

Recklessness, Greed, and Guinea Pigs: How Mass Tort Litigation Targets Women

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**RECKLESSNESS, GREED
& GUINEA PIGS:
How Mass Tort Litigation
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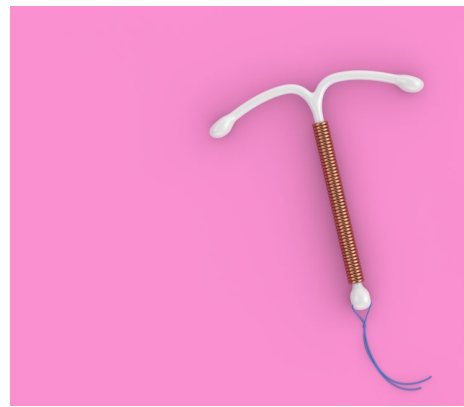
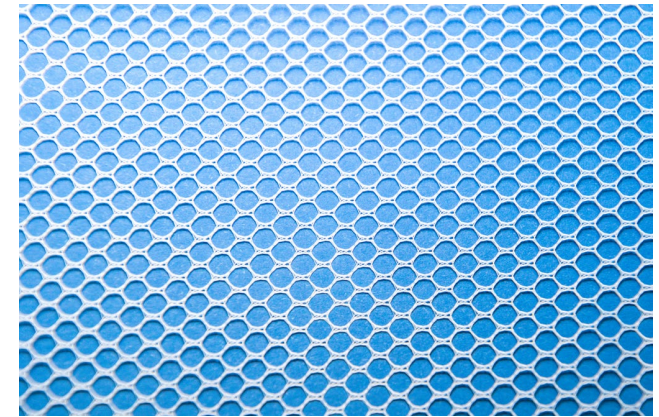




**“Every new contraceptive
for the last 50 years or so
has been the subject of litigation.”**

**–Eric Alexander, Drug & Device Law Blog,
October 7, 2022**

Why are mass torts disproportionately focused on products for women?



“Women, Medical Care, and Mass Tort Litigation,” by Joan E. Steinman 68 Chi.-Kent L. Rev. 409 (1992)

WOMEN, MEDICAL CARE, AND MASS TORT LITIGATION

JOAN E. STEINMAN*

Dow Corning whitecoat to a group of women: “We’re testing breast implants on you, to see if they’re safe for guinea pigs”¹

Everywhere I look in the popular press I see women expressing anger at their treatment in this society. One set of issues revolves around lack of equal opportunity in the workplace: unequal pay, sexual harassment on the job, exclusion from informal but important social/business networks, disadvantageous pension policies, and the like. Another set of issues revolves around women’s health care. It encompasses myriad matters. A sample from recent newspapers and magazines would include:

— the low level of funding by the National Institutes of Health of scientific research involving women subjects and on health issues of special concern to women (such as research on the causes of breast cancer);



1. Cartoon, 1992
Mike Luckovich
—ATLANTA CONST.

“Women Take It on the Chin”

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effects are not obviously entailed, women’s well-being seems to be of lesser concern. I do not know of a single mass tort in which men were injured by a product made for men to use or take, ostensibly to enhance their well-being. It appears that women, far more than men, take it on the chin from products made ostensibly for our good.⁸

One has to wonder what is going on here. Are there no medical products peculiarly for men? If there are, is it mere coincidence that they have not proven to be seriously harmful? I assume that if such products had caused widespread and serious harm, the injured would have sued; evidence of the problem would appear in the case reports. But it is not there.

Thirty Years Later . . .

PERCEPTIONS OF JUSTICE IN MULTIDISTRICT LITIGATION: VOICES FROM THE CROWD

Elizabeth Chamblee Burch† & Margaret S. Williams††

With all eyes on criminal justice reform, multidistrict litigation (MDL) has quietly reshaped civil justice, undermining fundamental tenets of due process, procedural justice, attorney ethics, and tort law along the way. In 2020, the MDL caseload tripled that of the federal criminal caseload, one out of every two cases filed in federal civil court was an MDL case, and 97% of those were products liability like opioids, talc, and Roundup.



Burch, E.C., Williams, M.S., “Perceptions of Justice in Multidistrict Litigation: Voices from the Crowd,” 107 Cornell Law Review 1835 (2022)

“Women Are Disproportionately Harmed”

foundational components.

