Recklessness, Greed and Guinea Pigs

How Mass Tort Litigation Targets Women

By Diana Katz Gerstel

Which new miracle pill—although blessed by regulators and recommended by doctors—will insidiously exact devastating harm on unsuspecting women?

The first oral contraceptive—Enovid, developed by G.D. Searle & Co.—revolutionized women's lives beginning in 1960. Some credit it with ushering in the feminist movement. Arguably, "the Pill" also ushered in an era of litigation: It has been noted that every contraceptive drug or device for the last half century has been the subject of litigation. (Alexander, E., "Another Attack on a Contraceptive Is Dismissed (For Now)," Drug & Device Law Blog, October 7, 2022.)

Women's drugs and devices generally are overrepresented in mass tort litigation—breast cancer drugs, breast implants, oral hormone replacement therapy (HRT), contraceptives, drugs for "morning sickness" and pelvic mesh, as well as products predominantly marketed to or utilized by women, such as talcum powder, infant formula, hair relaxers and human papilloma virus (HPV) vaccines.

Some legal theorists have proposed this reflects a recklessness in the development of products for women. In 1992, Professor Joan Steinman wrote: "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." (Steinman, J.E., *Women, Medical Care, and Mass Tort Litigation*. 68 Chi.-Kent L. Rev. 409, 1992.) She posited: "I strongly suspect that a disparity exists between the care invested in products for men and that invested in drugs and medical devices for women."

Thirty years later, Professor Elizabeth Chamblee Burch echoed that sentiment: "Harm from drugs and medical devices disproportionately affect[s] females.... Women account for 67% of the FDA's medical device adverse event reports; sex-neutral devices like hip implants and pacemakers disproportionately fail in women; and from 1997 to 2000, eight of the ten drugs pulled from the market posed greater risks to women." (Burch, E.C., *Perceptions of Justice in Multidistrict Litigation: Voices from the Crowd*. 107 Cornell L Rev. 1835, 2022.)

Women are the victims, Burch and Steinman proposed, of for-profit corporations, bias in medical practice, and under-representation of women in clinical studies. On the other hand, women are also unhappy with the litigation experience. Most of the pelvic mesh plaintiffs Burch based her article on were unsatisfied with their lawyers, who enlisted them as claimants, ignored their cases, and finally convinced them to accept low settlements.

The *New York Times* reported in 2019 that some pelvic mesh plaintiffs' lawyers had enriched themselves while mishandling their unwieldy pelvic mesh caseloads. (Goldstein, M., *Women Who Sued Makers of Pelvic Mesh Are Suing Their Own Lawyers, Too*, The New York Times, June 14, 2019.) In 2018, there was reporting that many pelvic mesh plaintiffs were encouraged by their lawyers to undergo unnecessary, even harmful, surgeries to increase the value of their lawsuits. (Goldstein, M., Silver-Greenberg, J., *How Profiteers Lure Women Into Often-Unneeded Surgery*, The New York Times, April 14, 2018.) In 2021, a surgeon and a patient recruiter pleaded guilty to federal charges arising from a scheme to pressure plaintiffs to get their mesh implants removed. (Goldstein, M., *Two men plead guilty in a personal injury scheme involving pelvic mesh implants*, The New York Times, Sept. 17, 2021.)

The apparent dissatisfaction of women with their experience as plaintiffs in mass tort litigation prompts a question: Are women targeted by corporations, or by litigations? And if women are targeted for mass tort litigation, how can drug and device manufacturers more effectively defend against such tactics?

Thalidomide and diethylstilbestrol (DES) are sometimes pointed to as drug

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companies' original sin against women. But these two drugs—for morning sickness and miscarriage prevention—were exceptions, not harbingers. Often forgotten is that thalidomide was never approved by the FDA for use in pregnant women in the U.S. Both drugs also had second lives as effective treatments for cancers and other conditions.

But the teratogenic effects of thalidomide and DES continue to haunt women's imaginations: Which new miracle pill—although blessed by regulators and recommended by doctors—will insidiously exact devastating harm on unsuspecting women?

