Open slather on the uterus: why the Essure class action demands a re-conceptualisation of the female body as a site of corporate experimentation.

Submitted in fulfilment of the requirements for **76040 Research Thesis**, Spring Semester 2023, in completion of a **Bachelor of Laws (Honours)** at the University of Technology Sydney.

This work is dedicated to my grandmother, who fought for her life in the 1960s, when unsafe contraception led to unsafe pregnancy terminations. It is dedicated to my mother, who was told she could never fall pregnant. It is dedicated to the women in my life who have persevered anyway and held onto each other tight.

No Generative AI and/or Large Language Models were used in this work.

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Abstract

How does the law respond to corporate contempt for the female body? This question has arisen again in the context of the national class action brought by Slater & Gordon against Bayer's hazardous contraceptive device, Essure. Designed to slice open a woman's fallopian tubes to generate occluding scar tissue, Essure was marketed to women as a safe, painless, and non-surgical form of permanent sterilisation. In reality, the device caused organ perforation, metal poisoning and death. How could a device like Essure be released to the market? By constructing a novel reconfiguration of the female body as a site of continued corporate experimentation, this article argues that the confluence of two masculine discourses, law and medicine, creates a landscape wherein female suffering is dismissed and minimised. Where corporations are able to consistently gaslight women through a rhetoric of repudiation, gendered experimentation cyclically repeats itself across generations. Adopting the language of tort law, this means that the non-harm standard for women, is harm.

How does tort law - designed to fairly compensate negligently inflicted harm - evaluate harm on women's bodies? This question has been considered by feminist legal theorists in different ways, broadly concluding that tort law has a proclivity to fundamentally minimise, and obscure harms faced predominantly by women.[1] Whilst an understanding of law as fundamentally masculine explains why tortious compensation often results in unsatisfactory damages for female plaintiffs, it fails to provide an answer that directly addresses why harms are continually inflicted on to their body in the first place. This question has re-emerged yet again in *Turner v Bayer Australia Ltd*[2]*,* a class action brought by Slater & Gordon in the Victorian Supreme Court, on behalf of over 1000 Australian women. The class action is a two-pronged claim in both product liability and negligence, centred on the contraceptive device, Essure. Description of the device mirrors that of a gothic horror novel. Designed to intentionally lacerate the soft tissue of a woman's reproductive organs, the Essure device is a short metallic coil that expands upon insertion into the fallopian tubes (Figure 1). This expansion causes iatrogenic trauma, stimulating both an initial and chronic inflammatory response. The subsequent scar tissue that develops grows within the coil, 'anchoring' it within the fallopian tube. The combination of the coil and scar tissue then occludes the tube, preventing the transit of a woman's egg (Figure 2). Removal of the device, even in circumstances where there were no product complications, requires removal of the fallopian tubes – a salpingectomy – at the minimum, or removal of the uterus – a hysterectomy – in more complex cases. When the device malfunctions, it can give rise to a variety of complications including organ perforation, metal poisoning, abdominal and pelvic pain, device migration and fragmentation, ectopic pregnancy, and in some circumstances, death. Over half of the women in the class action have undergone hysterectomies to remove the device as a result of these complications.[3]

How was a product like Essure released to the market? Recourse to the legacy of mass tort litigation arising from hazardous female healthcare products reveals that the suffering caused by the Essure device is not novel; rather, it is simply another instalment in a series of class actions brought against manufacturers who have designed reproductive products that harm. At the same time however, Essure is distinguishable from prior examples of medical violence, in that it is the first device where harm – the laceration of the fallopian tubes – is integral to its function, as opposed to a possible complication. The question then transforms from *how* into *why?* Why are women consistently subjected to hazardous medical care? And why is it getting *worse*?

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[1] Janice Richardson and Erika Rackley (eds), *Feminist Perspectives on Tort Law* (Taylor & Francis Group, 2012).
[2] [2023] VSC 71.
[3] Aisha Dow, 'I thought I was bleeding to death': The 'gentler' birth control device hundreds are suing *The Sydney Morning Herald* (online, 9 April 2023). https://www.smh.com.au/national/i-thought-i-was-bleeding-to-death-the-gentler-birth-control-device-about-to-go-on-trial-in-australia-20230406-p5cysz.html

In this article, I answer this question by developing a novel explanatory framework that draws links between a legal minimisation of women's harms and a corporate contempt for the female body. Whilst there is an increasing awareness of law's inability to meaningfully regulate corporations in both civil and criminal jurisdictions,[4] I re-frame mass medical device litigation as a confluence of two masculine discourses – law and medicine – to argue that law is unable to regulate impervious medical manufacturers because legal discourse is fundamentally complicit in a medical denigration of the female body. To demonstrate this, Part One of this paper undertakes a close textual analysis of the Statement of Claim, arguing that a clinical and detached description of both the device and injuries inflicted undermines the harm suffered by these women from the outset. Reflecting established feminist tort theories of harm minimisation, Part One of this paper therefore re-affirms a pre-existing legal tendency to dismiss female suffering, undermining the potential potency of legal remedies. Part Two of this paper elaborates upon this, by imagining a novel construction of the female body – a site of corporate experimentation. Where tort law fails as a deterrent, medical manufacturers have no incentive to prioritise safety over profit. This translates into continued egregious breaches of a duty to reasonably prevent harm. By situating Bayer's breach of this duty against similar historical class actions, Part Two of this article illustrates that the treatment of the female body as a human guinea pig is a reoccurring motif in the medical manufacturer imagination, enabled by a non-punitive legal system. Why are women repeatedly willing subjects in their own experimentation? Part Three of this paper draws upon a sociological understanding of gaslighting to explain how the convergence of two disciplines that deny a female capacity for rationality successfully promulgate narratives of denial. By stripping women of epistemic autonomy through fraudulent marketing and a rhetoric of repudiation – exemplar breaches of a duty to warn – pharmacology companies seek to divorce women from our lived realities, causing us to doubt the legitimacy of our experience. As a result, women collectively struggle to resist medical conglomerates, allowing these oppressive power structures to remain untouched and unexamined.

By constructing an interdisciplinary understanding of gender, this article will ultimately argue that the underlying purpose of tort law – the compensation of the individual for harm that would not have occurred but for the defendant's negligence – is stymied when the female body is perpetually treated with cavalier unconcern by medical manufacturers, embolden by a complicit legal system. Resulting in a continued cycle of intergenerational suffering, this conceptualisation of the female body as a site of corporate experimentation means that the 'non-harm' standard for women is harm.

[4] Penny Crofts, 'Three Recent Royal Commissions: The Failure to Prevent Harms and Attributions of Organisational Liability' (2020) 42(4) *Sydney Law Review* 395.

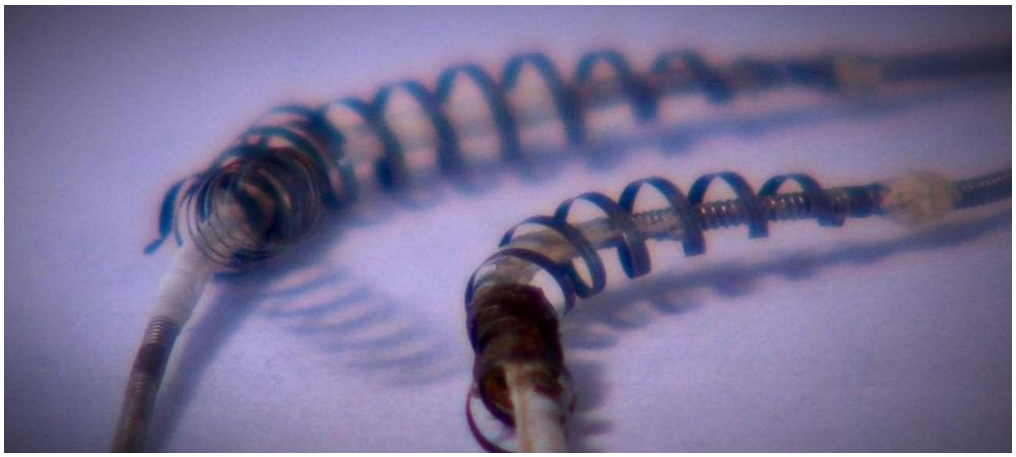

Figure 1 *– Essure Coil*

Part One: Law, Medicine, and Gendered Harm Minimisation

By way of Amended Statement of Claim filed 23 December 2022, Slater & Gordon, on behalf of Patrice Turner and over 1000 Australian women, bring a claim against Bayer Australia Ltd, Bayer AG, Bayer HealthCare LLC, Bayer Essure Inc (**'Bayer'**), Gytech Pty Ltd and Australasian Medical and Scientific Limited.[5] The claim prosecutes Bayer's design, manufacturing and supply of the Essure contraceptive device, by referencing four product deficiencies: (1) the 'Inherent Defects', (2) the 'Failure Defects', (3) the 'Removal Limitation, and (4) the 'Risk of Adverse Events' ('**Deficiencies'**). It is alleged that the design and distribution of the Essure device with the Deficiencies amounted to a breach of a duty to reasonably prevent harm and inform women of Essure's risks. The Plaintiff also alleges that Bayer breached statutory merchantable and acceptable quality guarantees.[6]

[5] Amended Statement of Claim filed in *Turner v Bayer Australia Ltd* [2023] VSC 71 ('*SOC*').
[6] *Competition and Consumer Act 2010* (Cth) sch 2; *Trade Practices Act 1974* (Cth) s 71. By adopting a critical feminist perspective on common-law tort, this article focuses less on the prosecution of the claim in statutory product liability, than it does on the claims in negligence.

