

University at Buffalo School of Law

## Digital Commons @ University at Buffalo School of Law

---

Journal Articles

Faculty Scholarship

---

Spring 1997

### Female Trouble: The Implications of Tort Reform for Women

Lucinda M. Finley

*University at Buffalo School of Law*

Follow this and additional works at: [https://digitalcommons.law.buffalo.edu/journal\\_articles](https://digitalcommons.law.buffalo.edu/journal_articles)



Part of the [Law and Gender Commons](#), and the [Torts Commons](#)

---

#### Recommended Citation

Lucinda M. Finley, *Female Trouble: The Implications of Tort Reform for Women*, 64 *Tenn. L. Rev.* 847 (1997).

Available at: [https://digitalcommons.law.buffalo.edu/journal\\_articles/195](https://digitalcommons.law.buffalo.edu/journal_articles/195)

This article was published originally at 64 *Tenn. L. Rev.* 847 (1997) and is reproduced here by permission of the Tennessee Law Review Association, Inc.



This Article is brought to you for free and open access by the Faculty Scholarship at Digital Commons @ University at Buffalo School of Law. It has been accepted for inclusion in Journal Articles by an authorized administrator of Digital Commons @ University at Buffalo School of Law. For more information, please contact [lawscholar@buffalo.edu](mailto:lawscholar@buffalo.edu).

# FEMALE TROUBLE: THE IMPLICATIONS OF TORT REFORM FOR WOMEN

LUCINDA M. FINLEY\*

## *Table of Contents*

I. LIMITATIONS ON NON-PECUNIARY LOSS DAMAGES: THE WORTH OF A WOMB . . . . .	850
II. THE "FDA DEFENSE": CONDONING THE TENDENCY TO TRIVIALIZE RISKS TO WOMEN'S HEALTH . . . . .	867
III. CONCLUSION . . . . .	879

Tort reform, particularly in products liability actions, has been on the federal legislative burner for over a decade.<sup>1</sup> Its latest incarnation, the Common Sense Product Liability Legal Reform Act of 1996,<sup>2</sup> came within

---

\* Professor of Law, State University of New York at Buffalo School of Law. This article grows out of legislative testimony I have presented on several occasions from 1993 to 1997 to Committees of the United States Senate and House of Representatives on various versions of tort reform legislation. Research for this article was supported by the Women's Health Policy Fellowship at the Center for Research on Women and Gender ("CRWG"), University of Illinois at Chicago, funded by the MacArthur Foundation. I would like to thank the staff of CRWG, particularly Dr. Alice Dan, Director, for their support and interest, and many fruitful opportunities for discussion. I have also benefitted from discussions with Amanda Sherman, Karen Renick, Barbara Seaman, Michelle Oberman, Jane Rutherford, Morrison Torrey, Joan Steinman, Jack Schlegel, Nancy Staudt, Isabel Marcus, Michael Rustad, Tom Koenig, Arthur McEvoy, Mark Galanter, Barry Boyer, Martha McCluskey, Margaret Shannon, Joan Vogel, Martha Chamallas, Shari Diamond, Joseph Sanders, and many others. I also received stimulating and valuable feedback from the participants at workshops where I have presented some of the ideas in this article, including those at SUNY-Buffalo Law School, DePaul Law School, Chicago-Kent Law School, NYU Law School Discourses Group, University of Wisconsin Institute for Legal Studies, and Law and Society Association annual meetings. Kim Sayoc, SUNY at Buffalo, J.D. 1998, provided valuable research assistance.

1. See Victor E. Schwartz & Mark A. Behrens, *Federal Product Liability Reform in 1997: History and Public Policy Support Its Enactment Now*, 64 TENN. L. REV. 595, 597-601 (1997).

2. H.R. 956, 104th Cong. (1996). H.R. 956 was approved by the Joint Conference Committee on March 19, 1996. See H.R. CONF. REP. NO. 104-481 (1996). President Clinton received the Conference Report bill on April 30, 1996, and vetoed it on May 2, 1996. See John F. Harris, *Clinton Vetoes Product Liability Measure*, WASH. POST, May 3, 1996, at A14; Neil A. Lewis, *President Vetoes Limits on Liability*, N.Y. TIMES, May 3, 1996, at A1;

a presidential veto of enactment during the recently concluded 104th Congress.<sup>3</sup> Legislatures in various states have also passed or proposed reform measures, including limitations on nonpecuniary loss and punitive damages.<sup>4</sup>

The ongoing legislative debates have taken on a somewhat surreal quality; the proponents of reform have based their argument that there is a "litigation crisis" on anecdote, distortion, fear, and perception with scant empirical grounding.<sup>5</sup> Advocates for products liability reform have been quite rhetorically successful in redefining the central policy goal of tort law away from reducing injury, to reducing claims. Legislators no longer attribute the problem confronting our legal system to the number of accidents, harmful products or insufficiently tested drugs and devices adversely affecting public health and individual well-being; rather, they now attribute the problem to the excessive number of claims brought by injured people.<sup>6</sup>

---

*The Lawyers' Veto*, WALL ST. J., May 3, 1996, at A12. A veto override that was attempted in the House on May 9, 1996 in order to preserve a record on the issue fell twenty-three votes short of passage. Victor E. Schwartz & Mark A. Behrens, *The Road to Federal Product Liability Reform*, 55 MD. L. REV. 1363, 1365 n.18 (1996).

For the full text of H.R. 956, see Symposium, *Is H.R. 956 Really "Common Sense"?: A Symposium on Federal Tort Reform Legislation*, 64 TENN. L. REV. 557, 559-94 (1997).

3. H.R. CONF. REP. NO. 104-481 (1996).

4. For a summary of state legislative limitations on nonpecuniary loss damages, see Lisa M. Ruda, Note, *Caps on Noneconomic Damages and the Female Plaintiff: Heeding the Warning Signs*, 44 CASE W. RES. L. REV. 197, 197-202 (1993). A summary of state measures that affect punitive damages is provided in Thomas Koenig & Michael L. Rustad, *His and Her Tort Reform: Gender Injustice in Disguise*, 70 WASH. L. REV. 1 (1995), see also AMERICAN TORT REFORM ASSOCIATION, TORT REFORM RECORD, Dec. 31, 1995 (summary of state legislative changes).

5. However, for a description of empirical studies that subject the rhetoric of the tort reform movement to the scrutiny of reality and refute the majority of the claims of crisis and runaway awards, see generally STEPHEN DANIELS & JOANNE MARTIN, CIVIL JURIES AND THE POLITICS OF REFORM 4-27 (1995) (documenting use of anecdotes and "horror stories" taken out of context or presented in distorted fashion as a technique to redefine the public perception and debate despite contrary reality); NEIL VIDMAR, MEDICAL MALPRACTICE AND THE AMERICAN JURY: CONFRONTING THE MYTHS ABOUT JURY INCOMPETENCE, DEEP POCKETS, AND OUTRAGEOUS DAMAGE AWARDS 11-22 (1995); Michael Rustad, *In Defense of Punitive Damages in Products Liability: Testing Tort Anecdotes with Empirical Data*, 78 IOWA L. REV. 1 (1992); Michael J. Saks, *Do We Really Know Anything About the Behavior of the Tort Litigation System—and Why Not?*, 140 U. PA. L. REV. 1147 (1992); W. John Thomas, *The Medical Malpractice "Crisis": A Critical Examination of a Public Debate*, 65 TEMP. L. REV. 459, 476-503 (1992).

6. This shift in perception is sadly ironic, particularly in light of empirical research indicating that very small percentages of people injured by tortious conduct ever file claims; a small percentage of claims filed ripen into lawsuits; plaintiffs prevail only in a minority of suits; and, while compensation does correspond with the severity of the injury, compensation

In the legislative rush to restore "common sense" to product liability law by passing measures intended to reduce claims, remarkably little attention has been paid to how these legal changes might impact the health, safety, and welfare of particular groups of people.<sup>7</sup> The social impact of tort reform is an important issue deserving far greater attention from legislatures. Tort law plays several important social functions. It provides compensation which can restore social and productive functioning and reduce the burdens on publicly and privately funded health, disability and social insurance programs. Tort suits often stimulate regulatory agencies, such as the FDA, to take stronger action to safeguard public health. The legal system can also prod research into product safety and health risks that should have been done before the product was marketed. Additionally, product liability suits inform the public about risks, and thus enhance more informed consumer choices. Finally, tort suits define and signify basic social values about what human activities are worthy of protecting and, therefore, can alert companies to take certain risks more seriously. For example, if society places a high value on preserving fertility and the ability to bear healthy children, tort law allows juries to express fully their valuation when this human capacity is impaired. Therefore, even though much of the impact of reproductive harm is experienced in ways deemed nonpecuniary by tort law, a company developing a drug meant to be taken during pregnancy should devote greater research to ascertaining whether the drug might harm a woman's reproductive health. In contrast, if the law limits compensation for this type of harm, that company may decide that such risks are now financially bearable no matter how devastating the impact on individual lives.

In its carefully orchestrated hearing process, Congress's slight consideration of the social impact of these laws focused on the repercussion of proposed legal changes for women and for drug and medical device safety. In testimony before Congress, I and the representatives of some women's health groups (such as DES Action) raised concerns that some of the suggested bill provisions could disparately affect women and weaken the

---

for the most serious injuries falls well below even the economic loss. See, e.g., DEBORAH HENSLER, *COMPENSATION FOR ACCIDENTAL INJURIES IN THE UNITED STATES* (1991); ELIZABETH KING & JAMES P. SMITH, *ECONOMIC LOSS AND COMPENSATION IN AVIATION ACCIDENTS* (1988); FRANK SLOAN ET AL., *SUING FOR MALPRACTICE* (1993); VIDMAR, *supra* note 5, at 15-20; PAUL C. WEILER ET AL., *A MEASURE OF MALPRACTICE: MEDICAL INJURY, MALPRACTICE LITIGATION AND PATIENT COMPENSATION* 109 (1993); Richard L. Abel, *A Critique of Torts*, 37 *UCLA L. REV.* 785, 796-98 (1990); Richard L. Abel, *The Real Torts Crisis—Too Few Claims*, 48 *OHIO ST. L.J.* 443, 445, 448-52 (1987); Marc Galanter, *The Day After the Litigation Explosion*, 46 *MD. L. REV.* 3, 6-7 (1986); Marc Galanter, *Why the "Haves" Come Out Ahead: Speculations on the Limits of Legal Change*, 9 *L. & SOC'Y REV.* 95, 144-48 (1974); Russell Moran, *System Self-Corrects Tort "Flaws"*, *N.J. LAW.*, March 13, 1995, at 6 (reviewing jury verdict statistics from New York, concluding that juries are tilting toward defendants).

7. See H.R. CONF. REP. NO. 104-481, at 25-26 (1996).

few incentives for pharmaceutical and medical device manufacturers to devote increased attention to risks their products may pose to women's health.<sup>8</sup> The proffered legal changes that most directly raise these concerns are caps or other forms of limitations on nonpecuniary loss damages; provisions that link punitive damages to the amount of economic loss only and exclude nonpecuniary loss from the calculation; and proposals to insulate drug or device manufacturers from punitive damages if the product received pre-market approval from the FDA.<sup>9</sup>

This article analyzes these proposals and their possible adverse impact on women and women's health. Even though a comprehensive bill containing all of these proposals has not yet been signed into law, a bill containing several of these proposals has been reintroduced into Congress this term.<sup>10</sup> Several states have also enacted or proposed provisions similar to H.R. 956. Thus, rather than making the issue moot, the Presidential veto of the 1996 version of the Federal Products Liability Reform Act merely postponed and reintensified the issue.

The article first examines damages for nonpecuniary or noneconomic loss, the reasons that this type of damages has been singled out for legislative attention, the gendered nature of the assumptions motivating the attack on nonpecuniary damages, and the implications of particular legislative proposals for women. The article then explores the so-called "FDA-defense" and the reasons why an unadulterated product liability cause of action in the drug and medical device area is an important women's health issue.