To explore this tension, we designed the first ever MDL procedural justice study, which was widely dispersed (from mentions in *The New York Times* to write-ups in *Reuters* and *Law.com*)⁸ and spent two years in the field getting to know hundreds of MDL plaintiffs. We focused on proceedings in which the defendant targeted its product toward women⁹ for three reasons. First, research demonstrates that most products liability MDLs include the same repeat-player attorneys, settlement provisions, and judicial techniques, so we could keep the sample size manageable without sacrificing generalizability.¹⁰ Second, harm from drugs and medical devices disproportionately affect females: women account for 67% of the FDA’s medical device adverse event reports;¹¹ sex-neutral devices like hip implants and pace makers

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disproportionately fail in women;¹² and from 1997 to 2000, eight of the ten drugs pulled from the market posed greater risks to women.¹³ Third, because of this, women’s health MDLs comprise a substantial subset of all products liability MDLs.

In 2018, when we began our study, 32% of all MDLs involved products that exclusively or primarily injured women, as compared with 6.4% that primarily affected men.¹⁴ Hundreds, sometimes thousands, and sometimes over a hundred thousand lawsuits have erupted from birth control like NuvaRing and Yaz; personal hygiene products like baby powder and Shower to Shower; medical procedures aimed at female incontinence like trans-vaginal mesh; and products designed to make women more “attractive” like diet drugs and breast implants.¹⁵

- **Silicone gel breast implants**
- **Dalkon Shield**
- **DES**
- **Bendectin**
- **Thalidomide**
- **Lippes Loop**
- **NuvaRing**
- **Yaz**
- **Talc products**
- **Pelvic mesh**
- **Prempro**
- **Diet Drugs**
- **Hair Products**



Are women targeted by corporations, or by litigations?

HRT for Menopause Symptoms

- 85% of women experience menopause symptoms – “chemical castration”
- Significant QOL impact: hot flashes, recurrent UTIs, urinary symptoms, painful sex, joint pain, insomnia, depression, memory loss
- 1960s - Oral HRT seen as empowering, feminist
- 1990s - Most common Rx for US women – 15M/year
- Estrogen considered essential —likened to fluoride



“Ethically Impossible to Continue HRT Study”

- 2002 – N.I.H Women’s Health Initiative study linked HRT to heart disease, stroke, blood clot, breast cancer
- “Adverse effects outweigh and outnumber benefits”
- NBC “Today” interview: “Invasive breast cancer risk increased by 26 percent”
- Prescriptions plummeted instantly
- “I remember where I was when John Kennedy was shot . . . And I remember where I was when the W.H.I. findings came out.” -- Dr. Mary Jane Minkin, Yale School of Medicine



“Medical Ventriloquism”



- 1000s of lawsuits filed against Wyeth, Pfizer, Upjohn (MDLs, NJ, MO, PA . . .)
- Claims: failure to adequately warn of the increased risk of breast cancer and other risks
- Media: HRT = corporations gaslighting women into believing a natural life stage is a disease
- NY Times: Manufacturers spent tens of millions of dollars on “influential physicians, professional medical societies, scientific publications and celebrity ads . . . to deflect users’ attention from cancer concerns”
- “This was a kind of medical ventriloquism on Wyeth’s part,” Dr. Jerome L. Avorn, Harvard Medical School

“Women Have Been Misled About Menopause”—N.Y. Times, 2/1/2023

- Pfizer prevailed in the vast majority of Prempro cases
- Dozens of studies have shown benefits outweigh risks, especially for women <60 experiencing the most severe menopause symptoms
- WHI later published subsequent findings, including that estrogen-only use significantly *decreased* breast cancer incidence
- However, “We have yet to see an N.I.H. press conference convened to reassure women of the benefits of estrogen.”
—Avrom Bluming, MD, and Carol Tavris, PhD
- Prempro survived the litigation; but HRT prescription levels still have not yet recovered



Pelvic Mesh

- Multiple pelvic mesh products to treat stress urinary continence and pelvic organ prolapse
- Multiple manufacturers – Johnson & Johnson, Bard, Boston Scientific, AMS, Coloplast, and others
- Incontinence slings – TVT 1998
- Prolapse mesh – Gynemesh 2002
- Ethicon Prolene polypropylene suture – 1969
- Prolene mesh used to treat hernias since 1970s
- Previously: 40-60% failure rate of native tissue prolapse repairs
- Major abdominal surgery requiring 6-week recovery to treat incontinence



- 2008 FDA Public Health Notification
 - 1000+ complaints regarding mesh from 9 manufacturers
 - Covered mesh products for POP and SUI
 - Pain, vaginal scarring, dyspareunia, additional surgery to address complications, “significant decrease in patient quality of life”
- 2010 Multicounty litigation in New Jersey
- 2011 MDL in Southern District of West Virginia
 - Design defect and failure to warn claims
- 2013 FDA: “The safety and effectiveness of multi-incision slings is well-established in clinical trials that followed patients for up to one-year.”
- Second largest mass tort in U.S. history (after asbestos) at that time – more than 100,000 lawsuits
- Litigations in multiple U.S. jurisdictions and other countries including Australia, Canada, U.K.