Women may be prime targets for drug and device mass torts because they worry more about their health than men do. Women see the doctor much more often—a Cleveland Clinic survey found men would rather clean the toilet and do other household chores than see a doctor. (Campbell, L., *Why So Many Men Avoid Going to the Doctor*, Healthline, September 14, 2019.) But women also seek out "alternative" treatments more, suggesting women may be more susceptible to anti-medicine narratives. (Shahvisi, A., *Medicine Is Patriarchal, But Alternative Medicine Is Not the Answer*, J Bioethical Inquiry, v. 16, pp. 99–112, 2019.)

Another reason that women may be targets of mass tort litigation is that more women watch TV and use social media—where mass tort litigations are advertised. (Nielsen, *American Video Habits by Age, Gender and Ethnicity*, August 2011; Dugan, M., *It's a Woman's (Social Media) World*, Pew Research Center, Sept. 12, 2013.)

The news media, in search of the next scoop, stokes fears with sympathetic portrayals of plaintiffs and credulous interviews with their experts. In December 1990, journalist Connie Chung reported during her eponymous CBS news program on the purported dangers of silicone gel breast implants. She featured a plaintiffs' expert who likened implants to a mass experiment on women, and interviewed patients struggling with flu-like symptoms, rheumatoid arthritis, and lupus.

The ensuing explosion of silicone breast implant litigation bankrupted manufacturer Dow Corning prompted moratoriums by the FDA and the World Health Organization, and led thousands of concerned women to have their implants removed. But claims of silicosis, autoimmune disease and cancer from breast implants were eventually shown in the scientific literature to be baseless. "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, wrote. (Schleiter, K.E., *Silicone Breast Implant Litigation*, AMA Journal of Ethics, May 2010.)

Litigation drove numerous breast implants off the market despite efforts to keep junk science out of the courtroom prompted by the preceding Bendectin lawsuits of the 1980s. Claims of teratogenic effects from the 'morning sickness' drug began in 1970, but by 1980, the FDA reported it had found no association with birth defects. Two meta-analyses, in 1988 and 1994, that assessed 200,000 Bendectin-exposed pregnancies found no increased risk of malformations. The *Daubert* decision (509 U.S. 579 (1993)), issued in a Bendectin case, heightened the federal standard for admission of expert testimony.

Silicone gel breast implants and the drug previously branded as Bendectin re-emerged after the conclusions of their mass tort quagmires based on science that refuted the supposed harms. In 2006, the

FDA approved new silicone breast implants from Mentor. In April 2013, doxylamine-pyridoxine (Bendectin) was reintroduced in the U.S. under a new name, Diclegis.

Also now regaining use after mass tort litigation is oral HRT. In the late 1990s, 15 million women were prescribed HRT annually to alleviate perimenopausal symptoms. Such symptoms, experienced by 85% of women, can significantly impair quality of life as hormone levels fluctuate. (Dominus, S., *Women Have Been Misled About Menopause*, The New York Times, Feb. 1, 2023.) Back in 2002, a National Institutes of Health Women's Health Initiative study linked HRT to increased risks of heart disease, stroke, blood clots and breast cancer. Media reports suggested that manufacturers had gaslit women into believing a natural life stage was a disease. A Harvard Medical School doctor characterized then-Prempro manufacturer Wyeth as conducting "medical ventriloquism." (Singer, N., Wilson, D., *Menopause, As Brought to You by Big Pharma*, The New York Times, Dec. 12, 2009.) Prescriptions plummeted, and thousands of lawsuits were filed.

Subsequently, dozens of studies showed that the benefits of oral HRT outweigh the risks for many women, especially for women under 60 experiencing the most severe perimenopause symptoms. Prempro endured and survived the litigation, but HRT prescription levels have not yet recovered due to fears stoked by lawyers, their paid experts, and sensational media reports.

The role of plaintiffs' experts in mass tort drug and device litigation who tout unproven or even disproved theories cannot be overstated. Plaintiffs' experts may say one thing in the courtroom while offering contradictory opinions in their professional sphere—at their hospitals, while attending conferences with peers, and in peer-reviewed journal articles.