#### I. LIMITATIONS ON NON-PECUNIARY LOSS DAMAGES: THE WORTH OF A WOMB

Nonpecuniary loss damages have been a favorite target of tort reformers, singled out as a seemingly easy mark. Under prevalent economic theories in contemporary tort scholarship and policy, nonpecuniary damages appear less justifiable than damages for lost income and medical costs.<sup>11</sup> Nonpe-

---

8. See, e.g., *The Product Liability Fairness Act of 1995: Hearings on S. 565 Before the Subcomm. on Consumer Affairs, Foreign Commerce, and Tourism of the Senate Comm. on Commerce, Science, and Transportation*, 104th Cong. 164 (1995) [hereinafter *Hearings on S. 565*] (statement of U.S. Rep. Patsy Mink); *Id.* at 131 (statement of Prof. Lucinda M. Finley); *The Product Liability Fairness Act: Hearings on S. 687 Before the Senate Comm. on the Judiciary*, 103d Cong. 78 (1994) (statement of Prof. Lucinda M. Finley); *Product Liability Standards: Hearings on H.R. 1910 Before the Subcomm. on Commerce, Consumer Protection, and Competitiveness of the House Comm. on Energy and Commerce*, 103d Cong. 43 (1994) (statement of Stephanie Kanarek).

9. See *infra* text accompanying notes 64-70, 74-76, 86.

10. S. 5, 105th (1997) (this bill is the same as the conference committee version of H.R. 956).

11. See *Enterprise Responsibility for Personal Injury (Reporters' Study)*, 2 A.L.I.

cuniary loss damages include pain and suffering, emotional distress, fear and anxiety, diminished quality of life, or reduced ability to enjoy activities that lend meaning to life.<sup>12</sup> Damage awards for these losses have been assailed as too subjective and irrationally governed by jury sympathy rather than determinable criteria, as well as inherently arbitrary, and not truly compensatory.<sup>13</sup> Economists assert that nonpecuniary damages are not actually compensatory because providing monetary compensation for an intangible loss cannot make the person whole in the same way that it can for lost income. Law and economics scholars further argue that nonpecuniary loss damages are illegitimate because people do not purchase insurance to cover them.<sup>14</sup>

Inherent in these arguments is a value judgment that nonpecuniary loss is less real, less serious, and thus less deserving of compensation than pecuniary loss.<sup>15</sup> Tort law has long been distrustful of emotional harm claims, fearful that such harm can easily be feigned or is too individually subjective to be susceptible to meaningful proof and evaluation.<sup>16</sup> This value judgment rests on the assumption that the wage earning and economic aspects of human life are more important and worth protecting than emotional, relational, dignitary, and other whole-person aspects of life. Those aspects of life and loss that have a readily available market reference or price are regarded as more real and important and are privileged in the tort system just as they are privileged in the market.

These criticisms leveled at nonpecuniary loss damages and their underlying value judgments are seriously questionable, if not fundamentally

---

APPROACHES TO LEGAL AND INSTITUTIONAL CHANGE 201-04 (1991) [hereinafter *Enterprise Responsibility*].

12. See, e.g., H.R. 956, 104th Cong. § 108(8) (1996).

13. For a summary of the critiques of nonpecuniary loss damages, see generally *Enterprise Responsibility*, *supra* note 11, at 199-217; Randall R. Bovbjerg et al., *Valuing Life and Limb in Tort: Scheduling "Pain and Suffering"*, 83 NW. U. L. REV. 908 (1989); Edward C. Martin, *Limiting Damages for Pain and Suffering: Arguments Pro and Con*, 10 AM. J. TRIAL ADVOC. 317 (1986); Ruda, *supra* note 4.

14. For an explication and critique of the insurance theory of damages, see generally Steven P. Croley & Jon D. Hanson, *The Nonpecuniary Costs of Accidents: Pain-and-Suffering Damages in Tort Law*, 108 HARV. L. REV. 1785 (1995); Ellen S. Pryor, *The Tort Law Debate, Efficiency, and the Kingdom of the Ill: A Critique of the Insurance Theory of Compensation*, 79 VA. L. REV. 91 (1993).

15. See Martha Chamallas & Linda K. Kerber, *Women, Mothers, and the Law of Fright: A History*, 88 MICH. L. REV. 814, 814 (1990).

16. See, e.g., *Id.* at 816-19; Lucinda M. Finley, *A Break in the Silence: Including Women's Issues in a Torts Course*, 1 YALE J.L. & FEMINISM 41, 65-66 (1989) [hereinafter Finley, *A Break in the Silence*]. For a classic article setting forth the traditional view which disparages the seriousness or worthiness of emotional distress claims, see generally Calvert Magruder, *Mental and Emotional Disturbance in the Law of Torts*, 49 HARV. L. REV. 1033 (1936).

flawed. The claim that nonpecuniary damages are too subjective has two related components: 1) nonpecuniary loss varies too much from individual to individual, turning the tort system into a lottery; and 2) the lack of a readily available market based reference point leaves no measurable criteria to rein in jury discretion.<sup>17</sup> However, the first criticism can also be applied to pecuniary loss damages. Pecuniary damages lack objectivity because two people injured in the same way during the same accident will have widely disparate economic loss recoveries depending on the individual's occupation, income, race, gender, and age.<sup>18</sup> The market assigns widely varying values to different types of people; values that often have more to do with stereotype and prejudice than with intrinsic talent or worth. Particularly when trying to project future lost earning capacity, the calculation of economic loss can become an exercise in arbitrary guesswork replete with gender, race, and class based assumptions about the relative abilities, prospects, and desires of different groups of people. Therefore, the calculation of economic loss is no more objective or neutral than the calculation of nonpecuniary damages.

The second component of the attack essentially is the assertion that these nonpecuniary losses are not fully fungible with money. It is hardly value neutral to privilege those activities or types of loss that have a market price over those that are seriously undervalued or not readily valued by the market.<sup>19</sup> Money is not the measure of all human value; activities or losses that are not easily fungible with money are not, therefore, unimportant or unreal.

---

17. See Neil K. Komisar, *Injuries and Institutions: Tort Reform, Tort Theory, and Beyond*, 65 N.Y.U. L. REV. 23, 57 (1990).

18. For example, if a young white female homemaker, an elderly retired latina woman, a black male janitor and a white male corporate manager are all physically disabled in an elevator accident in a building, their economic loss damages will vary dramatically. The disparity in recovery of economic damages is due to the vast gaps between the wages they earn, the amount of working years still remaining, and the disparate social worth assigned to their various non-wage earning activities such as household maintenance. See, e.g., Jamie Cassels, *Damages for Lost Earning Capacity: Women and Children Last!*, 71 CAN. B. REV. 445 (1992); Martha Chamallas, *Questioning the Use of Race-Specific and Gender-Specific Economic Data in Tort Litigation: A Constitutional Argument*, 63 FORDHAM L. REV. 73 (1994); Frank M. McClellan, *The Dark Side of Tort Reform: Searching for Racial Justice*, 48 RUTGERS L. REV. 761, 772-76 (1996) (describing willingness of defendants to offer more favorable settlements to white plaintiffs than to black plaintiffs, because of their assumption that juries will be biased against black plaintiffs); Finley, *A Break in Silence*, *supra* note 16, at 51-54.

19. See, e.g., Margaret J. Radin, *Compensation and Commensurability*, 43 DUKE L.J. 56 (1993) (discussing the conflict between commodified and noncommodified concepts of damages); Margaret J. Radin, *Market-Inalienability*, 100 HARV. L. REV. 1849 (1987) [hereinafter Radin, *Market-Inalienability*] (discussing the shortcomings of universal commodification and universal noncommodification).

The criticism that nonpecuniary losses are not fungible with money leads to an attack on such damages for not neatly fitting the function of compensatory damages—to make the individual whole. Again, this criticism can easily be leveled at pecuniary loss as well. Economic loss damages really perform more of a substitution role rather than a make whole or restorative service.<sup>20</sup> For example, damages to cover the medical bills stemming from a broken spine do not restore the spine to its pre-accident condition. The money merely enables the injured person to obtain treatment that can alleviate the pain or to afford substitute ways of functioning, such as wheel chairs. No one sustaining physical injuries would ever say that wage replacement and medical cost coverage made them whole in the sense of restoring them to their pre-injury condition.<sup>21</sup> Damages for lost income are an equally imperfect form of restoring compensation for job loss or reduction in earning capacity. The work that an individual performs often means much more than the money that the job provides. For many people, their work, or lack thereof, is intertwined with self-esteem, status, place in the community, and social networks. These nonpecuniary aspects of work may be more important or self-defining than the income stream generated by a job.

This realization demonstrates that those who challenge nonpecuniary loss as less real and serious than pecuniary loss profoundly misunderstand what human beings value. How many people would give up their fertility, sexual functioning, ability to relate to people and enjoy human interaction, and their favorite activities in exchange for a guaranteed income stream to cover wages and medical bills? How many would willingly submit to a life maimed by pain and impaired mobility or other senses in return for money? Even conceding that pain, anxiety, depression, shredded self-esteem, loss of dignity, humiliation, pregnancy loss, the loss of a child or loved one are all real, serious, and life-altering, the critics of nonpecuniary damages may still argue that the tort system which trades in money should only try to replace lost funds, or at least determine a monetary price for these non-monetizable losses. The problem with that argument is that it ignores or underestimates the social function of tort law—signaling and reinforcing messages about the aspects of human life and types of people that our society values and deems worth protecting. Thus, a jury's award of significant monetary compensation for a sexual assault or damage to reproductive health is meant to signal

---

20. It is widely assumed that economic loss damages replace what has been lost, while nonpecuniary loss damages are justified as having a substitution function. *See, e.g.,* Croley & Hanson, *supra* note 14, at 1913-14. When one realizes the limited restorative power of money, however, any such distinction between the function of economic loss recovery and the purpose of nonpecuniary loss damages collapses.

21. The assumption that economic loss damages make one whole seems rooted in a world view that is persistently blind to the reality of the ill and disabled. *See* Pryor, *supra* note 14, at 110-17, 131-36.



the social importance of the human interest at stake and to make a moral judgment about activity that callously injures this human interest. If tort law adopts rules that make nonpecuniary harm less worthy than pecuniary harm, or that circumscribe the jury's role in responding to individualized situations with the limiting device of caps, then the law assigns a greater value to the monetized aspects of human life and deflates the value of those aspects of life that society may in fact most cherish.<sup>22</sup> The law may also be erecting an artificial, wholly arbitrary barrier to efforts to get society better able to recognize and seriously respond to certain types of harm. For example, large tort judgments have helped draw attention to and improve societal responsiveness to domestic violence and sexual abuse, which are harms that often are perceived to affect their victims in many nonpecuniary ways.<sup>23</sup> If nonpecuniary damages are artificially capped, or made harder to collect, product manufacturers or other potential injurers will lack incentive to consider this type of harm and to take steps to reduce it.<sup>24</sup> When tort law favors market-referenced damages over the nonpecuniary, it is also reinforcing the discriminatory valuations of the market and entrenching the tendency for higher income white males to receive better results in the tort system than people of color, women, and the poor.

The value judgments and assumptions fueling the attack on nonpecuniary loss damages are particularly problematic for women, because many aspects of women's injuries are more likely to be redressed as nonpecuniary

---

22. The work of sociologist Viviana Zelizer is instructive on this point. See VIVIANA A. ZELIZER, *PRICING THE PRICELESS CHILD: THE CHANGING SOCIAL VALUE OF CHILDREN* (1985) [hereinafter ZELIZER, *PRICING THE PRICELESS*]. In this book, Zelizer explores how, as children became valued less as economic contributors to the household and more for their priceless, joy-enhancing sentimental quality, their social value increased, as did tort awards for causing wrongful death to a child. *Id.* at 150-57. Those courts that refused to award anything more than the nominal economic value of a dead child were greeted with social opprobrium. *Id.* See VIVIANA A. ZELIZER, *THE SOCIAL MEANING OF MONEY* (1994) [hereinafter ZELIZER, *SOCIAL MEANING*]. In this book, Zelizer argues that, while people do not regard money as fungible with various human activities and interests, they do assign important moral significance to money, such as recoveries in wrongful death suits. *Id.* at 26-29.