The Role of 'Profiteers'

Plaintiffs had been convinced by a network of lawyers, doctors and 'personal injury lawsuit marketers,' into having their mesh removed to make their lawsuits more lucrative.

---“How Profiteers Lure Women Into Often-Unneeded Surgery,” Matthew Goldstein and Jessica Silver-Greenberg, N.Y. Times, 4/14/2018

Urogynecologist Dr. Christopher Walker and 'patient recruiter' Wesley Blake Barber were indicted and then plead guilty to federal charges arising from a scheme to pressure hundreds of women to get their pelvic mesh implants removed.

---“Two men plead guilty in a personal injury scheme involving pelvic mesh implants,” Matthew Goldstein, N.Y. Times, 9/17/2021

Australia's Landmark Mesh Class Action

Timeline:

- **October 2012:** Shine Lawyers files class action against Johnson & Johnson/Ethicon
- **July 2017 - February 2018:** 7-month trial in Federal Court
- **November 2019:** Federal Court rules in favor of 3 lead applicants (\$2.6 million damages)
- **March 2021:** Full Federal Court dismisses J&J appeal
- **November 2021:** High Court rejects J&J's application for special leave to appeal
- **September 2022:** \$300 million settlement reached
- **March 2023:** Settlement approved by Federal Court

Scale:

- **11,000+** women joined the class action
- **Largest product liability settlement in Australian history**
- **9 different mesh products found defective**
- **Additional class actions filed against Boston Scientific (\$105 million settlement) and others**

Shine Lawyers: Profits Before Clients?

- Shine Lawyers is a publicly-listed company on ASX.
- Federal Court found Shine "preferred its own financial interests over clients."
- While handling mesh litigation:
 - Paid \$36.4 million in dividends to shareholders.
 - Allowed 20%+ interest on disbursement loans.
 - Tried to charge victims \$30+ million in finance costs.
- Shine sought \$100 million in fees from \$300 million settlement.



Where Did the \$300 Million Go?



- Total Settlement: \$300 million (11,000+ women)
- Breakdown:
 - Shine's fees: ~\$100 million
 - Finance costs: ~\$30 million
 - Administration: ~\$37 million
 - Left for victims: ~\$174 million
 - Average payout: ~\$15,800
 - "Fast track" option: \$7,500
 - Time to receive: 10+ years total

Australia vs New Zealand - Two Different Systems

Australia (Litigation):

- Can sue manufacturers.
- 10+ years to resolve cases.
- Lawyers take 30-40%.
- One-time payment only.
- Average payout: ~\$15,800.
- Must prove fault.

New Zealand (Accident Compensation Corporation):

- Cannot sue - must use ACC.
- Weeks to months for decision.
- No legal fees.
- Ongoing medical & wage support.
- Up to NZ\$140,000 lump sum.
- No-fault system.

Silicone Gel Breast Implants

1960s – Silicone breast implants first sold (pre-Medical Device Act 1976)

1984 – First personal injury lawsuit: \$200k verdict

1988 – FDA: silicone-gel breast implants → Class III

2 million U.S. women receive implants by 1990



“We’re About to Experiment on 2 Million Women”



<https://www.youtube.com/watch?v=7BsNa2htJbk>

- 1990 – Congressional hearings
- 1991 – Litigation claiming manufactures failed to warn of risks of breast cancer and autoimmune disease
- Multiple jury verdicts for plaintiffs including Pamela Johnson (\$25M)
- 1991 - FDA banned implants outside of approved research studies
- Jan. 1992 - WHO issued moratorium on the sale of silicone gel breast implants

Media Frenzy, Verdicts and Bankruptcy . . . But No Science

1992 - Studies fail to show link to breast cancer (lawsuits turned to autoimmune diseases)