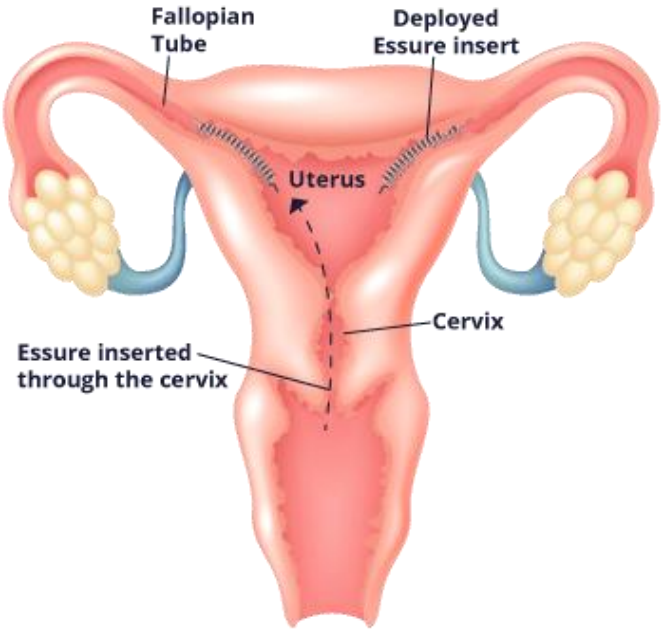

Figure 2 *– Insertion Diagram*

In order to establish *why* corporations are able to imperviously experiment on the female body, Part One of this paper re-establishes feminist tort theories of gendered harm minimisation; where harm is discounted and dismissed, manufacturers have little impetus to refrain from hazardous experimentation. Whilst feminist legal scholars often utilise damages as a tool to assess how the law evaluates negligently inflicted harm,[7] this article demonstrates gendered harm minimisation as an integral element of legal *language*, through a close analysis of how the injuries are particularised within the Statement of Claim. By situating a critical reading of the pleadings within the broader medico-legal context, Part One of this paper therefore argues that even though the Statement of Claim is filed on behalf of women injured by the Essure device, compliance with medico-legal discourse demands that the pleadings themselves reflect the pervasive ideas of law, gender and medicine they seek to challenge.

'INHERENT DEFECTS'

The Statement of Claim pleads that once inserted and 'anchored' into the fallopian tube, the Essure device 'disrupts' the soft tissue, triggering an acute inflammatory response by the body. The continued presence of the Essure device triggers a chronic inflammatory response. Slater & Gordon

[7] Reg Graycar, 'Damaging Stereotypes: the Return of 'Hoovering as a Hobby'' in Janice Richardson and Erika Rackley (eds) *Feminist Perspectives on Tort Law* (Taylor & Francis Group, 2012) 205.

label the stimulation of both the acute and chronic inflammatory responses as the 'Inherent Defects.'[8]

Critical feminist theory is expanded by a linguistic analysis that demonstrates that legal language conceals not only harm severity,[9] but intentionality. By characterising the functional methodology of the Essure contraceptive device as an 'Inherent Defect,' the Statement of Claim obfuscates the deliberate injury inflicted upon the female body. Under statute, 'goods have a defect if their safety is not such as persons are generally entitled to expect.'[10] The statutory defect test therefore centres itself around safety rather than functionality.[11] The legal definition of a defect is arguably at odds with the plain English definition, which describes a defect as 'a shortcoming, imperfection, or lack.'[12]

The laceration of the fallopian tubes, creation of both acute and chronic inflammatory responses and development of occluding scar tissue was not a harmful by-product or design shortcoming. Rather, harm was functionally integral to the design of the Essure device. By assaulting the fallopian tubes with an intrauterine metallic coil, the Essure device effectively destroys the biological function of the organ – marketed as a 'non-surgical' and 'gentler' equivalent of a tubal ligation or salpingectomy.[13] Without the stimulation of the foreign body response and development of scar tissue, the device would be ineffective – or rather, functionally *defective*. Ironically, the Statement of Claim constructs the functional purpose of the Essure device as an 'Inherent Defect', thereby obscuring the fact that harm was not an unwanted side-effect or unforeseen complication, but rather an intentional and necessary element of the product design.

This construction is result of the legislation governing product liability – where the defect test is expressed as a measure of safety, the characterisation of the product design as 'Inherently Defective' translates into a legal argument that the product design was inherently unsafe. Forcible adherence to legal jargon inevitably creates a protective shield wherein the characterisation of the device as 'Inherently Defective' disguises the reality that the device was not only unsafe but intended to harm. The Statement of Claim is therefore a prisoner to legal discourse that conflates defectivity with

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[8] SOC (n 5) paragraph 18.
[9] Nikki Godden, 'Tort Claims for Rape: More Trials, Fewer Tribulations' in Janice Richardson and Erika Rackley (eds), *Feminist Perspectives on Tort Law* (Taylor & Francis, 2012) 163, 166-172. Godden argues that the judicial comparison of rape to 'much more serious' tortious personal injuries conceals the psychological pain of sexual assault by focusing solely on physical harm.
[10] *Trade Practices Act 1974* (Cth) s 75AC(1).
[11] Marnie Hammond, 'The defect test in Part VA of the Trade Practices Act 1974 (Cth): defectively designed?' (1998) 6 *Torts Law Journal* 29, 52.
[12] *Oxford English Dictionary* (online at 11 August 2023) 'defect' (def 1425). https://www.oed.com/dictionary/defect_n?tab=factsheet#7184249
[13] Dow (n 3).

safety, requiring a paradoxical re-construction of a deliberate design element as a design *defect.* This in turn allows Bayer to deflect culpability for the intentional harm inflicted upon the female body.

'FAILURE DEFECTS AND ADVERSE EVENTS'

Slater & Gordon describe the following implantation risks as the 'Failure Defects': device breakage, fragmentation, corrosion, and migration into the abdominal cavity, expulsion from the fallopian tube/uterus, perforation of the fallopian tube, uterus and other organs such as the bowel, leaching of nickel and other metals, and the exacerbation of pelvic pain and menstrual bleeding conditions.[14] The culmination of both the 'Inherent' and 'Failure Defects' are described as the 'Adverse Events.' The Adverse Events listed are pain, or increased pain (inclusive of serious, chronic, and recurring pain) new, increased or worsened menorrhagia (protracted periods), new, increased or worsened dysmenorrhoea (intense uterine cramping and pain), and/or damage to internal organs.[15]

Just as interrogation of the term 'Inherent Defect' reveals a legal proclivity to conceal intentional harm, analysis of the labels 'Failure Defect' & 'Adverse Events' confirm feminist theories of gendered harm minimisation.[16] Women within the class action have described their experiences as so extreme, they thought they '*were bleeding to death*.'[17] Jackie Sacqualini shared that '*I was in <u>that</u> much pain, I thought my uterus was inverting*,' whilst Monique Emmett reported that '*I would have to crawl if someone was at the front door because I just couldn't get up*.'[18] A 42-year-old woman had her bowel punctured and strangled by the Essure device, requiring an emergency laparotomy and ileocecal resection, complicated by a post-operative wound infection.[19] In 2013, a woman presented to the emergency department with abdominal pain two days after insertion of the Essure device. A pelvic examination revealed that the woman's cervix, fallopian tubes and uterus were necrotic. Shortly after, she went into renal failure and died.[20] In 2015, a woman's uterus was perforated during device insertion, and she died during the procedure.[21] A woman died from intestinal perforation sustained

[14] SOC (n 5) paragraph 19.
[15] SOC (n 5) paragraph 20.
[16] Godden (n 9), 172.
[17] Dow (n 3).
[18] Ibid.
[19] Hendrik Mantel, 'Small bowel obstruction and perforation after Essure sterilization: a case report' (2012) 87(1) *Contraception* 121, 122.
[20] 'MAUDE Adverse Event Report: Bayer Pharma AG Essure Transcervical Contraceptive Tubal Occlusion Device' *U.S Food & Drug Administration* (Report, 18 September 2018).
[21] MAUDE Adverse Event Report: Bayer Pharma AG Essure; Insert, Tubal Occlusion' *U.S Food & Drug Administration* (Report, 20 February 2015).

during a laparoscopy, performed to remove fragmented metallic Essure remains within her fallopian tubes.[22]

The Statement of Claim reduces the experiences of women having their internal organs ruptured, suffering from chronic pain, and *dying* as 'Failure Defects' and 'Adverse Events,' displaying a callous disregard for female suffering.