23. For example, a Connecticut jury awarded \$2 million in damages against the town police department to a woman slashed by her abusive ex-husband despite repeated pleas to the police for protection. *Thurman v. City of Torrington*, 595 F. Supp. 1521, 1524-26 (D. Conn. 1984). In response to the verdict, the state enacted major legislation requiring domestic violence training for police officers and mandating arrest. See CONN. GEN. STAT. § 7-294g (1994) (state and local police training programs for domestic violence); 1996 Conn. Adv. Legis. Serv. 246 (West) (discussing arrest guidelines for domestic violence); see, e.g., Douglas D. Scherer, *Tort Remedies for Victims of Domestic Abuse*, 43 S.C. L. REV. 543 (1992).

24. See, e.g. Komesar, *supra* note 17, at 58-60 (analyzing how caps on nonpecuniary loss damages in product and service liability cases undermine the incentive to prevent injuries that harm the most important nonpecuniary aspects of life).

loss. There are several prevalent types of injuries that disproportionately happen to women, and cause harms considered to be nonpecuniary loss. These injuries include: hostile environment sexual harassment; sexual assault or coercive sexual abuse from teachers, parents, and health care providers; reproductive harm, such as infertility caused by a drug or contraceptive, like DES or the Dalkon Shield, used only by women in connection with sex or reproduction; and the painful disfigurement of capsular contracture of the breasts caused by a highly gendered product like breast implants. All of these injuries can certainly adversely impact a woman's earnings potential and cause her to incur medical expenses. However, the primary impact of these injuries is in eviscerating self-esteem, dignity, or a sense of security; causing physical and psychic pain; or impairing sexual or relationship fulfillment. Reproductive or sexual harm caused by drugs and medical devices has a highly disproportionate impact on women, because far more drugs and devices have been devised to control women's fertility or bodily functions associated with sex and childbearing than have been devised for men.<sup>25</sup> These drugs and devices have harmed women by rendering them infertile, causing malformed reproductive organs, causing miscarriages or septic abortions, or causing menstrual chaos.<sup>26</sup>

These harms represent aspects of life and human wholeness that either have little or no value in the marketplace or that society feels most uncomfortable about commodifying by assigning a market value. How much is a whole functioning womb worth? Should its value vary according to whether the woman wants to make a profit from it, as through a surrogacy contract, or whether the woman has not yet married or borne

---

25. See Lucinda M. Finley, *The Pharmaceutical Industry and Women's Reproductive Health*, in CORPORATE VICTIMIZATION OF WOMEN 59-60 (Elizabeth Szockyj & James G. Fox eds., 1996) [hereinafter Finley, *Pharmaceutical Industry*].

26. The drug DES has resulted in misshapen uteruses and cervixes, an increase in the rate of ectopic pregnancies, late miscarriages, and the inability to conceive among the daughters of women who took DES while pregnant. See *id.* at 61-77; see also DIANA B. DUTTON, *WORSE THAN THE DISEASE: PITFALLS OF MEDICAL PROGRESS* (1988); ROBERT MEYERS, *DES: THE BITTER PILL* 126-42 (1983). The Dalkon Shield and some other IUDs caused pelvic inflammatory disease which frequently led to permanent sterility or hysterectomy, and also caused septic abortions if a woman became pregnant while the device was still inserted. See e.g., NICOLE GRANT, *THE SELLING OF CONTRACEPTION: THE DALKON SHIELD CASE, SEXUALITY, AND WOMEN'S AUTONOMY* 37-69 (1992); KAREN M. HICKS, *SURVIVING THE DALKON SHIELD IUD: WOMEN V. THE PHARMACEUTICAL INDUSTRY* 27-33 (1994). Hormone based contraceptives like Depo-Provera and Norplant can cause wild aberrations in menstrual bleeding, ranging from persistent heavy bleeding to amenorrhea, along with nausea, headaches, dizziness, excessive weight gain, and fatigue. See e.g., LESLEY DOYAL, *WHAT MAKES WOMEN SICK* 112-14 (1995); PEGGY FOSTER, *WOMEN AND THE HEALTH CARE INDUSTRY* 19-23 (1995); BARBARA SEAMAN, *THE DOCTOR'S CASE AGAINST THE PILL* 245-50 (1995).

children,<sup>27</sup> or whether she is economically well-off or on public assistance? While some economists might well debate these questions with few qualms,<sup>28</sup> most people find such inquiries profoundly disturbing, distasteful, and inappropriately objectifying.<sup>29</sup> Moreover, efforts to translate these types of women's injuries into pecuniary loss terms reduce the value of the harm by only examining a scant portion of the ways that these injuries impair one's life. For example, the pecuniary loss associated with reproductive harm or infertility might include the cost of infertility treatment or adoption. However, these items of compensation do not capture the devastation to a woman's sense of self-worth from being "barren" or "damaged goods" in a society that still sees childbearing as a woman's highest calling. In addition, the pecuniary loss translation cannot easily comprehend the sometimes fatal anguish that can afflict the relationship between an infertile couple, or the irretrievable harm to the relationship caused by the way in which the infertile couple will have to time sex only according to thermometers and cycles instead of according to passion. Nor does the calculation of pecuniary loss acknowledge the slow little death that a woman struggling to overcome infertility can feel every time the period comes or the latest in vitro fertilization doesn't work. One woman who could not conceive because of damage caused by DES to her reproductive organs told me: "Just giving me the cost of adoption makes me feel like all this is about is being able to go out and buy a child." Despite these difficulties or discomfort that society confronts when commodifying precious aspects of human wholeness such as reproductive health, these nonpecuniary aspects of the injuries are just as real, profoundly life-altering, and worth redressing by tort law.

Another reason why nonpecuniary loss damages remain particularly important for women is that the pecuniary harm caused by many types of injuries that disproportionately affect women is not readily appreciated or is easily overlooked by lawyers, judges, and juries. For example, when a woman has to endure a sexually hostile environment at work, and suffers the accompanying elevated stress and erosion of dignity and self-esteem, her

---

27. See, e.g., *Hawkinson v. A.H. Robins*, 595 F. Supp. 1290 (D. Colo. 1984) (court awarded varying damages to women rendered infertile by Dalkon Shield based on factors such as marital status, number of children, and partial or total hysterectomy).

28. See, e.g., Elisabeth M. Landes & Richard A. Posner, *The Economics of the Baby Shortage*, 7 J. LEGAL STUD. 323 (1978); Richard A. Posner, *The Ethics and Economics of Enforcing Contracts of Surrogate Motherhood*, 5 J. CONTEMP. HEALTH L. & POL'Y 21 (1989); Richard A. Posner, *The Regulation of the Market in Adoptions*, 67 B.U. L. REV. 59 (1987).

29. See, e.g., VIVIANA A. ZELIZER, *MORALS AND MARKETS: THE DEVELOPMENT OF LIFE INSURANCE IN THE UNITED STATES* 61-65 (1979); Croley & Hanson, *supra* note 14, at 1872-85; Radin, *Market-Inalienability*, *supra* note 19, at 1870-74; ZELIZER, *PRICING THE PRICELESS*, *supra* note 22, at 138-68.

productivity, work performance, career aspirations, and promotion or relocation prospects will all be adversely effected. These effects in turn diminish her earning capacity. Yet until Title VII was expanded in the 1991 Civil Rights Act<sup>30</sup> to include nonpecuniary loss damages, many courts awarded little or no monetary damages to female plaintiffs despite finding that they had been victimized by an illegal sexually hostile environment.<sup>31</sup>

Sexual assault or abuse can similarly impair a woman's earning potential by eviscerating her self-esteem, which can lead to reduced career aspirations and success. Yet, in sexual battery cases, women are rarely awarded lost earning damages, even in the few instances where a lawyer has tried to prove such loss with expert testimony.<sup>32</sup> Reproductive system harm can also impact earning potential in unanticipated ways. One woman with severe bladder and reproductive system harm from her DES-caused cancer and resulting radiation treatment recounted to me about her embarrassment at having frequently to empty her catheter. Her embarrassment caused her to shun promotions that would require client contact and travel, to the detriment of her career progress and earnings. However, her attorneys proceeded on the assumption that her harm other than her medical costs was primarily nonpecuniary and had never even discussed with her whether she had any lost income damages.

Similarly, in a case involving a woman who suffered severe breast disfigurement from a botched breast reduction surgery, the court described how her injuries made her avoid human contact and kept her largely housebound, which obviously would impair earning capacity.<sup>33</sup> Yet both the court and the American Law Institute characterized her loss as nonpecuniary, and the appellate court reduced as excessive the damages awarded by the jury.<sup>34</sup>

When a woman experiences reproductive loss, infertility, sexual harassment, or assault, mental health therapy is often necessary. Mental health services could be compensated as pecuniary loss damages for future medical expenses, however, this item of pecuniary loss is also frequently ignored.<sup>35</sup>

---

30. 42 U.S.C. § 1981a (1994).

31. See, e.g., Civil Rights and Women's Equity in Employment Act of 1991, H.R. REP. NO. 102-40, pt. 1, at 64-69 (1991); NATIONAL WOMEN'S LAW CENTER, TITLE VII'S FAILED PROMISE: THE IMPACT OF A LACK OF A DAMAGES REMEDY (1991) (collecting cases) reprinted in part in H.R. REP. NO. 102-40, pt. 2, at 25-27 (1991).

32. See Bruce Feldthusen, *Discriminatory Damage Quantification in Civil Actions for Sexual Battery*, 44 U. TORONTO L.J. 133, 137-38 (1994).

33. See *Baez v. Dombroff*, 530 N.Y.S.2d 847, 848 (App. Div. 1988).

34. *Id.*; see also *Enterprise Responsibility*, *supra* note 11, at 202 n.9.

35. See Feldthusen, *supra* note 32, at 136-37.

This tendency in tort law to overlook or diminish a woman's pecuniary loss is connected to the fact that the injuries from reproductive loss, sexual harassment or assault seem more emotional than physical. Unlike an external physical injury that can be seen, such as a broken limb, the physical effects of stress and anxiety or the malformed reproductive organs are not visually tangible. Thus, their effects are often attributed to a woman's emotional complexion or fortitude, or to her personal choices about education, career, or partner. In addition, the effects on earnings are not as linear and temporally direct as when a more tangible physical injury or disease physically disables a person from working or forces her to take a reduced job. The adverse effects on earnings potential from women's sexualized injuries may accrue slowly, almost imperceptibly over time, from the way a woman shrinks back or fails to seek certain assignments or a slow accumulation of too many stress induced absences. This behavior makes it easy to perceive that a woman's inherent personality is the cause for any reduction in earnings potential, rather than understanding the reduction as directly and logically connected to the sexualized harm and its attendant alteration of the woman's sense of self and security.

Additionally, some types of women's injuries more frequently are medically regarded as emotional in nature and thus compensated, if at all, through nonpecuniary loss damages. There is a well documented tendency of the medical profession to dismiss or trivialize women's complaints of physical illness or pain and attribute women's ailments to psychological factors.<sup>36</sup> This tendency is especially pronounced for "female trouble" injuries to women's reproductive systems, such as those associated with heavily gendered products like contraceptives or drugs taken in connection with pregnancy.<sup>37</sup> The medical profession has historically viewed women's reproductive systems as deviant, or abnormal because they differ from the norm of male bodies.<sup>38</sup> Women's reproductive health has been poorly understood.<sup>39</sup> Physicians fail to listen to women's reports about what is happening to their bodies and do not respect these accounts as a valuable source of knowledge.<sup>40</sup>

---

36. See, e.g., GENA COREA, *THE HIDDEN MALPRACTICE: HOW AMERICAN MEDICINE MISTREATS WOMEN* 79-89 (1985); EILEEN NECHAS & DENISE FOLEY, *UNEQUAL TREATMENT: WHAT YOU DON'T KNOW ABOUT HOW WOMEN ARE MISTREATED BY THE MEDICAL COMMUNITY* 123-39 (1994); DIANA SCULLY, *MEN WHO CONTROL WOMEN'S HEALTH: THE MISEDUCATION OF OBSTETRICIAN-GYNECOLOGISTS* 91-101 (1980); ALEXANDRA D. TODD, *INTIMATE ADVERSARIES: CULTURAL CONFLICT BETWEEN DOCTORS AND WOMEN PATIENTS* 28-36 (1989) [hereinafter TODD, *INTIMATE*].

