Schedule B to these orders anywhere in Australia without including in the patient information leaflets and any promotional material relating to those devices advice in the following terms or to the following effect:

Prolene mesh is designed to, and will invariably elicit in all patients, an acute inflammatory reaction followed by a chronic inflammatory response. The chronic inflammatory response will result in continuously regenerating scar tissue within and surrounding the implant for as long as the implant remains in the body. The scar tissue will cause the mesh to contract to some degree in all patients. It is not possible to predict the severity of the chronic inflammatory response in any individual patient. In some patients the chronic inflammatory response will have adverse effects. It is not possible to identify in advance the patients who will experience those effects, although some patients are at greater risk than others. At-risk patients include healthy patients. The severity of a patient’s chronic inflammatory response can be affected by physical activity and mechanical loading of the pelvic floor. It can also be affected by conditions which affect the immune response and healing, such as autoimmune and connective tissue disorders. The mechanical forces in the pelvic floor may influence the compatibility and function of the implant.

The adverse events which may result include:

(a) infection;

(b) erosion of the mesh into the vaginal canal resulting in infection which may be difficult to treat, cause offensive vaginal discharge and pain;

(c) erosion of the mesh into surrounding organs such as the bladder, urethra or rectum which may cause pain and damage those organs;

(d) damage to nerves in the scar tissue surrounding the implant or elsewhere;

(e) chronic pain, which may be severe;

(f) dyspareunia, which may be severe and may become chronic;

(g) apareunia;

(h) leg weakness;

(i) *de novo* or recurrent urinary incontinence;

(j) difficulty voiding; and

(k) vaginal discharge.

Adverse events may occur years after implantation. The risk will endure for as long as the implant remains in the patient.

Each of these events may occur regardless of the skill of the surgeon.

While the true incidence of these complications is unknown, they are not rare.

Removal of the implant in whole or in part will not necessarily alleviate the patient’s symptoms. Removal of part of the implant can be difficult. Removal of the whole of the implant may be practically impossible. Surgery to remove the whole or part of an implant can result in further scarring and tissue damage which, in turn, may have adverse outcomes including severe chronic pain which may not be able to be satisfactorily treated. Surgery to remove the whole or part of the implant may also result in recurrence of stress urinary incontinence.

Removal of the eroded mesh will not necessarily prevent further erosions or other adverse events.

3 Pursuant to s 232 of the Australian Consumer Law, being Schedule 2 to the *Competition and Consumer Act 2010* (Cth), after 30 June 2020 the respondents may not supply, distribute, market or promote any of the medical devices identified in Schedule B to these orders anywhere in Australia without including in the instructions for use the above advice or advice to the same effect.

**Schedule B**

|  |  |
| --- | --- |
| **Product name** | **ARTG no.** |
| Gynecare Tension-free Vaginal Tape System (TVT) | supplied under 99193 |
| Gynecare TVT Obturator System | supplied under 99193 |
| Gynecare TVT Exact Continence System | supplied under 99193 |
| Gynecare TVT Abbrevo Continence System | supplied under 99193 |