'REMOVAL LIMITATION'

The apogee of harm minimising language is found within Slater & Gordon's characterisation of Essure's permanency as a 'Removal Limitation.'[23] By expanding *into* the walls of the fallopian tubes and encouraging scar tissue to develop within and around it's coils, clean extrication of Essure is surgically complex. Removal is further complicated by the device's propensity to fragment, leaving residual metal pieces of the devices possibly un-'anchored' and free to migrate within a woman's body; this was the case for a 46 year old woman whose device fragments remained in-situ for 17 months post her initial removal surgery.[24] As a result, removal of the Essure device often requires removal of a woman's reproductive organs - either her fallopian tubes and/or uterus. Due to the risk of fragmentation during a salpingectomy, hysterectomies are more commonly performed.[25] Whilst the Statement of Claim acknowledges that the device can only be removed via salpingectomy or hysterectomy, it fails to register this as an acute violation of bodily autonomy – particularly when the device was marketed as a non-surgical alternative – instead, framing this harm as a lesser 'limitation.' The term inherently discounts the fact that hysterectomies carry with them higher costs, increased rates of morbidity and overall complication risks such as severe blood loss, and a prolonged recovery time.[26] Instead of articulating the need for invasive organ resection as a harm in and of itself, the term 'limitation' of removal merely describes something that impedes or hinders device withdrawal when contextualised in plain English. The hinderance is arguably then the *female body* that makes removal difficult by growing in and around a delicate device prone to disintegration. This invariably shifts the onus of harm *back into the bodies of the plaintiffs,* rather than the manufacturer who designed a device that could not be removed. Legal jargon at paragraph 67(b)(ii) describes the risk of

[22] Chenyu Zou, 'Safety reporting of Essure medical device: a qualitative and quantitative assessment on the FDA manufacturer and user facility device experience database in 2018' (2023) *Frontiers in Reproductive Health* 1, 4.
[23] SOC (n 5) paragraph 21.
[24] Danielle van Gastel et al, 'Challenges in Removing the Essure Device' (2020) *Case Reports in Obstetrics and Gynaecology* 1, 2.
[25] A questionnaire provided to women who had requested device removal revealed that 64.9% of them had chosen to undergo a complete hysterectomy to prevent the retention of device fragmentation. See E Scott Sills, 'Analysis of surgeries performed after hysteroscopic sterilization as tabulated from 3,803 Essure patient experiences' (2017) 60(3) *Obstetrics and Gynaecology Science* 296, 299.
[26] Gastel (n 24) 4.

this 'limitation' as 'inherently not insignificant' – further obscuring the extent of harm behind confusing double-negatives. As a result, the legal pleading intended to stake suffering at its highest, relegates a particularly invasive harm as a mere design 'limitation' and re-imagines the female body as culpable for its own resection.

PERVASIVE CLINICISM

Whilst critical analysis of the Deficiencies reveals that harm minimisation lies at the very nucleus of their constructed meaning, broader recourse to the language of the Statement of Claim generally confirms feminist critiques of a legal preference for clean and dispassionate language, at the expense of emotive descriptions of suffering.[27] Paragraph 17 describes the operational design in terms that conceal the brutality of the device – '*on expansion, the edges of the Outer Coil disrupted* (read **lacerated**) *the soft tissue in the walls of the fallopian tube and the Essure Insert anchored* (read, **embedded itself within the lacerated soft tissue**) *in the fallopian tube.'* The violent mechanism of the Essure device is outlined clinically – '*chronic inflammatory responses*,' (read, **distress responses to the penetration of the fallopian tubes by a sharp, metallic coil designed to slice tissue**); '*tissue in-growth into the coils of the Essure Insert and around the PET fibres*' (read, **scar tissue developing as a defence response to an invasive source of iatrogenic trauma**). Paragraph 4A describes Patrice Turner's ongoing psychiatric injuries following a device malfunction induced hysterectomy as '*mild ongoing residual traumatisation features; and chronic adjustment disorder with depressed and anxious mood, now resolved*.' Arguably the first injury is an oxymoron; the very nature of trauma indicates a level of severity, beyond what could be considered 'mild.' The second diagnosis is perhaps more illuminating of medicine's need to pathologize and categorise – how does a woman 'adjust' to medical violence inflicted upon her body? Where a woman refuses to make accommodations for the violence inflicted upon her by medical practitioners, instead choosing to experience her trauma rather than denying it – i.e suffer from 'mild' ongoing residual traumatisation features – is she suffering from a chronic failure to 'adjust?' Detached diagnoses define the scope of this Statement of Claim – 'dysmenorrhoea,' 'menorrhagia', 'dyspareunia,' 'fatigue' – yet the experiences of women believing they were dying, the acknowledgement of women actually dying, descriptions of women crawling to the front door due to pain so severe they could not walk, are absent. Their voices are replaced by terminology that minimises harm, obfuscates intensity and strips away the emotion of their suffering in the very document that supposedly advances their maltreatment at its highest. The voice of Patrice Turner, and every woman she represents, is therefore silenced by a Statement of Claim that disregards experience in favour of diagnosis.

[27] Alena Allen, 'The Emotional Woman,' (2021) 99(4) *North Carolina Law Review* 1028, 1080-1081.

SITUATING THE STATEMENT OF CLAIM WITHIN THE LITERATURE

Close analysis of the Statement of Claim confirms and extends broader feminist theories that common law tort undervalues women's harms by demonstrating that conceptual harm minimisation begins in the linguistic construction of meaning itself.[28] By examining the Statement of Claim as a nexus between law and medicine, Part One situates the pleadings within interdisciplinary feminist literature, concluding that gendered harm minimisation is inevitable - even within the document intended to present harm at its highest.

Feminist Perspectives on Tort

Feminist tort scholars have built upon the radical argument that the law's allegiance to neutrality, translates into an allegiance to androcentricity, by extending this framework to the law's adjudication of harm.[29] Where harm is assessed against masculine frameworks such as the 'reasonable man', harms specific to women - such as sexual harassment or the effects of violent pornography on social understandings of consent and rape – are minimised and erased.[30] Parallels can be drawn between the harm of sexual harassment and assault – harms inherently focused upon and suffered by the female body[31] – and that of the harms caused by a contraceptive device designed to lacerate fallopian tubes and destroy a woman's reproductive tissue. Just as theorists have argued that sexual harassment is a gendered harm that arises out of the institutional power dynamics that subordinate women <u>because they are women</u>,[32] this article also suggests that corporate conglomerates are able to experiment on the female body <u>specifically</u> because of masculine legal structures that dismiss female suffering. Legal feminist critique therefore finds fresh footing beyond the realm of sexual harassment and pornography discourse, in the harms suffered by women at the hands of medical device manufacturers. Is it so surprising that a legal system that still struggles to specifically account for a woman's perspective on sexual harassment,[33] constructs the invasive removal of an exclusively female organ – the uterus – as a mere limitation of removal, or relegates the destruction of the

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[28] Ralph Sandland, 'Between Truth and Difference: Post Structuralism, Law and the Power of Feminism,' (1995) 3(1) *Feminist Legal Studies* 3, 5; Carol Smart, 'Law's Power, the Sexed Body and Feminist Discourse' (1990) 17(2) *Journal of Law and Society* 194.

[29] Catharine MacKinnon, *Toward a Feminist Theory of the State* (Harvard University Press, 1989) 238.

[30] Joanne Conaghan, 'Gendered Harms and the Law of Tort: Remedying (Sexual) Harassment' (1996) 16(3) *Oxford Journal of Legal Studies* 407, 408; MacKinnon (n 29) 238; Robyn Martin, 'A Feminist View of the Reasonable Man: An Alternative Approach to Liability in Negligence for Personal Injury' (1994) 23(3) *Anglo-American Law Review* 334.