37. COREA, *supra* note 36, at 77-78.

38. TODD, *INTIMATE*, *supra* note 36, at 28-29.

39. COREA, *supra* note 36, at 232.

40. TODD, *INTIMATE*, *supra* note 36, at 33.

These attitudes or gaps in medical knowledge have led to an ironic double bind for women. On the one hand, the medical field has labeled normal female bodily processes, such as menstruation, menopause, or pregnancy, as disease conditions that disable or require medical management.<sup>41</sup> On the other hand, physicians either disregard women's reports of what they know to be aberrations from the normal functioning of their bodies or attribute the complaints to emotional problems. Thus, women reporting severe cramping, excessive bleeding, nausea, weight gain, or dizziness from contraceptives are told that they are exaggerating, being hysterical, it is "nothing," "all in their head," or just a normal "side effect" that should be tolerated.<sup>42</sup> Numerous women suffering from excruciating pain, infections, disabling cramping, and profuse bleeding from the Dalkon Shield IUD were told by their doctors that they were suffering from neuroses, rather than a serious and very real physical problem that portended dangers associated with the IUD.<sup>43</sup> According to one DES daughter whom I interviewed, every time she tried to talk to physicians about the implications of her DES exposure for her present and future health and fertility of her malformed reproductive system, she was told that she should see a psychiatrist for these matters. Since she had not yet tried to get married or have children, her physical deformities were not really considered to be a physical injury. Similarly, other DES daughters have described to me how their efforts to deal with and seek treatment for their infertility have been deemed largely within the purview of psychiatrists. Women with breast implants have described similar struggles to get their health complaints taken seriously and not to be dismissed as hysterical women with emotional adjustment problems.<sup>44</sup>

---

41. See, e.g., EMILY MARTIN, *THE WOMAN IN THE BODY* (1987) (a study of the history and ideology of technological medical intervention in women's reproductive processes); see also Susan E. Bell, *Changing Ideas: The Medicalization of Menopause*, 24 *SOC. SCI. & MED.* 535, 536 (1987); Alexandra D. Todd, *Women's Bodies as Diseased and Deviant*, 5 *RES. IN L., DEVIANCE & SOC. CONTROL* 83, 83-95 (1983).

42. See, e.g., FOSTER, *supra* note 26, at 18, 21; Joyce McConnell, *For Women's Health: Uncoupling Health Care Reform from Tort Reform*, in *MAN-MADE MEDICINE: WOMEN'S HEALTH, PUBLIC POLICY, AND REFORM* 99, 113 (Kary L. Mossed., 1996); Finley, *Pharmaceutical Industry*, *supra* note 25, at 80.

43. See, e.g., GRANT, *supra* note 26, at 130-31; HICKS, *supra* note 26, at 17, 27-33; MORTON MINTZ, *AT ANY COST: CORPORATE GREED, WOMEN, AND THE DALCON SHIELD* 13, 107 (1985); Finley, *Pharmaceutical Industry*, *supra* note 25, at 80.

44. See, e.g., SUSAN ZIMMERMAN, *THE MEDICAL MANAGEMENT OF FEMININITY: WOMEN'S EXPERIENCES WITH SILICONE BREAST IMPLANTS* 128-29, 141-47 (forthcoming publication, Temple Univ. Press 1997); MARSHA L. VANDERFORD & DAVID H. SMITH, *THE SILICONE BREAST IMPLANT STORY: COMMUNICATION AND UNCERTAINTY* 32-48 (1996). This tendency to attribute reports of physical symptoms by women with breast implants to their emotional problems rather than to an illness is particularly ironic in the case of breast implants, since the American Society of Plastic Surgeons had categorized small breasts as a

If medicine is more likely to regard women's physical problems as emotional, then tort law will also tend to see some types of women's injuries as either emotional in origin or impact. Thus, if the tort system recognizes harm to a woman's reproductive system or sexualized part of her body, like the breasts, it is more likely to classify the injury as an emotional injury and compensate the harm with nonpecuniary loss damages.

Historically, women have been over represented as plaintiffs in emotional harm cases.<sup>45</sup> Claims for very real physical reproductive harms, such as miscarriages, were often classified as emotional distress "fright" claims.<sup>46</sup> This tendency of the law to view reproductive system damage as purely emotional in nature is not just a nineteenth century relic. For example, in the contemporary case of *Payton v. Abbott Labs*,<sup>47</sup> in which a class of women sought compensation for a variety of injuries caused by the drug DES, the court held that the plaintiffs could not seek damages for their "purely emotional" harm because they had no accompanying physical injury.<sup>48</sup> The court ruled in this manner despite the fact that many DES daughters have malformations of their cervixes and uteruses, as well as cellular changes to the vaginal and cervical lining. Moreover, gynecologists recommend as a practice that women exposed to DES undergo regular medical monitoring and far more extensive internal exams than non-exposed women.<sup>49</sup> Similarly, courts have characterized physical deformities resulting from breast reduction or enlargement surgery gone awry as claims for emotional or nonpecuniary harm.<sup>50</sup>

---

disease requiring medical treatment. Kerith Cohen, *Truth & Beauty. Deception & Disfigurement: A Feminist Analysis of Breast Implant Litigation*, 1 WM. & MARY J. WOMEN & L. 149, 169 (1994).

45. Chamallas & Kerber, *supra* note 15, at 847; Hubert W. Smith, *Relation of Emotions to Injury and Disease: Legal Liability for Psychic Stimuli*, 30 VA. L. REV. 193 (1944). After noting that women were the principal plaintiffs in emotional distress cases, Dr. Smith dismissed women's reactions as "abnormal." Chamallas & Kerber, *supra* note 15, at 847.

46. *Id.* at 824-34.

47. 437 N.E.2d 171 (Mass. 1982).

48. *Id.* at 181.

49. *Id.* at 192. The dissent emphasized these facts in arguing that the emotional distress claim should be recognized. However, even the dissenting justices apparently accepted the underlying demarcation of the impact on plaintiffs as emotional rather than physical. *Id.* at 192-94 (Wilkins, J., dissenting).

50. See, e.g., *Baez v. Dombroff*, 530 N.Y.S.2d 847 (App. Div. 1988); discussion *supra* text accompanying notes 35-36. In breast implant litigation, defendants' settlement offers and juries' verdicts often are based more on the lifestyle and emotional make-up of the plaintiff than on the nature or degree of her physical problems. See, e.g., Mark Curriden, *Courthouse Lottery: Implant Verdicts Often Depend on Victims' Affability*, DALLAS MORNING NEWS, Jan. 22, 1997, at 1D.

The ultimate assumption or value judgment fueling the assault on nonpecuniary loss damages—that the market is the appropriate measurement of loss and the monetizable aspects of our lives are the most important and deserving of compensation—is especially problematic for women. The market is hardly objective, fair, or the only method to measure human value, productive or reproductive capacity, and loss. Women have been particularly disadvantaged in the market. Therefore, tort reforms that prefer market-based loss evaluations entrench and perpetuate the bias in the market.

The disparate impact of market-based damage measurement is derived from two principal sources: 1) the generally lower value the market assigns to women's work and to women wage earners and 2) the market's failure to recognize or value many productive activities in which women engage when those activities, such as household management and caretaking, are performed in the private realm.<sup>51</sup> Damages for past lost income simply replicate the unequal wage rates of the market, and thus make assessments about the relative worth of human lives that many people would find distasteful. As Professor Chamallas has noted, earnings-based damages calculations "signal[] that white men are worth more, and reinforce[] beliefs that they will achieve more than white women or minority men and women."<sup>52</sup>

Courts often calculate damages for projected future income or lost earning capacity by using gender and race based earnings tables. These tables lock tort damages into the assumptions that past inequities will continue unabated in the future, and that no woman or person of color will ever break out of stereotypical patterns for her gender or race.<sup>53</sup> In addition, courts frequently discount projections of women's future earning capacity by incorporating gender-biased assumptions about the effect of marriage and childbearing on women's work force participation, advancement, and earnings.<sup>54</sup>

Pecuniary loss calculations usually fail to recognize or assess adequately the productive economic value of women's household and caretaking

---

51. See, e.g., Cassels, *supra* note 18, at 445-48 (discussing gender bias in the award of personal injury damages to women); Chamallas, *supra* note 18, at 75, 81-82; Finley, *A Break in Silence*, *supra* note 16, at 51-54; see also Nancy C. Staudt, *Taxing Housework*, 84 GEO. L.J. 1571 (1996) (examining how the Federal Income Tax Code treats household labor).

52. Chamallas, *supra* note 18, at 77.

53. *Id.* at 79-84. In this article, Prof. Chamallas documents the use of race and gender based earnings tables and argues that for a court to base a decision on such evidence amounts to unconstitutional state action in violation of the Equal Protection Clause. *Id.* at 104-11. A few courts have recently questioned the appropriateness of using race and gender-based earnings tables to calculate damages. See *Wheeler Tarpeh-Doe v. United States*, 771 F. Supp. 427, 455 (D.D.C. 1991), *rev'd on other grounds*, 28 F.3d 120 (D.C. Cir. 1994); *Reilly v. United States*, 665 F. Supp. 976, 991-92 (D.R.I. 1987), *aff'd in pertinent part*, 863 F.2d 149 (1st Cir. 1988); see also Chamallas, *supra* note 18, at 98-100.

54. See Cassels, *supra* note 18, at 81-82; Chamallas, *supra* note 18, at 453-65.



activities. For example, if a woman wage earner is injured, the calculation of pecuniary loss damages rarely includes the lost value of her ability to clean and manage the home or to care for family members, despite the productiveness and economic importance of these services.<sup>55</sup> Similarly, if a family member requires extensive caretaking services, that person will be able to recover something for the market value of such services. However, if another family member, more often a female, leaves or curtails her job to provide this care, neither she nor the injured person will be able to recover the caretaker's lost market income, even though the economic unit of which the injured person is a part has undoubtedly suffered a pecuniary loss.<sup>56</sup> Even when courts do acknowledge the economic value of household services, as they are now likely to do when calculating pecuniary loss damages for the wrongful death or disability of a homemaker,<sup>57</sup> the market assigns much lower values to these activities than their true social importance or value, precisely because they are "women's work." Wage rates for home health care aides, child care workers, cooks, food servers and dishwashers, and household or "domestic" cleaners, hover near the bottom of the economic scale.

As a result of the interaction of market bias against women and the depressed valuation of women's work, women's roles and activities are undercompensated or undervalued by the pecuniary loss category of damages. Several empirical studies and evaluations of case reports have demonstrated that women's tort recoveries, particularly for pecuniary loss, are on average well below recoveries for men.<sup>58</sup> These studies magnify the importance of the nonpecuniary loss category of damages for women. Women tend to receive larger nonpecuniary awards, especially in cases of gendered injuries<sup>59</sup> and, thus, nonpecuniary loss damages can help to

---

55. See, e.g., Cassels, *supra* note 18, at 460-65; Finley, *A Break in Silence*, *supra* note 16, at 48-51, 52-54. Under loss of consortium claims, one spouse is able to recover something for loss of the value of household services when the other spouse is injured, yet loss of consortium is usually considered a type of nonpecuniary loss. The loss of consortium claim does nothing to recognize the loss to the injured spouse or parent of the ability to provide services. *Id.* at 53.

56. See Cassels, *supra* note 18, at 469-71; Finley, *A Break in Silence*, *supra* note 16, at 53.

57. For a discussion of the evolution of courts' evaluations of the value of homemakers, see Finley, *A Break in Silence*, *supra* note 16, at 52-54.