1994 - Dow Corning (176,000 lawsuits) files for Chapter 11 bankruptcy; other manufacturers and plaintiffs agree to settle 90% of cases for \$3.4B

1994 & 1995 – NEJM studies show no association between implants and connective tissue disorders

1996 – Federal courts rule that plaintiffs' evidence linking silicone implants to autoimmune disease was scientifically invalid

1996 - *New York Times* reports that breast implant manufacturers had won 80 percent of the cases against them

2006 - FDA lifts ban on silicone gel-filled breast implants



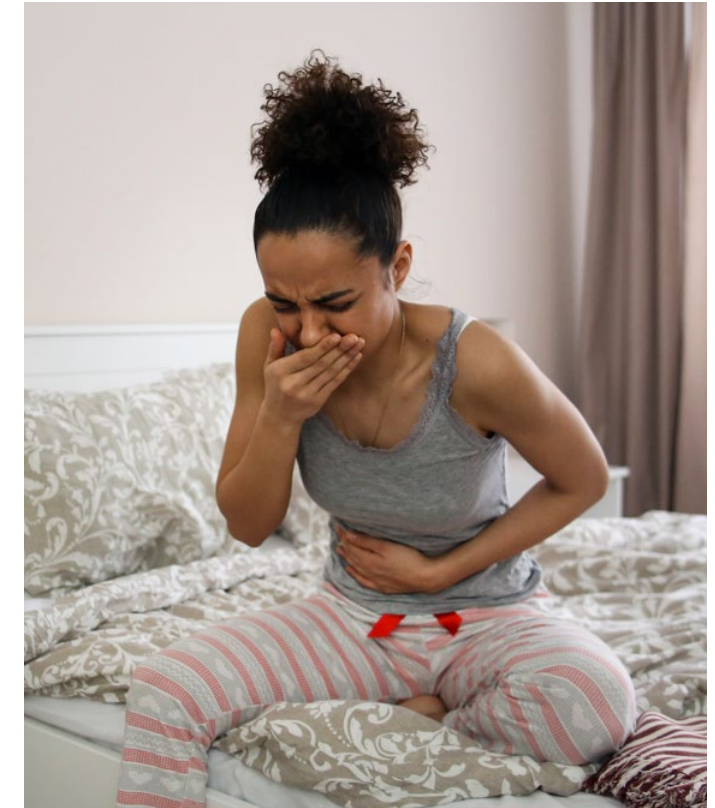
“Somewhere Between Slimy, Skuzzy and Sleazy”

“Lawsuits alleging harm from silicone gel breast implants were successful largely because of the support of a group of ‘silicone doctors’ who . . . claimed to trace a broad range of symptoms (chronic fatigue, insomnia, depression, headaches, and muscle or joint pain) to silicone poisoning.”

Kristin E. Schleiter, JD, LLM, “Silicone Breast Implant Litigation,” AMA Journal of Ethics, May 2010