[31] MacKinnon (n 29); Rebecca Thurston, 'Association of Sexual Harassment and Sexual Assault with Midlife Women's Mental and Physical Health,' (2019) 179(1) *Journal of the American Medical Association* 48, 51.

[32] Conaghan (n 30) 408.

[33] Leslie M. Kerns, 'A Feminist Perspective: Why Feminists Should Give the Reasonable Woman Standard Another Chance' (2001) 10(2) *Columbia Journal of Gender and Law* 195, 206.

female body as an 'Adverse Event' or 'Failure Defect'? The answer is arguably no; the Statement of Claim merely repeats a textbook devaluation of harms incurred exclusively against the female body.

Feminist tort scholars have also focused on the perceived masculinity of legal method to argue that emotional harms – often associated with women – are devalued in comparison to physical injuries.[34] The reasonable man represents a clinical and methodological approach to legal liability which rebukes emotional morality in favour of scientific method.[35] Feminist theorists have argued that the exclusion of emotion in decision making is the result of masculine values of separation, autonomy and rationality, creating an adjudicative framework known as 'legal sense' that perpetuates gendered perspectives on conflict resolution.[36] In her seminal work, *In a Different Voice,* Carol Gilligan challenged the assumption that 'legal sense' was a truly objective conceptualisation of conflict resolution,[37] outlining an alternative feminine ethic of 'care,' which approaches problem solving more holistically, in reference to relationships and values. Whilst subject to essentialist critique, by highlighting the gendered reality of 'reasonableness', Gilligan demonstrated how a masculine view of decision-making translates into a legal erasure of women's 'different' voice.[38] However, the framing of women as inherently emotive and relational is a double-edged sword where emotional and relational harms are often relegated as less worthy of legal compensation than individual, tangible injuries.[39] This crystalises into a compounding of legal erasure - a masculine legal system that denigrates emotional harm also robs women of the voice to give meaning to these experiences. No where is this more evident than the Statement of Claim, which roots suffering in the clinical description of physical injury, making passing reference to the psychological impact of debilitating pain as a 'chronic adjustment disorder' with 'mild traumatisation' features, and completely ignores the documented impact the Essure device has had on women's relationships and care-giving abilities.[40]

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[34] Martha Chamallas and Jennifer Wriggins, *The Measure of Injury: Race, Gender and Tort Law* (New York University Press, 2010) 38.
[35] Allen (n 27) 1068.
[36] Jenny Steele, 'Duty of Care and Ethic of Care: Irreconcilable Difference?' in Janice Richardson & Erika Rackley (eds) *Feminist Perspectives on Tort Law* (Taylor & Francis Group, 2012) 14, 20; Allen (n 27) 1078.
[37] Carol Gilligan, *In a Different Voice: Psychological Theory and Women's Development* (Harvard University Press, 1982).
[38] Nicola Lacey, John Bell and Claire Kilpatrick, *Unspeakable Subjects: Feminist Essays in Legal and Social Theory* (Bloomsbury Publishing, 1998) 201; Allen (n 27) 1080.
[39] Nicky Priaulx, 'Endgame: On Negligence and Reparation for Harm' in Janice Richardson & Erika Rackley (eds) *Feminist Perspectives on Tort Law* (Taylor & Francis Group, 2012) 36, 40-41; Chamallas and Wriggins (n 34) 92; Dayna Scott, 'Pollution and the Body Boundary: Exploring Scale, Gender and Remedy' in Janice Richardson & Erika Rackley (eds) *Feminist Perspectives on Tort Law* (Taylor & Francis Group, 2012) 55, 61-62, 66.
[40] Jennifer Block, 'The battle over Essure' *The Washington Post* (online, 26 July 2017). https://www.washingtonpost.com/sf/style/2017/07/26/essure/

Feminist Perspectives on Medicine

Even where a woman's harms are physical, masculine medical discourse that conceives the female body as a site of pain compounds a legal minimisation of gendered suffering. Like law, medicine is a phallocentric discipline, resulting from its legacy as a male dominated field, and historical conceptual exclusion of the female body.[41] Studies into clinician perspectives on differences in pain across gender reveal that up to 47% of practitioners believe women are able to tolerate *more* pain than men,[42] possibly as a result of biological essentialism that links reproductive function to a 'natural capacity to endure pain.'[43] Where it is assumed that women are able to 'cope' with pain, they are less likely than men to be taken seriously when they report pain and are less likely to have their pain adequately treated.[44] Gender parity increases have done little to disrupt the pervasive androcentricity that constructs gendered ideas of pain.[45] Through the educational process, the experiential knowledge of female clinicians is minimised, subsequent of a forced acculturation into a masculine environment where the price of success is conformity.[46] Where medicine represents an apotheosis of scientific thinking, a legal system that prioritises clinical rationality over emotion inevitably defers to medical perspectives at expense of women's lived experiences[47] – a perspective that minimises the physical pain of women. The Statement of Claim therefore represents a broader legal partiality for medical diagnostic language over the emotive language of suffering; a partiality that inevitably imbues harm minimisation into the very kernel of terms like 'Removal Limitation' and 'Adverse Events,' simultaneously discounting the pain that these injuries inflict onto the female body.

Consequently, when both medicine and law converge at the intersection of medical device litigation, the result is total gendered suppression. Tortious principles applied to medicalised harm offer a direct snapshot into how the intersection of law and medicine triply compounds the minimisation of female suffering: women's harms are minimised simply because there exists no 'precise masculine

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[41] Connie Newman, Kim Templeton and Eliza Lo Chin, 'Inequity and Women Physicians: Time to Change Millennia of Societal Beliefs' (2020) 24 *The Permanente Journal* 1; Patricia Peppin, 'Knowledge and Power: Drug Products Liability Actions and Women's Health' in Janice Richardson and Erika Rackley (eds), Feminist Perspectives on Tort Law (Routledge, 1st ed, 2012) 105, 114.
[42] Diane Hoffmann & Anita Tarzian, 'The Girl Who Cried Pain: A Bias Against Women in the Treatment of Pain' (2001) 29(1) *The Journal of Law, Medicine & Ethics* 13, 19.
[43] Gillian Bendelow, 'Pain Perceptions, Emotions and Gender' (1993) 15 *Sociology of Health and Illness* 273, 286.
[44] Hoffmann and Tarzian (n 42) 19.
[45] Kate Young, Jane Fisher and Maggie Kirkman, 'Do mad people get endo or does endo make you mad? Clinician's discursive constructions of Medicine and women with endometriosis' (2019) 29(3) *Feminism and Psychology* 337, 340.
[46] Ibid; Rosemary Pringle, *Sex and Medicine: Gender, Power and Authority in the Medical Profession* (Cambridge University Press, 1998).
[47] Jose Miola, 'The Standard of Care in Medical Negligence – Still Reasonably Troublesome?' in Janice Richardson and Erika Rackley (ed), *Feminist Perspectives on Tort Law* (Taylor and Francis Group, 2012) 126, 134.

analogue',[48] women's harms are minimised when they are not physical injuries, and women's harms that *are* physical injuries are minimised by medical discourse – to which the law panders – that conceives the female body as a site of pain. These discursive coordinates forcibly shape the Statement of Claim into a document that disguises suffering behind non-emotive and clinical language, simultaneously silencing the voices of the women it seeks to amplify.

Part Two: Re-imagining the Female Body as a Site of Experimentation

Where the contours of medico-legal discourse undermine the efficacy of any pleading that prosecutes gendered harm, there exists little impetus for corporations to exercise their duty to reasonably prevent harm. Part Two of this article builds upon a feminist framework of harm minimisation by examining Bayer's breach of this duty as an example of corporate contempt for the female body. By situating the Essure class action against a history of mass tort litigation arising out of hazardous gendered medical products, this article identifies a trend of escalating commercial unconcern, which demands a novel construction of the female body as a site of wanton corporate experimentation.

BAYER'S BREACH OF A DUTY TO PREVENT HARM

What does it mean to owe someone a duty of care? A fundamental principle within the law of tort, the concept of a 'duty of care' was originally framed as an obligation to '*take reasonable care to avoid acts or omissions which you can reasonably foresee would be likely to injure your neighbour*.'[49] To fulfil a duty of care within the confines of product liability, the 'manufacturer's principle' requires care in both the design and production of a product so as to avoid foreseeable harm to the ultimate consumer.[50] As a manufacturer, the Statement of Claim alleges that Bayer owed women who had the device inserted (as consumers) a duty of care to reasonably prevent harm. In reference to the Deficiencies, Slater & Gordon argue that it was reasonably foreseeable that the devices as designed gave rise to a 'not insignificant' risk of harm, with the seriousness of that harm being 'significant.' By examining Bayer's knowledge that the risk of harm was clear, that the probability of harm was likely and that the harm itself was severe, this article argues that the design, development and distribution of Essure amounts to not only a breach of a duty to reasonably prevent harm, but also calculated corporate contempt for the female body.