58. For a summary of the findings of gender bias in the courts on this point, and similar studies, see Chamallas, *supra* note 18, at 84-89; see also Cassels, *supra* note 18, at 456-57; Elaine Gibson, *The Gendered Wage Dilemma in Personal Injury Damages*, in *TORT THEORY* 185 (Ken Cooper-Stephenson & Elaine Gibson eds., 1993) (examining gender bias in the methodology of damage assessments); Jane Goodman et al., *Money, Sex, and Death: Gender Bias in Wrongful Death Damage Awards*, 25 *L. & SOC'Y REV.* 263 (1991).

59. See Koenig & Rustad, *supra* note 4, at 80-87; David W. Leebron, *Final Moments: Damages for Pain and Suffering Prior to Death*, 64 *N.Y.U. L. REV.* 256, 306

equalize or reduce disparities between men's and women's recoveries. Nonpecuniary loss damages are also crucial in compensating women for the gender-specific types of harm that they disproportionately suffer.

Because nonpecuniary loss damages take on magnified importance for women, legislative efforts to curtail these damages or to make them harder to recover disparately affect women. The various legislative limitations on nonpecuniary loss exacerbate the preferred position of wage-based pecuniary loss damages and, therefore, serve to entrench the gender and race-based disparities of the market in damages law. Limitations on nonpecuniary loss damages also undermine the prevention function of tort law. These limitations artificially deflate the potential value of women's sexualized and reproductive harms, signaling that these types of injuries can never be worth more than the arbitrary amount plucked out of the air by the legislature. These artificially capped valuations reduce women's and lawyers' ability to use tort law as a means for placing a higher social worth on women's bodily integrity and sexual or reproductive wholeness. Limitations on recoveries for nonpecuniary harm also reduce the incentive for lawyers to pursue claims for gendered nonpecuniary injuries, particularly when the claims may involve complex medical issues that are expensive to develop and try. This disincentive, in turn, increases the likelihood that even fewer injured women will be able to find representation and, therefore, a larger proportion of the harm caused by an activity or product may go unrecognized. For example, a lawyer who has represented women injured by the drug DES, as well as clients injured by the Dalkon Shield IUD and other medical products, discussed with me the potential effect of capped nonpecuniary loss damages. She admitted that she and her clients probably would not have been able to afford to undertake some of her key legal efforts to get juries to return high damages verdicts for the injury of loss of fertility, ectopic pregnancy, or pregnancy loss if her cases had been subject to a state law that capped nonpecuniary loss damages.<sup>60</sup>

---

(1989) (discussing statistical regression analyses which show that being "male" had a negative effect on the amount of pain and suffering damages).

60. In the early years of DES litigation, only one case of infertility, unaccompanied by cancer, was litigated all the way to a jury verdict. Interview with Andrea Goldstein, in Buffalo, N.Y. (1989). The low \$50,000 damages assessment of that jury had been used subsequently by some attorneys in settlement negotiations as a bellwether figure for assessing the value of infertility. *Id.* New York attorney Sybil Shainwald, who specializes in women's health issues, stated that, in her opinion, infertility is a much more serious injury with devastating life consequences for a woman than was reflected in the amounts defendants were offering in settlement based on this one verdict. Interview with Sybil Shainwald, in New York, N.Y. (Jan. 1997). Consequently, in 1994, she pursued a bifurcated trial on behalf of eleven women injured by DES, where she presented the damages phase first. *Id.* The jury returned damages ranging from \$125,000 to \$12,000,000 for women with reproductive tract malformations or infertility. *Id.* This bifurcated procedure was affirmed on appeal. In re New York County DES Litigation, 621 N.Y.S.2d 332 (App. Div. 1995). This verdict

Caps or other limitations on recovery for nonpecuniary loss also send a message to potential injurers, such as pharmaceutical manufacturers or sexually abusive medical providers, that women's injuries will continue to be low value injuries, so that they do not have to make as great an effort to prevent them. For example, consider a contraceptive drug such as Norplant, which can cause severe menstrual disruption, dizziness, nausea, weight gain, and fatigue. If the manufacturer knows that these effects will be regarded as "lifestyle" or "emotional adjustment" problems and will be compensated, if at all, as nonpecuniary loss, that manufacturer may decide that paying a few low value tort claims is an easier course of action than investing money to research the level of hormone reduction required to maintain effectiveness with the fewest harmful side effects.

The above observations directly apply to outright caps on nonpecuniary loss damages. While many states have enacted this direct form of limitation,<sup>61</sup> and the new Republican-led House of Representatives passed a measure in 1995 that limited nonpecuniary loss damages in health care liability cases,<sup>62</sup> Congress in recent years has also attempted other less obvious ways of limiting the value of nonpecuniary loss.<sup>63</sup> One proposal limited punitive damages to the greater of three times the economic loss or \$250,000; nonpecuniary loss would not be included in calculating punitive damages.<sup>64</sup> Due largely to opposition from consumer groups and women's health advocates who pointed out the adverse implications of this proposal for women,<sup>65</sup> the bill that emerged from Congress in 1996 ameliorated this proposal to permit punitive damages to be calculated as a multiplier of both pecuniary and nonpecuniary loss.<sup>66</sup> Both houses of Congress also approved a provision that eliminates joint liability for nonpecuniary loss, while retaining the usual tort rule of joint and several liability for economic loss.<sup>67</sup>

These proposals attacking nonpecuniary loss damages have negative implications for women, although varying in impact. Any limitation that

---

resulted in substantial increases in the settlement amounts received by women injured from DES exposure.

61. See *supra* note 4 and accompanying text.

62. H.R. 956, 104th Cong. § 201 (1996).

63. There are various reasons why direct caps on nonpecuniary loss have been politically unpalatable at the federal level, compared to the state level, including: a more open federal hearing process; more input from consumer and women's health groups; and the White House.

64. H.R. 956, 104th Cong. § 201(b) (1996).

65. See, e.g., *Hearings on S. 565, supra* note 8, at 164 (statement of U.S. Rep. Patsy Mink); *id.* at 131 (statement of Prof. Lucinda M. Finley).

66. See H.R. CONF. REP. NO. 104-481, at 10 (1995) (limiting punitive damages to the greater of twice the total sum awarded "for economic loss and noneconomic loss" or \$250,000).

67. *Id.* at 12.

focuses on health care liability will disproportionately affect women simply because, overall, women consume more health care services than men and women comprise the majority of malpractice plaintiffs.<sup>68</sup>

Women have more interactions with the health care system throughout their lives because many normal healthy aspects of being female, such as pregnancy, the avoidance of pregnancy, childbirth, and menopause, have become medicalized conditions that require visits to health care providers. Women are also more likely to experience malpractice because of the unfortunate history of gender discrimination in medicine. This discrimination has included: abuse of and disrespect for women patients; the tendency of physicians to ignore or diminish the import of what women patients report; and the fact that notions of appropriate treatment, drug efficacy and dosage were developed on the basis of research and clinical trials that excluded women.<sup>69</sup>

Damage caps on medical malpractice recoveries will also fall most heavily on the gendered injury categories of sexual assault, reproductive harm, and cosmetic injuries. These injuries are compensated primarily through nonpecuniary loss damages, affect women almost exclusively, and make up a disproportionate number of malpractice cases brought by women.<sup>70</sup>

Proposals that would link punitive damages only to economic loss, thereby excluding nonpecuniary loss from the calculation, are particularly problematic from the perspective of gender equity. Indeed, any such formula will only exacerbate the devaluation of women's injuries that already occurs in the tort system.<sup>71</sup> If only the economic loss component of damages counts towards assessing punitive damages, then higher wage earners injured primarily in ways that affect their earning capacity will be able to recover significant punitive damages, without regard to the gravity of the defendant's conduct or the overall health impact of their actions on

---

68. See, e.g. Joyce McConnell, *For Women's Health: Uncoupling Health Care Reform from Tort Reform*, in MAN-MADE MEDICINE 99, 110 (K. Moss ed., 1996); Koenig & Rustad, *supra* note 4, at 58

69. See, e.g. EILEEN NECHAS & DENISE FOLEY, UNEQUAL TREATMENT: WHAT YOU DON'T KNOW ABOUT HOW WOMEN ARE MISTREATED BY THE MEDICAL COMMUNITY 13-37 (1994); see generally SUE ROSSER, WOMEN'S HEALTH: MISSING FROM U.S. MEDICINE (1994); JOHN M. SMITH, WOMEN AND DOCTORS (1992); THE COMMONWEALTH FUND SURVEY OF WOMEN'S HEALTH (1993) (documenting inadequate health care for women, lack of basic preventive care, women's dissatisfaction with their health care and treatment they receive from health care providers); Vanessa Merton, *The Exclusion of Pregnant, Pregnable, and Once-Pregnable People (AKA Women) from Biomedical Research*, 19 AM. J.L. & MED. 369, 369-73 (1993).

70. See Koenig & Rustad, *supra* note 4, at 61-70.

71. See *Hearings on S. 565*, *supra* note 8, 311-31 (statement of Prof. Lucinda M. Finley).

large numbers of people.<sup>72</sup> Those who are injured primarily in nonpecuniary ways, such as women who have suffered reproductive or sexual injuries, will rarely be able to recover more than the amount of the cap, no matter how egregious the defendant's disregard of health and safety.<sup>73</sup>

An examination of the types of injuries for which punitive damages have been awarded to women in products liability and medical malpractice cases demonstrates that the cap would primarily serve to devalue women's reproductive and sexual well-being. Punitive damage awards have clustered around contraceptive and cosmetic products, including: IUDs; breast implants; sexual assault by health care providers; unnecessary reproductive surgery, such as hysterectomies, performed on women without their consent; grossly deficient cosmetic surgery; and abuse or neglect of elderly women in nursing homes.<sup>74</sup> The incentives to take women's sexual and reproductive health more seriously will be seriously undermined if a potential injurer knows that the punitive damages for these nonpecuniary injuries will rarely exceed a readily manageable amount such as \$250,000.

For example, A.H. Robins continued to market the Dalkon Shield IUD, despite mounting reports of pelvic inflammatory disease, perforated uteruses, infertility, septic abortions, and internal corporate reports acknowledging that the infection causing propensity of the product could be greatly reduced for a cost of a few cents per device.<sup>75</sup> Indeed, until juries started awarding large punitive damages judgments in Dalkon Shield litigation, A.H. Robbins continued to market, promote, and defend the device.<sup>76</sup> A.H. Robbins did not urge physicians and women to remove the Dalkon Shields, until the company was assessed punitive damage awards in excess of one million dollars in cases that otherwise had low compensatory damages that averaged \$11,000 to \$40,000.<sup>77</sup> In the several years preceding the large punitive damages verdicts, while the company stonewalled and managed to survive the low-level compensatory awards, several hundred thousand women remained exposed to danger and tens of thousands suffered damage to their reproductive systems. Yet, if caps on punitive damages are enacted, especially caps based solely on economic loss, companies like A.H. Robbins might decide they can financially ride out the cost of litigation without improving or withdrawing a product that destroys women's reproductive health.

---

72. *Id.* at 320.