Federal Rule of Evidence 702 was developed based on the "*Daubert* trilogy" of 1990s Supreme Court cases setting forth standards for the admission of expert testimony. *Daubert v. Merrell Dow Pharms., Inc.* 509 U.S. 579 (1993); *Gen. Elec. Co. v. Joiner*, 522 U.S. 136 (1997); and *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999). The December 1, 2023, amendment to Rule 702 arose out of years of analysis by judges, law professors and the Lawyers for Civil Justice revealing that the rule was being applied inconsistently within and across jurisdictions. (Mark A. Behrens & Andrew J. Trask, *Federal Rule of Evidence 702: A History and Guide to the 2023 Amendments Governing Expert Evidence*, 12 Tex. A&M L. Rev. 43 (2024). Junk science was influencing judges and juries in too many lawsuits—one study found that 83% of district court judges in Florida were substantially unable to differentiate junk science from real science. (Kovera, M.B., McAuliff, B.D., *The Effects of Peer Review and Evidence Quality or Judge Evaluations of Psychological Science: Are Judges Effective Gatekeepers?*, 85 J. Applied Psych. 4, 574 (2000).)

It remains to be seen how successful the amendment of Rule 702 will ultimately prove. Efforts are underway to make the standard for expert testimony more stringent in state courts as well. Lawyers for Civil Justice reports that six states have amended their equivalent rule to Rule 702 and that more than a dozen other states have efforts underway to amend their equivalent rules. (Lawyers for Civil Justice, ***https://dontsaydaubert.com/state-evidentiary-rule-reform/, accessed 6/8/2025***.)

Not uncommonly, doctors express interest in serving as defense experts when they realize that a mass tort may otherwise threaten their ability to offer patients beneficial treatments. By that point, however, the mass tort may have already enlisted thousands of plaintiffs and notched some well-publicized 'nuclear' verdicts in plaintiff-friendly jurisdictions. The ability of doctors to self-regulate against junk science before the litigation reaches the nuclear-verdict stage could potentially be a more effective way to reduce the threat to safe and effective treatment options.

According to the American Medical Association, doctors must ensure that their expert testimony reflects current scientific thought and standards of care that have gained acceptance among peers, among other requirements. (American Medical Association Code of Ethics, Opinion 9.7.1, Medical Testimony, accessed 6/8/2025.) Many associations for individual medical specialties have their own such requirements, and the American Association of Neurological Surgeons (AANS) has a particularly effective 'self-regulation' process through its Professional Compliance Program.

Lawyers cannot enforce doctors' compliance with such requirements, but they can depose plaintiffs' experts regarding the standards of the esteemed medical associations to which they belong and whether they are in compliance with those standards. (Timmons, S.D., *Medical Expert Witness Testimony and the Need for Professional Self-regulation*, AANS Neurosurgeon, Aug. 27, 2020, aansneurosurgeon.org/InsideNeuro/medical-expert-witness-testimony-and-the-need-for-professional-self-regulation, accessed 6/8/2025; Pelton, R.M., *Medical Societies' Self-Policing of Unprofessional Expert Testimony*, 13 Annals Health L. 549 (2004).)

The most unfortunate consequence of mass tort drug and device litigations that target women as plaintiffs is that women, collectively, lose when they are left with fewer options. The impact on women's lives can be profound—because the positive impact that drug and medical device companies have had on women's lives is profound.

The five-year survival rate for breast cancer is now more than 90% (Ulrich, J., *Protecting Treatment Advances for Breast Cancer*, PhRMA Blog, October 31, 2022); new cervical cancer diagnoses have been quite literally eliminated in populations receiving HPV vaccination (Arbyn, M., Xu, L., Simoens, C., & Martin-Hirsch, P. P., *Prophylactic vaccination against human papillomaviruses to prevent cervical cancer and its precursors*, Cochrane Database of Systematic Reviews, 2020(3)); and researchers are tantalizingly close to a cure for multiple sclerosis, which affects four times as many women as men, and had no treatment options thirty years ago. (Gonzalez, L.L., *A Cure for Multiple Sclerosis? Scientists Say Within Our Lifetime*, UCSF, June 12, 2024; Robare, E., *Man of Steel: An MS Hero*, National MS Society, May 20, 2014.) There are plentiful other examples, and defense counsel and their clients must reclaim the narrative as the champions of women's health and well-being that they are.