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[48] Martha Chamallas and Linda Kerber, 'Women, mothers and the law of fright: A history' (1990) 88 *Michigan Law Review* 814, 814.
[49] *Donoghue v Stevenson* [1932] AC 562, 580.
[50] Ibid 599.

Reasonably Foreseeable Harm

Whilst Slater & Gordon assert that the risk of harm was reasonably foreseeable in reference to scientific research published in the last two decades,[51] the Statement of Claim fails to articulate that the harm to women was reasonably foreseeable, *because the harm was intentional.* By adopting the term 'Inherent Defect,' the pleadings failed to construct an initial conceptualisation of the device that centres it's intentional harm. By minimising this design aspect, Slater & Gordon are unable to unflinchingly prosecute risk as reasonably foreseeable in the later section(s) of the Statement of Claim. This mistake is compounded when foreseeability is particularised largely in terms of research outcomes, as opposed to emphasising the harm fundamental in the design itself. This construction of foreseeability enables the reactivity of tort law by examining the harm *after it occurs* rather than prosecuting devices knowingly designed to harm in the first place, emphasising Essure's effect of harm, as opposed to Essure's function of harm. Failure to legally revile products that function to harm implicitly condones the corporate contempt that led to their design in the first place.

Standard Of Care

Scrutiny of scientific research and legal documents filed in international class actions arising out of the Essure device, reveals that Bayer had concrete knowledge that their device was not only significantly likely to cause harm, but that the harm itself was severe. In 2015, a citizen petition filed by Koch, Parafinczuk & Wolf on behalf hundreds of American women, accused Bayer of fraudulently obtaining pre-market approval status from the FDA by altering medical records of trial participants.[52] The alterations generated more favourable data, including lower experiences of pain, adverse events, unusual pain and unusual health related events. It is the sworn testimony of clinical trial participants that their answers were physically crossed out and changed by Bayer's researchers.[53]

Evidence also exists that where data could not be tampered with, Bayer systematically failed to uphold their reporting obligations and share this data with regulatory authorities. In 2020, non-profit advocacy group Public Justice was successful in its motion to unseal hundreds of documents pertaining to internal audits, quality assurances and reports of device malfunction, after Bayer mass-designated 99% of discovery documents in a Californian class action as 'confidential.'[54] Solicitors for

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[51] SOC (n 5) paragraph 57.
[52] Marcus J Susen, 'Citizen Petition from Koch Parafinczuk and Wolk, PA,' (Petition, 20 February 2015).
[53] Ibid; Sabrina Tavernise, 'F.D.A Panel Weighs Complaints on Essure Contraceptive Implant' *The New York Times* (online, 24 September 2015). https://www.nytimes.com/2015/09/25/health/fda-panel-discusses-essure-contraceptive-implant.html
[54] Edvard Pettersson, 'Bayer Accused of Underreporting Contraceptive Issues to FDA' *Bloomberg* (online, 10 July 2020) https://www.bloomberg.com/news/articles/2020-07-09/bayer-didn-t-report-essure-issues-to-fda-court-filings-say#xj4y7vzkg ; Kristin Kemnitzer, 'Memorandum of Points and Authorities in Support of Motion For

the plaintiffs provided these documents to a forensic statistician who concluded that out of a sample of over 5000 product complaints in Essure's possession, 24% of them should have been reported to the FDA.[55] Only 5.5% were. This means that hundreds of injury complaints indicating the possible severity of harm inflicted by the Essure device were submitted to the corporation, who then failed to provide this information to public health authorities. 89% of the complaints exhibited some form of non-compliance with regulations governing complaint investigations, including a failure to investigate, deficiencies in the execution of those investigations, and the documentation of those investigations,[56] amounting to either a brazen attempt at wilful blindness or calculated unconcern. Bayer has sponsored 11 clinical trials into the safety of the Essure device - only two have published the results.[57] In light of a historic failure to report adverse data, an inference can be drawn that the unpublished material possibly confirms the testimony of women who assert that the device stimulated chronic autoimmune diseases, led to debilitating pain and cognitive impairment.[58]

Common law has established that implantable devices require a significantly higher standard of care.[59] Where the standard of care owed also turns on the probability and severity of harm,[60] it is arguable that in light of the complication risks of Essure (a permanent implantable contraceptive device), tort law imposes the highest standard of care upon Bayer to prevent harm. Despite this, Bayer proceeded to design a product that functioned to harm, concealed the severity of this harm by failing to report injury complaints and publish scientific research, and tampered with data that indicated harm probability to ensure that the product would receive regulatory market approval.

This amounts to an 'example of women's bodies used as guinea pigs'[61] – a flagrant disregard for legal regulations designed to uphold the inviolability of the body, in pursuit of profit. The female body therefore becomes not only a site of corporate contempt, but a variable to be studied – how much harm can women be subjected to, before the law intervenes? This article now answers this question by situating the class action within a history of similar product liability cases. Unsurprisingly, the answer is 'a lot' - Bayer's corporate contempt is a result of a legal lenience toward injuries suffered

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Leave to Participate as Amicus, to Unseal Court Records and to Amend this Court's Protective Order' filed in *Essure Products Cases,* Superior Court of Alameda County, JCCP 4887 (Motion, 21 February 2020).

[55] Anne Holland, 'Second Corrected Expert Report' filed in *Essure Products Cases* JCCP 4887 (Expert Testimony, 1 May 2020) 8.

[56] Ibid 9.

[57] Zou (n 22) 5.

[58] Block (n 40).

[59] *Hollis v Dow Corning Crop* [1995] 4 SCR 634.

[60] *Bolton v. Stone* [1951] AC 850.

[61] Sarah Abo and Natalie Clancy, 'Dying from the inside out: Pharma giant fights on against Australian women after US payouts' *The Sydney Morning Herald* (online, 13 November 2022). https://www.smh.com.au/healthcare/dying-from-the-inside-out-pharma-giant-fights-on-against-australian-women-after-us-payouts-20221111-p5bxm8.html

exclusively by women, in turn sanctioning the destruction and experimentation of the female body by medical manufacturers.

WOMEN AS GUINEA PIGS: A PATTERN OF EXPERIMENTATION

The Essure class action is another instalment in the history of mass tort litigation against gendered medical products. Thalidomide was promoted to pregnant women in 1957 as a sedative and remedy for morning sickness.[62] A failure to conduct foetal impact testing meant that the drug was promoted as 'the best drug for pregnant and nursing mothers.'[63] Later studies revealed that thalidomide caused the deaths of up the 100,000 babies, and those that were born alive were born with significant limb impairments, cleft palates, organ defects and visual impairments (Figure 3).[64] Whilst US drug supplier Richarson-Merrell was aware that a drug could cross a placenta to affect a foetus, in the period prior to FDA application approval, Richardson-Merrell failed to conduct clinical trials during pregnancy, choosing instead to distribute the drugs to doctors for use on pregnant women, without adequate consent, oversight or outcome reporting.[65] The lack of clinical scrutiny directed toward thalidomide is an example of medicine's masculine bias that translates into an insufficient testing of drugs on women's bodies.[66] By declining to investigate the probability and severity of harm caused by their drug, Richardson-Merrell, along with other pharmaceutical companies responsible for distribution, perpetuated this bias, displaying cavalier unconcern for the health of pregnant women.