73. *Id.*

74. See Koenig & Rustad, *supra* note 4, at 53, 61-77.

75. Finley, *Pharmaceutical Industry*, *supra* note 25, at 80-84.

76. See, *id.* at 86; see also MINTZ, *supra* note 43, at 250; RICHARD B. SOBOL, *BENDING THE LAW* 11 (1991).

77. SOBOL, *supra* note 76, at 14-17; Finley, *Pharmaceutical Industry*, *supra* note 25, at 86-87.

The proposal that actually passed both houses of Congress, § 110 of H.R. 956,<sup>78</sup> which eliminated joint liability for nonpecuniary loss damages, would have had a less drastic impact than the types of legislative enactments and proposals discussed above. This bill would have affected only those products liability cases with multiple tortfeasors. It did not cap nonpecuniary loss damages and, therefore, would not have overtly contributed to the devaluation of women's injuries.<sup>79</sup> This does not mean the proposal is entirely benign from a gender equity standpoint, however. Under a regime of joint and several liability, when an injured plaintiff cannot collect their full damages from all parties judged at fault for causing an indivisible injury, the plaintiff can look to one of the wrongdoers for payment in full.<sup>80</sup> Thus, joint and several liability operates to insulate a wrongfully injured person from the risk of non-recovery and to place that risk instead on a solvent and jurisdictionally available wrongdoer.<sup>81</sup> By removing joint liability, people with nonpecuniary loss injuries will find it more difficult to collect their full damages, while those with economic loss damages will not bear a similar burden.<sup>82</sup> Thus, the proposal fundamentally favors economic loss over nonpecuniary loss and, consequently, raises all the gender-bias problems of market-referencing previously discussed. To the extent that the category of people with nonpecuniary loss injuries includes women, then the risk of non-collection will be shifted disproportionately onto women.

## II. THE "FDA DEFENSE": CONDONING THE TENDENCY TO TRIVIALIZE RISKS TO WOMEN'S HEALTH

In addition to the attack on nonpecuniary loss damages, the "FDA defense" or the "regulatory compliance" defense is another focus of tort

---

78. H.R. 956, 104th Cong. § 110 (1995).

79. From colloquy and questioning at Congressional hearings at which I testified, it appears that some members of Congress supported this provision simply because it was the least unfair to women of the various proposals propounded to cut back nonpecuniary loss damages. According to my recollection, during one hearing I was asked by a Senator whether I would agree that this provision was less disadvantageous to women than an outright cap, as if that was all that needed to be established to prove that the proposal was sound social policy.

80. See, e.g., Komesar, *supra* note 17, at 68.

81. See, e.g., *id.*; see also Richard W. Wright, *Allocating Liability Among Multiple Responsible Causes: A Principled Defense of Joint and Several Liability for Actual Harm and Risk Exposure*, 21 U.C. DAVIS L. REV. 1141 (1988) (discussing the debate over the propriety of the joint and several liability rule).

82. See, e.g., Elizabeth Graddy, *Tort Reform and Manufacturer Payout—An Early Look at the California Experiences*, 16 LAW & POL'Y 49 (1994) (empirical study of impact of similar provision adopted by California; study shows that manufacturers are paying a lower proportion of plaintiff awards which means some injured plaintiffs are recovering less of their damage awards).

reform efforts that has particularly problematic implications for women. The pharmaceutical and medical device industries have been seeking protection from punitive damages for a drug or device which received pre-market approval from the Food and Drug Administration ("FDA").<sup>83</sup> Unable to obtain shelter from tort liability for drugs and devices that meet government approval criteria through the courts,<sup>84</sup> manufacturers have had to turn to the legislature. Traditionally, tort law has viewed government regulatory standards as a floor, not a ceiling for safety.<sup>85</sup> The basis for this traditional view, as summarized by one court, is:

The warnings required by such agencies may be only minimal in nature and when the manufacturer or supplier knows of, or has reason to know of, greater dangers not included in the warning, its duty to warn may not be fulfilled. Although the manufacturer or supplier of a prescription drug has a duty to adequately warn the medical profession of its dangerous properties or of facts which make it likely to be dangerous, an adequate warning to the profession may be ordered or even nullified by overpromotion of the drug through a vigorous sales program which may have the effect of persuading the prescribing doctor to disregard the warnings given.<sup>86</sup>

In addition, the traditional resistance to an FDA compliance defense recognizes that regulatory agencies are not perfect guarantors of public safety. Regulatory agencies can be hampered by inadequate information or insufficient testing provided by manufacturers and buffeted by political agendas, which include cutbacks in enforcement resources and pressure to act in a certain way.<sup>87</sup> They can sometimes respond too slowly to accumu-

---

83. See, e.g., S. 672, 104th Cong. §103(c) (1995); S. 687, 103d Cong. § 203(b) (1993); H.R. 1910, 103d Cong. § 6(d) (1993). Several states have enacted similar provisions, insulating manufactures of FDA-approved products from punitive damages. See ARIZ. REV. STAT. ANN. § 12-701(A) (1992); COLO. REV. STAT. § 13-21-403(1)(B) (1987); 735 ILL. COMP. ANN. STAT. 5/2-2107 (West 1996); N.J. STAT. ANN. § 58C-5(c) (West Supp. 1996); N.D. CENT. CODE § 32-03.2-11(6) (1996); OHIO REV. CODE ANN. § 2307.80(C) (1995); OR. REV. STAT. § 30.927 (1995); UTAH CODE ANN. § 78-18-2(1) (1996). Michigan and Indiana have enacted a complete government standards defense from liability if the product was approved by the FDA. IND. CODE ANN. § 33-1-1.5-4.5 (Michie Supp. 1996); MICH. COMP. LAWS ANN. § 600.2946(5) (West Supp. 1996).

84. See, e.g., *Medtronics, Inc. v. Lohr*, 116 S. Ct. 2240 (1996). In *Medtronics*, the U.S. Supreme Court ruled that the Medical Devices Amendments of 1976 to the Food and Drug Law, 21 U.S.C. § 360k(a) (1994), does not preempt state tort liability for claims premised on failure to warn and design defect. *Id.* at 2256-58.

85. See, e.g., *Stevens v. Parke Davis & Co.*, 507 P.2d 653, 661 (Cal. 1973).

86. *Id.* (citations omitted).

87. For example, the FDA's reluctance to classify nicotine as a drug, and thus to bring cigarettes under its purview, is a classic illustration of the agency's sensitivity to political factors. See generally HERBERT BURKHOLZ, *THE FDA FOLLIES* (1994) (arguing

lating post-approval information regarding product dangers.<sup>88</sup> Furthermore, the FDA has a limited role in policing how manufacturers actually promote drugs and "off-label" uses. Congress has recognized in several oversight hearings that FDA regulation can sometimes be ineffective in preventing seriously defective and dangerous drugs and devices from being approved or remaining on the market.<sup>89</sup> A 1990 Report by the General Accounting Office ("GAO") found that of 198 drugs approved by the FDA between 1976 and 1985, 102 of them, or fifty-one percent, wound up presenting serious health risks that came to light post-approval, as evidenced by labeling changes or market withdrawals.<sup>90</sup>

---

that the Reagan administration started budget cuts and other attacks on the FDA that have seriously eroded its regulatory effectiveness).

88. See Finley, *Pharmaceutical Industry*, *supra* note 25, at 83-85. For example, the FDA sat on mounting reports of deaths and sterilizing infections caused by the Dalkon Shield for three years, until pressure from Congress forced it to hold hearings and recommend withdrawal from the market. See *id.* Although recommending marketing cessation, the FDA did not recall existing stock nor did it require the manufacturer to warn doctors and women to have the IUD's removed. *Id.* at 84. It took another decade before the manufacturer warned about the need to have the deadly devices removed and, during this ten years of insufficient regulatory action, thousands of women were injured. See *id.* at 84-86; see also MINTZ, *supra* note 43, at 54-56, 125-27. The FDA was similarly dilatory with regard to the ineffective and deadly lactation suppressant drug Parlodel. After receiving numerous reports of women killed or disabled by strokes or heart failure caused by the drug, the FDA merely requested, but did not demand that the manufacturer, Sandoz, stop making the drug as a postpartum lactation suppressant. Sandoz continued to market the drug for this purpose while more women were injured. The FDA did not act to ban its use by postpartum women until the consumer group Public Citizen sued the agency. See, e.g., Rick Weiss, *Drug Will No Longer Be Sold to Stop Breast Milk*, WASH. POST, Aug. 23, 1994, at 27; David Olmos, *Sandoz to Stop Selling Parlodel as Treatment to Halt Lactation*, LOS ANGELES TIMES, Aug. 19, 1994, at D1.

89. See *FDA and the Medical Device Industry: Hearings Before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 102d Cong. 1 (1992); HOUSE COMM. ON GOVERNMENT OPERATIONS, DEFICIENCIES IN FDA'S REGULATION OF THE NEW DRUG "ORAFLEX", H.R. REP. NO. 98-511 (1983) (documenting how FDA backlogs and lack of resources led the agency to overlook evidence of serious and sometimes fatal adverse kidney and liver reactions to anti-arthritis drug in clinical trials resulting in the drug being withdrawn from market shortly after FDA approval); STAFF OF SUBCOMM. ON OVERSIGHT AND INVESTIGATIONS OF THE HOUSE COMM. ON ENERGY AND COMMERCE, 103D CONG., 1ST SESS., REPORT ON REFORMS NEEDED IN THE ORGANIZATION, MANAGEMENT AND RESOURCES OF THE FOOD AND DRUG ADMINISTRATION'S CENTER FOR DEVICES AND RADIOLOGICAL HEALTH III, 1-3 (Comm. Print 1993); STAFF OF SUBCOMM. ON OVERSIGHT AND INVESTIGATIONS OF THE HOUSE COMM. ON ENERGY AND COMMERCE, 101ST CONG., 2D SESS., REPORT ON SHILEY INC.'S BREACH OF THE HONOR SYSTEM AND FDA'S FAILURE IN MEDICAL DEVICE REGULATION 2-3 (Comm. Print 1990).

90. GENERAL ACCOUNTING OFFICE, FDA DRUG REVIEW: POSTAPPROVAL RISKS 1976-1985, GAO REP. GAO-PEMD-90-15 (1990).



An FDA-approval defense from punitive damages should be of particular concern to women. An unusually high number of the drugs and devices that have gone wrong and become alarming public health problems have been gender-specific products for use in women's bodies, usually in connection with sexuality and reproduction.<sup>91</sup> Many of these defective and unsafe drugs have been intended for use by healthy women to affect, interrupt, or enhance natural bodily processes or shape, rather than to treat an illness or disease.<sup>92</sup> The alarming list includes:

- DES, a synthetic estrogen marketed to prevent miscarriage which was ineffective for that purpose, elevated the risk of breast cancer among the exposed mothers by forty percent, and has caused cancer, reproductive tract abnormalities, and infertility in the exposed daughters and sons of the pregnant women who took it;<sup>93</sup>
- the early versions of birth control pills which had unduly high hormone levels that caused strokes, heart attacks, and blood clots;<sup>94</sup>
- IUD's, such as the Dalkon Shield and Copper-7, which presented an exceedingly elevated risk of pelvic inflammatory disease, sterility, perforated uteruses, and septic abortions;<sup>95</sup>
- Parlodel, a drug prescribed to suppress lactation, which has proved ineffective and has caused several deaths from strokes or heart attacks;<sup>96</sup>

---

91. See Koenig & Rustad, *supra* note 4, at 53 (documenting that most punitive damages judgments in pharmaceutical product cases have involved reproductive drugs and devices used in women's bodies).

92. See, e.g., Finley, *Pharmaceutical Industry*, *supra* note 25, at 59-60; Joan E. Steinman, *Women, Medical Care, and Mass Tort Litigation*, 68 CHI.-KENT L. REV. 409, 410-12 (1992).

93. DUTTON, *supra* note 26, at 6-7; MEYERS, *supra* note 26, at 93-162; see also Finley, *Pharmaceutical Industry*, *supra* note 25, at 70-72.

94. See, e.g., SEAMAN, *supra* note 26, at 72-103.

95. For the history of the Dalkon Shield and its dangers, see Finley, *Pharmaceutical Industry*, *supra* note 25, at 77-92; see also GRANT, *supra* note 26, at 68-69, 74-75; HICKS, *supra* note 26, at 1-2; MINTZ, *supra* note 43, at 25-26. While the Copper-7 IUD had a lower relative risk of pelvic inflammatory disease than the Dalkon Shield, it still had a higher risk than claimed by the manufacturer. See GRANT, *supra* note 26, at 89-90. After FDA approval, the manufacturer failed to follow up on mounting reports of infections in women using the device and engaged in an advertising campaign designed to belittle or assuage physicians' concerns. See *Kociemba v. G.D. Searle Co.*, 707 F. Supp. 1517, 1524 (D. Minn. 1989) (upholding jury's punitive damages verdict and summarizing evidence against company). Moreover, medical evidence revealed that this IUD was particularly inappropriate for use by sexually active young women who had never previously given birth (nulliparous women). *Id.* at 1524-25. Despite this knowledge, the manufacturer heavily promoted the device to precisely this class of women most at risk. *Id.* at 1525.