Bendectin

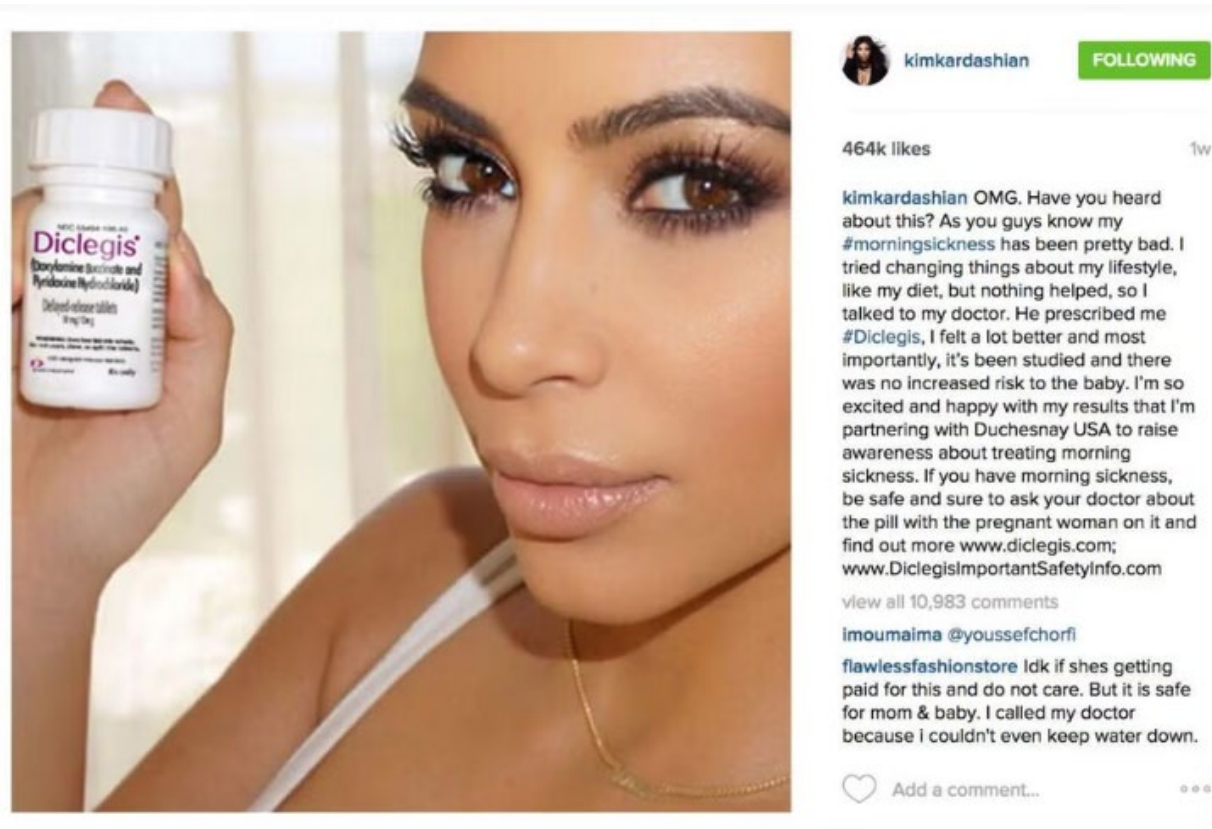
- Nausea and vomiting in pregnancy affects 70-85% of pregnant women
- 1956 - Bendectin first marketed in the U.S. (pyridoxine/doxylamine)
- 1970 - Lawsuits began, claiming fetal malformations and problems
 - Limb deformities, brain damage, respiratory, gastrointestinal, cardiovascular and genitourinary problems, blood disorders, cancer
 - Variety of harms itself was a red flag -- teratogens affect fetal development at specific times
- Paid \$120M to settle most of the lawsuits (3rd largest settlement in U.S. history)
- 1983 – Merrell Dow voluntarily ceased production of the drug in 1983
- "We were forced for business reasons to take a safe and effective medication off the market."



Not a Teratogen, But a Tortigen

- 1980 – FDA determined there was no association between Bendectin and birth defects
- Two meta-analyses assessed outcomes of 200,000 Bendectin-exposed pregnancies and found no increased risk of malformations
 - 1988 - combined data from 12 cohort and 5 case-control studies
 - 1994 - combined data from 16 cohort studies and 11 case control studies
- 1989 - Canadian and American experts presented to a Health Canada panel concluding that “numerous studies in animals and in humans that have been reported in the scientific and medical literature demonstrate that Bendectin is not a teratogen.
- Plaintiffs’ expert Dr. William McBride (also a thalidomide expert) was found to have deliberately falsified research and was struck off the medical register in Australia for 5 years in 1983
- Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993)

Diclegis: Will History Repeat Itself?



- FDA approved April 8, 2013
- Same drug as Bendectin (doxylamine-pyridoxine)
- Manufactured by Duchesnay Inc.
- October 2015 - Canadian physicians recommended reconsidering the drug as the "first-line pharmacological treatment" for NVP
- January 2019 - *Canadian Family Physician* stated that articles recommending the drug as a first line pharmacologic treatment for NVP were not subjected to standard peer review
- Plaintiffs' lawyers: "Will history repeat itself? Will litigation from devastated parents follow?"

“What Is Going On?”

- Legacy of DES and thalidomide
- Women are more focused on their health
- Women are more likely to endorse “alternative” treatments
- Women make better plaintiffs
- Women are more likely to seek health info on social media
- Women watch more TV



Strategies for the Defense



- Reclaim the narrative of drug & device companies as the true champions of women's well-being
- Attack plaintiffs' experts for promoting junk science—are they violating their medical associations' professional code?
- Notify co-counsel of plaintiff-friendly doctors who want to 'help' plaintiffs
- Emphasize courts' gatekeeping role
- Look out for plaintiff recruitment
- Expose third-party litigation funding

Merci Beaucoup!

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