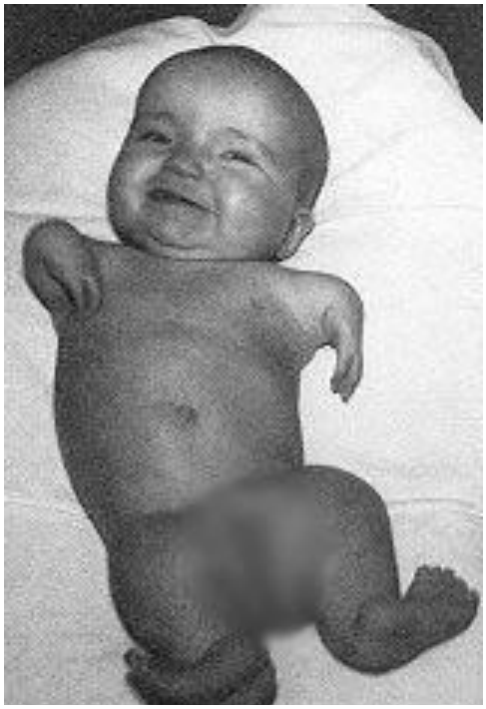

***Figure 3** – Defect caused by Thalidomide*

Despite evidence of the carcinogenic effect of diethylstilbesterol (synthetic estrogen – 'DES') appearing in scientific studies from the 1930s, DES was prescribed from 1947 to 1971 to pregnant women to prevent miscarriage.[67] By the 1950s it became apparent that DES was not effective for this purpose, but the drug continued to be promoted in what 'amounted to mass experimentation on pregnant women.'[68] DES has since been revealed to cause a higher risk of miscarriage, still

[62] Peppin (n 41) 109.
[63] William Silverman, 'The Schizophrenic career of a "monster drug"' (2002) 110(2) *Paediatrics* 404, 405.
[64] Peppin (n 41) 109.
[65] Ibid 110.
[66] Richardson and Rackley (n 1) 2.
[67] Peppin (n 41) 110.
[68] Diana Dutton, *Worse Than the Disease: Pitfalls of Medical Progress* (Cambridge University Press, 1988) 54.

birth, premature delivery and breast cancer in women,[69] and a rare form of vaginal cancer in their daughters.[70] Carcinogenic parallels can be drawn with the contemporary class action against Johnson & Johnson, whose talcum power products have been linked to ovarian cancer in women.[71] In 1971, the FDA announced that DES was contraindicated during pregnancy, however it continued to be used in the morning-after pill for another decade.[72] Johnson & Johnson denies that their products cause cancer, arguing that the evidence represents 'a fundamentally flawed trial, grounded in a faulty presentation of the facts.'[73] The proliferation of DES – and by extension, talcum powder – in the face of evidence that not only indicated inefficacy, but horrendous harm, represents an escalation in corporate recklessness towards the female body, trending away from unconcern to knowing disregard.

Figure 4 *– Dalkon Shield*

In the 1970s and 80s, the Dalkon Shield intra-uterine device (Figure 4) was aggressively marketed to women as a safe form of contraception – just as Essure was. In reality, A.H Robins Co, the manufacturer, was aware that the transvaginal filaments of the device acted like a wick for bacteria, that caused pelvic inflammatory disease, fatal infection and sterility.[74] When reports emerged of septic abortions and uterus perforation, the manufacturer continued to shirk responsibility by refusing to investigate the device, instead promoting it's longevity and efficacy. [75] In the face of full and total knowledge, A.H Robins Co escalated the trend of reckless disregard towards women once more, to complete contempt. Johnson & Johnson offers yet another cotemporary case study in corporate disdain, in the form of their pelvic mesh products. Similar to the Essure device, Johnson & Johnson's pelvic mesh products

[69] Ibid 87.
[70] Peppin (n 41) 111.
[71] Roni Caryn Rabin, 'Women With Cancer Awarded Billions in Baby Powder Suit' *The New York Times* (online, 27 July 2021). https://www.nytimes.com/2020/06/23/health/baby-powder-cancer.html
[72] Dutton (n 68) 32.
[73] Rabin (n 71).
[74] Richard Sobol, 'Bending the Law: the Story of the Dalkon Shield Bankruptcy' (University of Chicago Press, 1991) 7.
[75] Peppin (n 41) 112.

were marketed as a safe implantation device, used to treat organ prolapse. In reality, they led to organ perforation, painful sex and scarring of reproductive tissue.[76] Not only did Johnson & Johnson know about the extent of harm women faced, but they also took active steps to suppress efforts by French healthcare authorities to publish a report that outlined the product's testing deficiencies.[77] In doing so, they intentionally treated women as 'guinea pigs'[78] – over 70 years *after* women were subjected to DES experimentation, and alongside their pharmaceutical rival Bayer, who was manufacturing Essure.

In the face of increasing corporate disregard for the female body, Essure represents a radical apex in manufacturer contempt. Harm is no longer a known but disregarded side effect; it is a functional design element embedded into the product. Efforts to turn a blind eye to harms suffered by women have egregiously transformed into efforts to actively consider and then conceal these harms. Against this background it is clear that women's harms are foreseeable, yet do not translate into an increased standard of care. Rather, the female body as a guinea pig remains a perennial motif, where harm is either wilfully ignored, or increasingly, known and discounted.

Legal Lenience

Why are corporations increasingly emboldened to flagrantly disregard their obligation to reasonably prevent harm? The answer lies within law's complicity; a failure to legally validate harm translates into a total destruction of its deterrent effect.[79] The feminist theories canvassed in Part One are vindicated by women's poor outcomes in each of the class actions referenced above. Merrell's settlements with American and Canadian victims of thalidomide ranged from $100,000 to just under $1M; objectively small amounts for lifelong impairments.[80] Prosecution of DES's negligence was hindered by the lapse of time between product consumption and injury, difficulty in identifying which manufacturer had produced the specific variation of DES that was consumed, and access issues regarding medical records.[81] If women received compensation, it was generally low, as a result of a limited value placed by the Courts upon the loss of ability to give birth.[82] A Missouri appeals

[76] Melissa Davey, 'Johnson & Johnson reaches $300m settlement over pelvic mesh implants', *The Guardian* (online, 12 September 2022). https://www.theguardian.com/business/2022/sep/12/johnson-johnson-reaches-300m-settlement-over-pelvic-mesh-implants
[77] Christopher Knaus, 'Johnson & Johnson tried to prevent report about pelvic mesh devices, court hears,' *The Guardian* (online, 10 July 2017). https://www.theguardian.com/australia-news/2017/jul/10/johnson-johnson-tried-to-prevent-report-about-pelvic-mesh-devices-court-hears
[78] Ibid.
[79] Peppin (n 41) 113.
[80] Ibid 110.
[81] Ibid 111.
[82] Lucinda Finley, 'The Pharmaceutical Industry and Women's Reproductive Health' in E Szockyj and J Fox (eds), *Corporate Victimization of Women* (Northeastern University Press, 1996) 59, 75.

courted slashed a talcum powder award of $4.69B by over half, when it ordered Johnson & Johnson pay $2.1B in damages, after dismissing some of the claims made by women.[83] Participants of the Dalkon Shield class-actions faced invasive and aggressive questions into their sexual practices, identity of their sexual partners, and quality of their general character, deterring other women from making a claim.[84] Over $100M of the $300M awarded to victims of the pelvic mesh disaster has been siphoned out of the settlement sum on account of legal fees; women are being encouraged to accept an interim 'fast track' payment of $7,500 which will result in a lower payout once distribution is assessed.[85] Having failed to recuperate $32M in interest payments from Johnson & Johnson, Shine Lawyers then endeavoured to recover these costs from the settlement sum, attempting to pass the bill onto their very own clients.[86]

Where harm is minimised, awards of compensation suffer the same fate. In turn, this allows the cycle to continue; tort law fails to act as a deterrent for corporations who increasingly persist in their medical contempt for the female body, emboldened by the knowledge that law is complicit in the grand narrative that female harms are not worthy of significant legal reprimand. Whilst Slater & Gordon seek to establish that the harm of the Essure device was reasonably foreseeable (it was), that the probability of harm was 'not insignificant' (it was) and that the severity of harm was 'significant' (it was), it fails to articulate the deeper questions that arise as a result of each of these elements being made out – how could the female body become so desecrated in the first place? By situating the class action within a broader litigious context, this article has highlighted that the very metric against which the action is assessed – a duty to reasonably prevent harm – is a duty that corporations have decided simply does not apply to the subject of their experimentation: women.

Part Three: Institutionalised Gaslighting as a Tool of Corporate Manipulation

Why do women repeatedly allow themselves to be experimented upon by medical manufacturers? This question naturally arises from a novel re-imagination of the female body which draws upon a repeated pattern of corporate disdain, but inadvertently assumes that women are willing and informed participants in these trials. Rather, women are deceived through fraudulent and aggressive

[83] Rabin (n 71).
[84] Miles Lord, 'The Dalkon Shield Litigation: Revised Annotated Reprimand by Chief Judge Miles Lord' (1985) 9 *Hamline Law Review* 7, 9.
[85] Jessica Longbottom, 'Pelvic mesh victims left unsure of futures as legal fees threaten to slash class action payout' *ABC News* (online, 4 December 2022). https://www.abc.net.au/news/2022-12-04/mesh-implant-class-action-shine-lawyers-payout-dispute/101728850
[86] Myriam Robin, 'Shine's pelvic mesh victory turns sour' *Australian Financial Review* (online, 10 August 2023). https://www.afr.com/rear-window/shine-s-pelvic-mesh-victory-turns-sour-20230807-p5dund

marketing schemes, and subject to a rhetoric of corporate repudiation that firstly denies the mere existence of risk, and then when that risk materialises, the severity of the injuries sustained. The Statement of Claim prosecutes this conduct as a breach of a duty to warn.[87] However, where women's pain and biology are weaponised against us, creating narratives of hysteria and disbelief, corporations step beyond breach and into the realm of medicalised gaslighting. Part Three of this paper therefore conceptualises Bayer's breach of a duty to warn as a fundamental form of epistemic oppression. By creating hazardous female healthcare products marketed as 'safe', medical manufacturers essentially present women with a Hobson's choice, ensuring that the power structures that enable female experimentation remain unexamined and untouched.