96. Lauran Neergaard, *FDA Sued Over Milk Inhibitor: 19 Deaths Connected*, LEGAL

- Ritodine, the only drug approved for the suppression of premature labor in pregnant women, which has been shown in post-marketing testing to be ineffective and to pose sometimes fatal health risks to women;<sup>97</sup> and
- silicone gel breast implants, which, despite raging controversy over whether they cause immune system diseases, incontrovertibly have exceedingly high rates of rupture and bleeding of the silicone gel through the envelope, and frequently cause the painful and disfiguring condition of capsular contracture or localized granulomas.<sup>98</sup>

This list is likely to grow. The two latest hormonal contraceptives, Depo-Provera and Norplant, have come under scrutiny for causing severe disruptions in the menstrual cycle, excessive weight gain, seriously heightened risks for diabetic women, nausea, dizziness, and fatigue.<sup>99</sup> There are also studies linking Depo-Provera to an increased risk of breast cancer, and Norplant users often have to undergo painful, prolonged, and risky surgery to have the rods removed when they migrate or become deeply imbedded in the arm.<sup>100</sup>

---

INTELLIGENCER, Aug. 17, 1994, at 9-10.

97. Gina Kolata, *Drug to Aid Birth is Found Ineffective and Risky*, N.Y. TIMES, July 30, 1992, at A1, A18.

98. See, e.g., JOHN A. BYRNE, INFORMED CONSENT 9-11, 17 (1996); ZIMMERMAN, *supra* note 44, at 121-24. Even Dr. Marcia Angell, who has become the leading critic of the science of breast implants and connective tissue diseases, acknowledges that they do cause localized health problems from rupture, leakage, and contracture. MARCIA ANGELL, SCIENCE ON TRIAL: THE CLASH OF MEDICAL EVIDENCE AND THE LAW IN THE BREAST IMPLANT CASE 40-41 (1996).

99. SEAMAN, *supra* note 26, at 244-45; Barbara A. Cromer et al., *A Prospective Study of Adolescents Who Choose Among Levonorgestrel Implant (Norplant), Medroxyprogesterone Acetate (Depo-Provera), or the Combined Oral Contraceptive Pill as Contraception*, 94 PEDIATRICS 687 (1994).

100. See, e.g., SEAMAN, *supra* note 26, at 239-52; WOMEN'S HEALTH ACTION FOUNDATION, NORPLANT: UNDER HER SKIN 56 (Barbara Mintzes et al. eds., 1993); Cromer et al., *supra* note 99, at 687-94. But see *Depo-Provera and Breast Cancer*, 5 REPRODUCTIVE HEALTH MATTERS 145 (1995). The media have tended to castigate lawyers bringing suits against Norplant as fueled by greed and as basing their claims on unproven science. See, e.g., Gina Kolata, *Will the Lawyers Kill Off Norplant*, N.Y. TIMES, May 28, 1995, §3, at 1. The controversy over Depo-Provera and breast cancer is far from resolved. The package insert provided by Upjohn states that "women under 35 years of age whose first exposure to Depo-Provera was within the previous 4 years may have a slightly increased risk of developing breast cancer similar to that seen with oral contraceptives." *Depo Provera and Breast Cancer*, REPRODUCTIVE HEALTH MATTERS, May, 1995, at 145. The FDA approved the drug on the basis of studies that showed that women taking it had a comparable risk of breast cancer as women taking other hormonal contraceptives; the studies did not compare women who were not taking hormones. See INSTITUTE OF MEDICINE, CONTRACEPTIVE RESEARCH AND DEVELOPMENT: LOOKING TO THE FUTURE 297 (Polly F. Harrison & Allan

It is not mere coincidence that a disproportionate number of these drugs and devices that have presented serious health risks have been developed for women's healthy bodies. The reasons include: the under representation of women in medical research; the relative paucity of attention to women's health problems; the fact that so many more drugs and devices are targeted at women's reproductive systems than men's; and the gender bias prevalent in medicine which results in a tendency to dismiss and trivialize health complaints by women. Ironically, while women's normal bodies, particularly their reproductive systems, have been "medicalized" as abnormal and in need of constant medical intervention, when these medical interventions turn out to disrupt normal bodily processes, these risks have been "normalized." Severe bleeding, cramping, pain, nausea and other bodily signals of something amiss have been labeled as normal risks, or inevitable side effects, rather than being regarded as health problems that warrant attention.<sup>101</sup> Signs of "female trouble" caused by reproductive drugs have been dismissed because of attitudes about women's presumed irresponsibility, stupidity, or hypersensitivity.

The attitude that "side effects" from contraceptives are women's cross to bear in the name of societal good has led to the trivialization of serious health risks for women. Efficacy—preventing births and controlling population—has been a more salient concern than safety.<sup>102</sup> The most chilling example of this attitude is illustrated in introductory remarks made by Dr. J. Robert Wilson at a 1962 international conference on IUD's, sponsored by the Population Council.<sup>103</sup> After acknowledging that IUDs cause infections and frequently require hysterectomies, this physician then said: "How serious is that for the particular patient and for the population of the world in general? Not very. . . . Perhaps the individual patient is expendable in the general scheme of things, particularly if the infection she acquires is sterilizing but not lethal."<sup>104</sup>

The FDA approved many of these dangerous drugs and devices, despite signs of health problems in women.<sup>105</sup> When punitive damages have been awarded or sought in litigation resulting from these products, the nonpecuniary damages have often resulted from post-marketing or post-FDA approval actions. Such actions have included: covering up evidence of risks; failing

---

Rosenfield eds., 1996) [hereinafter INSTITUTE OF MEDICINE, CONTRACEPTIVE RESEARCH].

101. See, e.g., GRANT, *supra* note 26, at 19-36; Cromer et al., *supra* note 99.

102. BETSY HARTMANN, REPRODUCTIVE RIGHTS AND WRONGS: THE GLOBAL POLITICS OF POPULATION CONTROL AND CONTRACEPTIVE CHOICE 4-5 (1987).

103. HICKS, *supra* note 26, at 19.

104. *Id.*

105. Of the drugs and devices listed above, see *supra* text accompanying notes 93-98, only the Dalkon Shield and silicone gel breast implants did not receive pre-marketing FDA approval. These devices were first marketed before the FDA was granted regulatory authority over medical devices in 1976. 21 U.S.C. § 360k (1994).

to take readily available inexpensive corrective action; failing to alert physicians and women to the mounting evidence of problems; engaging in misleading marketing and promotion campaigns; and failing to withdraw obviously ineffective and dangerous products from the market.<sup>106</sup> For example, after the drug DES was proven ineffective in preventing miscarriage in 1953, the drug companies continued to promote it for that purpose and expanded their efficacy claims to include the completely unproven assertion that DES would promote bigger healthier babies.<sup>107</sup> Thus, for almost two decades after the drug was proven ineffective, the manufacturers continued to expose hundreds of thousands of women and their offspring to needless risk. In addition, after the connection between DES and cancer was established, the FDA took no remedial action for months and the manufacturers continued to promote the drug without warning physicians about the cancer risk until the FDA finally ordered it off the market.<sup>108</sup>

With the lactation suppressant Parlodel, the manufacturer ignored the FDA's request to withdraw it from the market and continued to promote the drug to doctors despite proof that it could cause maternal death, disabling strokes, and heart attacks. Sandoz, the manufacturer, also persuaded hospitals to prescribe it automatically to all non-breast feeding postpartum patients, even though the company's warning literature acknowledged it was not safe for all women.<sup>109</sup> In response, the FDA took no stronger action than an appeal to the manufacturer's conscience, despite the FDA's awareness of the drug's deadly propensities.<sup>110</sup> In the case of breast implants, Dow Corning changed the thickness of the envelope and the viscosity of the gel to enhance market share, despite internal testing that showed these changes increased the propensity of the devices to rupture and bleed silicone gel into the body.<sup>111</sup> Manufacturers of super-absorbent tampons have been subject to punitive damages, because they ignored the compelling evidence of toxic shock syndrome, brushed off the medical reports of injured women, failed to engage in any further testing or product modification to make the devices safer, and failed to withdraw them from the market when it became clear the risk was simply too high.<sup>112</sup> A.H.

---

106. See Finley, *Pharmaceutical Industry*, *supra* note 25, at 65-68.

107. See *id.* at 66-67.

108. See *id.* at 66-68. While there has yet to be a punitive damages verdict in a DES case, frequently when plaintiffs' lawyers have pursued the case for punitive damages the result has been that the defendants have agreed to settle the case.

109. See Weiss, *supra* note 88; *Sandoz Pharm. Corp. v. Roberts*, Prod. Liab. Rep. (CCH) ¶ 14,765, 1996 LEXIS 126 (Ky. Ct. App. 1996).

110. See Weiss, *supra* note 88.

111. See, e.g., BYRNE, *supra* note 98, at 72-77; see also *Hopkins v. Dow Corning Corp.*, 33 F.3d 1116, 1119, 1127 (9th Cir. 1994).

112. See, e.g., *O'Gilvie v. International Playtex, Inc.*, 821 F.2d 1438, 1446 (10th Cir. 1987); *West v. Johnson & Johnson Prod.*, 220 Cal. Rptr. 437, 447-48 (Cal. Ct. App. 1985).

Robins's post-marketing behavior with regard to the Dalkon Shield enraged juries and resulted in punitive damages verdicts.<sup>113</sup> A.H. Robin's egregious behavior included: ignoring its own product safety staff who recommended an inexpensive change to the tail string that would have greatly reduced its tendency to "wick" bacteria into the uterus; stonewalling and lying to doctors and the public about the product's dangers for over a decade; engaging in an active campaign to disparage those who did try to bring out evidence of the harms; and steadfastly refusing to order recalls or recommend removal for over a decade despite a mounting toll to the reproductive health, and in some cases life, of numerous women.<sup>114</sup>

An "FDA defense" would preclude punitive damages in situations such as these where the manufacturer demonstrates blatant post-marketing behavior amounting to flagrant indifference to women's health. While not all of the products discussed above were approved by the FDA, the FDA did approve DES, the Copper-7 IUD, and Parlodel. In addition, the FDA made the Dalkon Shield and breast implants subject to its authority after their initial marketing. Each of these situations easily could be repeated in the future, so long as marketing considerations sometimes outweigh health concerns and signs of trouble in women's bodies continue to be ignored or diminished. Thus, it is important to consider some of the unappreciated salutary effects of punitive damages, such as improving women's health and stimulating regulatory action or beneficial research.

One of the positive effects of punitive damages on women's health is that punitive damages have often been the factor that finally convinces a recalcitrant company to take corrective action. Until it faced punitive damages, A. H. Robins had determined that it could weather the Dalkon Shield litigation and could avoid ordering a recall of the product.<sup>115</sup> It was not until corporate executives realized that juries reacted adversely to the company's decision not to order removal of existing Shields, despite the overwhelming evidence of dangers to women of continuing to use them, that A.H. Robins finally wrote to physicians and advertised to women advising and offering to pay for removal.<sup>116</sup> This step, which should have been taken ten years earlier, finally put an end to the carnage the Dalkon Shield caused to U.S. women.<sup>117</sup> The growing threat of lawsuits seeking punitive damages was also instrumental in eventually prompting Sandoz to cease marketing Parlodel as a lactation suppressant five years after the FDA had first requested that it take this action.<sup>118</sup> Similarly, punitive damages

---

113. See, e.g., MINTZ, *supra* note 43, at 17.

114. See, e.g., SOBOL, *supra* note 76, at 7-22; see also MINTZ, *supra* note 43, at 17.

115. See SOBOL, *supra* note 76, at 11-22.

116. *Id.* at 22.