BAYER'S BREACH OF A DUTY TO WARN

As a continuation of the manufacturer's principle, the duty to warn is assessed on the basis of what manufacturers know, or ought to know, about the risks inherent in their product.[88] In doing so, manufacturers not only bridge the knowledge gap between themselves and their consumer through product honesty, but also support the autonomy of their consumer by empowering their choice with the provision of full and accurate information.[89] The power imbalance between manufacturers and consumers is heightened in the case of medical products, distributed to doctors as intermediate suppliers.[90] Where the discursive coordinates of medicine are drafted to exclude women and the female perspective, a gendered approach to the doctor/patient relationship is constructed, where the knowledge of the doctor (assumed to be a man) is considered more legitimate than the self-knowledge of the patient (assumed to be a woman).[91] The convergence of the two dichotomies – doctor/patient & manufacturer/consumer, where doctors play both the role of healthcare provider disseminating superior medical knowledge, and that of intermediate supplier for a manufacturer dismissive of women's harms – compounds both the physician's positional power, and the vulnerability of women seeking medical advice.[92] In theory, the manufacturer's principle that enforces a duty to warn, coupled with an onus on medical practitioners to obtain informed consent, remedies this power differential. However, where doctors are assumed to know a woman's body

[87] Each defendant is accused of breaching this duty by promoting and marketing the Essure device '*without warning or without adequate warning about the Inherent Defects, the Failure Defects, the risk of Adverse Events and the Removal Limitation and, failed to make available to the Plaintiff and group members who had already received the Essure device, information disclosing the Inherent Defects, the Failure Defects, and/or the risk of Adverse Events.'*
[88] Peppin (n 41) 118.
[89] Ibid.
[90] Carl Elliot, 'Relationships between physicians and pharma' (2014) 4(2) *Neurology: Clinical Practice* 164, 165.
[91] Young, Fisher and Kirkman (n 45) 340; Pringle (n 46).
[92] Elliot (n 90) 165.

better than she knows it herself,[93] and law fails as a tortious deterrent, legal obligations to disclose and warn offer women little protection, resulting in the egregious proliferation of false narratives regarding product safety.

The international distribution of Essure as a 'safe' and 'non-surgical' form of permanent contraception despite Bayer's knowledge of the device's integral harm demonstrates this. In the United States, pharmaceutical companies can legally 'compensate' medical professionals for 'their expertise and services.' What is purported payment for research, arguably amounts to corporate bribery – doctors who accept payments from pharmaceutical companies, or participate in sponsored clinical trials, are more likely to prescribe the drug advertised, particularly for off label use.[94] Between August 2013 and December 2017, Bayer paid 11,850 doctors $2.5M in relation to Essure consulting fees.[95] The second highest paid doctor was female clinician Dr Cindy Basinski, who received $168,968. Christine Potts, who approached her regarding a tubal ligation, recalled her experience of Dr Basinski heavily recommending insertion of the Essure device instead as 'very pushy,' describing it as 'Dr Basinski's decision, more or less, because she said that this was the best, and I wasn't really given another option.' Dr Basinski's role as a complicit accomplice in Bayer's distribution of Essure is complicated by her gender, seemingly thwarting the masculinisation of medicine. However, Dr Basinski is arguably emblematic of the assimilation female clinicians are required to undergo in order to be successful in their field.[96] Whilst reporting of the monetary relationships between pharmaceutical companies and healthcare professionals is mandatory within the United States,[97] Australia's equivalent provisions are significantly weaker – data is not aggregated, making holistic assessment difficult and public access near impossible.[98] As a result, granular analysis of the role individual doctors played in the distribution of Essure within the Australian context is difficult, although patient testimony largely confirms that Australian women were subjected to the same inaccurate dialogue as women in the United States – Simone Burford noted that Essure 'was marketed as a quick fix; no downtime, painless, no side effects.'[99] Overall,

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[93] Young, Fisher and Kirkman (n 45) 340.
[94] Elliot (n 90) 165.
[95] Elizabeth Cohen and Aaron Kessler, 'Bayer paid doctors millions for questionable birth control device' *CNN Health* (online, 28 July 2018). https://edition.cnn.com/2018/07/27/health/essure-bayer-doctor-payments-eprise/index.html
[96] Young, Fisher and Kirkman (n 45) 340.
[97] *Physician Payments Sunshine Act 2013* (Federal Jurisdiction, United States).
[98] Melissa Davey, 'Pharmaceutical companies gave $12M to doctors, nurses and pharmacists,' *The Guardian* (online, 12 September 2017). https://www.theguardian.com/australia-news/2017/sep/12/pharmaceutical-companies-gave-12m-to-doctors-nurses-and-pharmacists#:~:text=The%20top%2010%20health%20professionals,%2439%2C000%20in%20the%20six%20months
[99] Abo and Clancy (n 61).

Bayer remained in the top five pharmaceutical companies bank-rolling Australian doctors in 2017 – the final year before Essure was retracted from the Australian market – spending $809,365 across 6 months.[100]

What this reveals is the layered nature of the power imbalance between women as consumers, and manufacturers who wield financial reward as a tool of manipulation. Interestingly, many doctors who receive compensation from pharmaceutical companies do not believe that the relationship affects the integrity of their clinical judgement.[101] Arguably, this just demonstrates the strength of pharmaceutical bribery; the most effective marketing schemes create the illusion of free will so that the consumer cannot observe the influence of the marketing upon their decisions.[102] As a result, fraudulent narratives of safety are perfidiously trickled from the top down, from corporations with full knowledge of their products hazards, to doctors who are susceptible to duplicitous bribery – which remains largely unregulated – and are repeatedly assumed to have a superior knowledge over their female patient, who then insert Essure into the bodies of trusting women like Christine and Simmone. Where Christine felt that her decision wasn't her own due to a lack of options, and Simmone was assured of a painless, quick procedure, it becomes clear that both women were presented with a classic Hobson's choice. A 70% decline in sales once a boxed warning was included in the device suggests that the majority of women who had Essure inserted would not have done so if they had been told the truth.[103] Instead, the repeated dissemination of false narratives in breach of a duty to warn robbed women of the opportunity to make informed choices and laid the foundations for institutionalised gaslighting.

GASLIGHTING & EPISTEMIC OPPRESSION

Constructing Bayer's repeated breach of their duty to inform as a form of medicalised gaslighting explains why a pattern of female experimentation persists. What does it mean to gaslight someone? Sociologists have advocated for a construction of 'gaslighting' that can be applied beyond interpersonal relationships, effectively describing institutional manipulation enabled by differences in power and privilege.[104] Shabot describes the term as 'a specific form of epistemic injustice, one according to which a more powerful person or group intentionally or unintentionally causes a weaker one to distrust their own perceptions, thus contributing to a further diminution or oppression of the

[100] Davey (n 98).
[101] Elliot (n 90) 165.
[102] Ibid.
[103] SOC (n 5) paragraph 40.
[104] Jennifer Sebring, 'Towards a sociological understanding of medical gaslighting in western health care' (2021) 43(9) *Sociology of Health & Wellness* 1951.

person or group that was weaker to begin with.'[105] A sociological conceptualisation of gaslighting also allows a re-working of psychological harm that extends beyond injuries such as a 'chronic adjustment disorder' to encompass the epistemic harm that arises when women cannot trust themselves.

Hysteria Discourse

Once Jackie Sacqualini had the Essure device inserted, she was regularly encouraged by researchers to alter her pain diaries, reducing pain scores of 8 and 10 out of 10 to 5 or 6.[106] Jackie recalls thinking to herself 'maybe I was having a bad day and maybe it was only a five or six.' The researcher would then amend her diary, requiring Jackie initial the changes.[107] After Simmone Burford felt like she was 'dying from the inside out', she approached her doctor who had inserted Essure. In response to her suffering, he 'said it was in (her) head and referred (her) to mental health.'[108] These responses – failures to acknowledge the reality of women's pain, pathologizing our injuries as simultaneously psychiatric, illegitimate and 'not that bad' – are enabled by Bayer's continued breach of a duty to inform and contributes to modern day hysteria discourse. The weaponisation of hysteria discourse to deny a woman's pain, consent and bodily self-knowledge is historical. During the eighteenth century, hysteria was described by Freud as the 'disease of women.'[109] Hysteria, as a diagnosis of irrationality, melodrama and insanity, was conceptualised as 'a woman's natural state' and was weaponised as a diagnostic box for imprisoning women who male doctors were unable to 'cure' within institutions.[110] Whilst 'hysteria' was formally removed from the DSM III in 1980, the latent stigmatisation of 'mental illness' in women continues in modern medicine; men who experience chronic pain are likely to be clinically perceived as brave and stoic, whereas women experiencing the same condition are liable to be considered hysterical and emotional malingers who fabricate their experience.[111] When law and medicine collide, hysteria discourse offers a medical explanation for a legal denigration of female rationality, evident in the 'reasonable man' standard. Where rationality and reason are conceptualised as exclusively masculine traits, women are perceived as inferior epistemic legal agents, liable to be rendered emotional and unbelievable.'[112]

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[105] Sara Cohen Shabot 'Amigas, sisters: we're being gaslighted' in Sara Cohen Shabot (ed), *Childbirth, Vulnerability and Law* (Routledge, 2019) 14, 18.
[106] Dow (n 3).
[107] Ibid.
[108] Abo and Clancy (n 61).
[109] Ceclia Tasca, Mariangela Rapetti, Mauro Giovanni Carta and Bianca Fadda, 'Women and Hysteria In the History of Mental Health' (2012) 8 *Clinical Practice and Epidemiology in Mental Health* 110, 115.
[110] D Morris, *The Culture of Pain* (The University of California Press, 1991) 109; Jane Ussher, *The Madness of Women: Myth and Experience* (Routledge, 2011) 9.
[111] Anke Samulowitz, Ida Gremyr, Erik Eriksson and Gunnel Hensing, ''Brave Men" and "Emotional Women": A Theory-Guided Literature Review on Gender Bias in Health Care and Gendered Norms towards Patients with Chronic Pain' (2018) *Pain Research and Management* 1, 5.
[112] Allen (n 27) 1048-1050.

Epistemic Injury as a Means to Sustain Power Structures

Re-constructing a woman's pain as less extreme or referring her to 'mental health' following her reports of pain, are direct examples of medicalised gaslighting rooted in hysteria discourse. Shabot argues that generating self-doubt and disbelief is the 'most effective' form of oppression, by convincing individuals that they are unworthy epistemic agents, in turn allowing dominant power structures to remain unquestioned and untouched.[113]

By broadcasting narratives of safety and pain minimization,[114] publicly denying liability on the basis that there is no 'signature' Essure injury because the two subject injuries – chronic pelvic pain and abnormal uterine bleeding – are injuries 'commonly experienced by women of reproductive age,'[115] and by reassuring women who already had the device implanted that there was no need to remove it, [116] Bayer gaslit women. By characterising the decision to cease Essure distribution in 2017 as a result of 'low market interest in permanent contraception,' and 'inaccurate and misleading publicity,'[117] rather than acknowledging the extensively documented device harms, Bayer continues to gaslight women. In doing so, Bayer has effectively sought to divorce women from our epistemic realities, firstly physically manipulating our bodies as sites of experimentation, followed by psychological manipulation that encourages us to deny the severity of our suffering. Despite the existence of a class action, their efforts have arguably been successful. Notwithstanding the responsibility imposed upon doctors and manufacturers to properly inform their patients of procedure risks, Keisha Carney continues to fault herself for inserting the Essure device which caused her to lose five teeth as a part of an autoimmune response, suffer from brain fog and severe fatigue: 'I blame myself for this part, that I never really thought about something foreign being in my body for the rest of my life.'[118] Jackie Sacqualini consented to the tampering of her data because she genuinely believed that a 'bad day' could cause her to pass blood clots the size of a cigarette packet, creating pain so severe she thought her 'uterus was inverting.'[119] Where women are robbed of self-belief, we are robbed of the capacity to make confident decisions. Bayer's medicalised gaslighting

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[113] Shabot (n 105) 19.
[114] Dow (n 3).
[115] Aisha Dow, ''It was a bad idea from the start': Contraceptive coil class action begins' *The Age* (online, 11 April 2023). https://www.theage.com.au/national/it-was-a-bad-idea-from-the-start-contraceptive-coil-class-action-begins-20230411-p5czgo.html
[116] Bayer Australia/New Zealand, 'Media Statement – Essure Information' (Media Release, 11 April 2023). https://www.bayer.com.au/en/media-statement-essure-information
[117] Sheila Kaplan, 'Bayer Will Stop Selling the Troubled Essure Birth Control Implants' *New York Times* (online, 7 July 2018). https://www.nytimes.com/2018/07/20/health/bayer-essure-birth-control.html
[118] Block (n 40).
[119] Dow (n 3).

then, not only cheated women out of the autonomy to choose, but the autonomy to believe that the outcomes of that choice were severely painful and unfair.

Where gaslighting is conceptualised as an ongoing process, medicine's secondary denial of pain following a denial of hazardous unsafety creates a rhetoric that denies a woman's epistemic empowerment from start to finish.[120] In a tragic full circle, Bayer's attempt to silence women's protest through psychological manipulation, is echoed in a Statement of Claim that erases female voice in favour of medical diagnosis. Utilisation of hysteria discourse to convince women that our pain is 'not that bad' is reinforced in pleadings that characterise psychological resistance to corporate manipulation - an insistence that it is 'that bad' - as a failure to adjust, termed as an 'adjustment disorder.' Where tort law pathologizes women's responses to corporate atrocity, both in harm minimising language, and recourse to psychiatric diagnosis, women are inflicted with injuries beyond physical pain; we are reminded that pharmacology companies can recklessly rob us of our uteruses, peace and dignity, but above all, the option of safety. Choice is a luxury, but to exercise it, women must step through the psychological minefield of corporate manipulation and contempt, unsure if in doing so, they are causing more harm than good. This reticence to enter the minefield, as a result of consumer disempowerment and disbelief uncured by legal intervention, is what allows cycles of corporate violence to continue, ultimately resulting in a perpetual experimentation of the female body, and the negation of harm it creates.

Conclusion

This article has undertaken a close study of the Australian Essure class action to examine *why* medical manufacturers repeatedly harm women. By situating the pleadings within the context of a masculine legal system that minimises harm, and a medical system that trivialises female pain, I have argued that a history of corporate contempt has become a pattern of gendered experimentation, emboldened by a complicit legal system. The conceptualisation of the female body as a site of repeated experimentation becomes less shocking when narratives of denial are considered; analysis of Bayer's continued breach of a duty to warn reveals institutionalised gaslighting that isolates women from their epistemic realities, allowing oppressive pharmacology power structures to remain undisrupted.

Earlier in this article, the poor settlement outcomes for women in similar product liability class actions were canvassed. It was argued that the harms experienced by these women were minimised and therefore, unfairly de-valued. Why exactly are gender specific damages liable to be minimised

[120] Shabot (n 105) 14.

however? The answer lies in the core principle underpinning tortious compensation – the 'but for' approach to damages, which entitles plaintiffs to awards that would put them in the position they would have been, but for the negligence. The current position of the plaintiff having suffered the harm is assessed against their prior 'non-harm' standard.[121] Perhaps – in a brutal admission – myself, and feminist tort scholars, have got it wrong. Perhaps our harms are not under-valued and minimised; perhaps small awards of compensation represent the small deviation from the non-harm standard that these injuries reflect. Yes, the suffering and loss of these women is immense and the injuries, cruel and severe. But were we really that well off to begin with? In a medico-legal landscape where corporations display blatant contempt for the female body, fraudulently conceal the harms inflicted upon women and then gaslight us when we suffer those harms directly – were we ever really safe? Where prior generations of women were poisoned with thalidomide, then DES and now talcum powder, where our grandmothers were inserted with Dalkon Shield devices that acted as conduits for infectious and debilitating disease, only for our mothers to have their organs punctured by pelvic mesh and our sisters *die* from an inter-uterine sterilisation device designed to rip apart our reproductive tissue, *is it not just a waiting game until we ourselves are subjected to a horrific injury*? Decade after decade women have suffered; perhaps in awarding women low damages, court's recognise that the injuries we suffer are simply inevitable manifestations of inescapable harm; the shift from the non-harm standard to the standard of injury is not so great after all.

[121] Suzanne Levitt, 'Rethinking Harm: A Feminist Essay' (1995) 34(3) *Washburn Law Journal* 531, 532.

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