117. The company did continue to market Dalkon Shields in other countries, where it did not face the risk of punitive damages. See HICKS, *supra* note 26, at 38-47.

118. See, e.g., Weiss, *supra* note 88; Sandoz Pharm. Corp. v. Roberts, Prod. Liab. Rep.

brought a demise to the deadly marketing adventure of super-absorbent tampons.<sup>119</sup>

In the tort reform debate, some pharmaceutical representatives have turned this argument around and contended that punitive damages have driven perfectly safe, beneficial products off the market. For example, an attorney for G.D. Searle Co., the manufacturer of the Copper-7 IUD, testified before the U.S. Senate that the first punitive damages verdict against this device, and the consequent withdrawal of coverage by the insurance carrier, led to the demise of this IUD.<sup>120</sup> While it may well be true that this drastically changed the financial picture facing the Copper-7 and contributed to the decision to withdraw it, the punitive damages verdict was based on compelling evidence that the company had ignored and covered up evidence of risks, as well as irresponsibly promoted the device to a group of women for whom it was medically unadvised.<sup>121</sup>

The companies that still market IUDs in the U.S. today have faced few lawsuits, because they have learned from the mistakes of the past and now advise that IUDs are not appropriate and safe for all women. Safety data establishes that IUDs are advisable and safe compared to other options only for women in long-term mutually monogamous sexual relationships.<sup>122</sup> If G.D. Searle had been more responsive to this safety evidence than to cost considerations, then it may well have never had a liability and punitive damages problem. The overall irony of the argument that litigation costs drove some IUDs off the market is that "[r]eports of injuries and deaths of women, which came years before the devices were withdrawn, never had that effect."<sup>123</sup>

The other favorite example offered by the pharmaceutical industry concerning the detrimental effect of punitive damages on women's health is the morning sickness drug Bendectin. Thousands of law suits filed on behalf of children with birth defects alleged that Bendectin, if taken during the period of pregnancy when fetal limb formation occurred, caused limb deformities.<sup>124</sup> At the time these lawsuits commenced, very little no

---

(CCH) ¶ 14,765, 1996 LEXIS 126 (Ky. Ct. App. 1996). Because the drug is still marketed for other medical uses, including to treat infertility and Parkinson's disease, it is still possible for Parlodel to be prescribed to pregnant women. See Michael Unger, *Moms Sue Maker of Antilactation Drug*, N.Y. NEWSDAY, Feb. 8, 1995, at A37.

119. See *O'Gilvie*, 821 F.2d at 1446.

120. *FDA Approval and Limits on Damage Awards: Hearings on S. 672, Before the Senate Comm. on the Judiciary*, 104th Cong. 3-7 (1995) (statement of Janice Toran, Counsel for G.D. Searle & Co.).

121. See *Kociemba*, 707 F. Supp. at 1537.

122. PARAGARD, Information Sheet, TODAY'S IUD IS EFFECTIVE, RELIABLE, AND CONVENIENT (1995) (distributed by Ortho Pharmaceutical Corp.); Anita Nelson, *Patient Selection Key to IUD Success*, CONTEMP. OB/GYN, Oct. 1995, at 49, 49-50.

123. GRANT, *supra* note 26, at 147.

124. For the story of Bendectin litigation, see MICHAEL D. GREEN, BENDECTIN AND

epidemiological research on this question had been performed, even though one of the drug's active ingredients was chemically related to a known animal teratogen and it had been marketed to pregnant women for years.<sup>125</sup> The mounting litigation stimulated the scientific research, which generally did not substantiate the connection with birth defects.<sup>126</sup> Thus, no punitive damages judgment was ever sustained on appeal, and most cases were dismissed at the outset. Nevertheless, rising insurance costs, public alarms about the drug's safety, and the declining market for Bendectin led the manufacturer, Richardson-Merrell, to withdraw it from the market.<sup>127</sup> Proponents of tort reform now lament before Congress that products liability suits and junk science drove the only known effective treatment for morning sickness off the market, to the detriment of women's health.<sup>128</sup>

There are several problems with using Bendectin as a case for curtailing punitive damages for any FDA approved drug or device. First, the dangerous drugs and devices that have been driven off the market by punitive damages far outweigh this one example of a benign drug so afflicted. As the poster child for tort reform, Bendectin is being asked to prove too much.<sup>129</sup> Moreover, Bendectin was of questionable effectiveness for mild cases of morning sickness, and was wildly over prescribed by physicians in instances where its benefits were equally as unproven as its risks.<sup>130</sup> As medical and societal concern about the safety and wisdom of over prescription of drugs during pregnancy increased, growing numbers of physicians became leery of prescribing it in cases other than those of severe morning sickness. This salutary caution about overprescriptive unnecessary drugs to pregnant women was an important factor in drying up the market

---

BIRTH DEFECTS: THE CHALLENGES OF MASS TOXIC SUBSTANCES LITIGATION (1996), see also Joseph Sanders, *The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts*, 43 HASTINGS L.J. 301, 303 (1992).

125. GREEN, *supra* note 124, at 90-91, 173-76, 228, 329.

126. See *id.* at 173-75, 314-15, 329-30; Sanders, *supra* note 124, at 346, 395.

127. See GREEN, *supra* note 124, at 182-84.

128. See GREEN, *supra* note 124, at 186-87, 339-40. On the occasions I have testified before Congress, I have heard several witnesses make such assertions during the question and answer colloquys. The Products Liability Coordinating Committee ("PLCC"), a defense-oriented lobbying consortium, created a Women's Issues Task Force which disseminated this claim about Bendectin. See PLCC Letter to Writers on Women's Issues (Nov. 22, 1993) (on file with the *Tennessee Law Review*); PLCC WOMEN'S ISSUES TASK FORCE POSITION PAPER, FEATURES OF THE PRODUCT LIABILITY FAIRNESS ACT, H.R. 1910, AND HOW THEY BENEFIT WOMEN 3 n.3 (Aug. 1993) (on file with the *Tennessee Law Review*).

129. See, e.g., STEVEN GARBER, PRODUCT LIABILITY AND THE ECONOMICS OF PHARMACEUTICALS AND MEDICAL DEVICES xxx-xi(1993); GREEN, *supra* note 124, at 339-41 (suggesting that the Bendectin example is sui generis and being overused to fuel most of the misperceptions and fears of products liability and mass torts).

130. Studies showed that Bendectin was only 10% more effective than a placebo for relieving morning sickness. See GREEN, *supra* note 124.

for the drug and undermining its profitability.<sup>131</sup> The litigation alone cannot be singled out. To the extent that Bendectin may have been effective and safe, its active ingredients are available in a combination of an over the counter antihistamine and B-6 vitamin. Several physicians advised their patients to use this less expensive alternative rather than take Bendectin.<sup>132</sup> Moreover, other substitute drugs are available to treat morning sickness.<sup>133</sup> Thus, the claim that litigation drove the only known treatment for morning sickness off the market is not accurate.

Another frequently overlooked positive health effect of punitive damages is their role in alerting the FDA to the need to take stronger action, and to stimulating further medical research into the health effects of products. The tort system and the regulatory system have an important synergistic relationship that could be undermined by the "FDA defense." The Dalkon Shield litigation, and in particular the punitive damages judgments, were a powerful inducement to the FDA to investigate and assert its regulatory authority over the Dalkon Shield.<sup>134</sup> With breast implants, the FDA was motivated to require more safety data from manufacturers by several large punitive damages judgments, combined with documents obtained by lawyers in breast implant litigation that showed high rupture and contracture rates, internal company knowledge of these risks, and shoddy manufacturing practices.<sup>135</sup> This belated exercise of regulatory responsibility led the FDA to conclude that the manufacturers' proof of safety was woefully inadequate, especially considering the many decades the product had been put in women, and the FDA ordered a moratorium on the marketing of the product until safety could be proven.<sup>136</sup> Whatever the eventual outcome of the ongoing epidemiological research into a possible connection between breast implants and connective tissue and immune system diseases, we all, and women in particular, are better off knowing than not knowing. As the FDA Commissioner noted, if the agency did not step into the fray over breast

---

131. *Id.* at 182-83.

132. *Id.* at 183, 337.

133. *Id.* at 337.

134. *See supra* note 88 and accompanying text.

135. *See* David A. Kessler, *The Basis of the FDA's Decision on Breast Implants*, 326 NEW ENG. J. MED. 1713, 1713 (1992).

136. *Id.* Although Dr. Kessler has been castigated by Dr. Marcia Angell for taking a paternalistic action that deprived women of choice when there was also no proof that the devices caused systemic illnesses, *see* ANGELL, *supra* note 98, at 19-25, the FDA law places the burden of proof of safety on the manufacturer. KESSLER, *supra* note 135, at 1713. The law has made a policy decision that drugs and devices should not be marketed until proven safe and effective, rather than the position advocated by Dr. Angell that they should be kept on the market until proven unsafe. *Id.* Dr. Kessler noted the long list of known risks and unanswered questions about the long-term safety of breast implants, *id.*, and observed that "[c]aveat emptor has never been—and will never be—the philosophy at the FDA." *Id.* at 1715.



implants, manufacturers would probably continue to market them for another thirty years without bothering to undertake basic research into their health effects.<sup>137</sup> It took tort litigation and punitive damages to move the FDA to require the research that will eventually better inform the public about safety.

Breast implants are hardly the only example of a product used in women's bodies that is marketed for years with insufficient knowledge about safety and risks. Lawyers and women's health activists aroused concerns about the safety of high hormone dose birth control pills, and the additional research stimulated by the pressure led to substantial health improvements in the drug and far more effective informed consent for women consumers. Even though the medical research on Bendectin did not bear out the concerns about an increased risk of birth defects, this is research that undoubtedly should have been done before the drug was marketed to tens of thousands of pregnant women. If not for the tort litigation, the medical research probably never would have been done. From this research, the medical community has learned more about birth defects and appropriate periods for prescribing certain kinds of drugs during pregnancy. The medical community has also learned that more conservative treatment methods are actually safer and more efficacious.<sup>138</sup>

DES provides another salient example of the positive effect of tort litigation in stimulating and supporting activism and medical research. Until women started bringing and winning lawsuits, many DES exposed women did not know about the risks they faced. Media interest aroused by legal judgments helped the activist group DES Action reach more women and, as DES Action grew in strength, it was able to successfully push the medical research agenda. Until the first wave of successful lawsuits, little follow up research had been done to learn about the health effects of DES exposure. As such research has been done, more and more adverse health effects have come to light. In addition, physicians and DES exposed women and men have learned information essential to monitoring and treating the DES exposed.

Mounting concerns about Norplant, growing litanies of health complaints, and lawsuits from women are starting to stimulate additional research about this contraceptive. Indeed, the manufacturer is attempting to devise a new formulation that exposes women to a lower hormone dose for a shorter period of time.<sup>139</sup> Still, the list of unanswered health questions about Norplant, despite risk signals and FDA approval, is alarming. What are the long-term effects on women who use Norplant for more than five years? Is it safe for long-term use by women who smoke, or who have high blood pressure, or who have diabetes, or who are over 40? Can the

---

137. *Id.*

138. See GREEN, *supra* note 124, at 336.

139. See INSTITUTE OF MEDICINE, CONTRACEPTIVE RESEARCH, *supra* note 100, at 321.

menstrual disruption caused by Norplant make it harder to detect early warning signs of reproductive cancers? Why does Norplant increase the risk of ectopic pregnancy, and how can this risk be reduced? What are the long-term health effects for babies born to the one in twenty-five Norplant users who become pregnant during the five year span of the drug? Is this the next potential DES? Should nursing women be given Norplant? Will women regain full use of their arm after having surgery to dig out Norplant capsules that become embedded in their limb? What are the long-term health effects when some of the rods migrate or become too deeply lodged to be safely removed, thus remaining in a woman's body far longer than the anticipated five years?<sup>140</sup> The fact that this drug is being marketed despite so many serious questions about its health effects may well arouse the indignation of juries. While the drug's manufacturer should have more thoroughly investigated these health questions before pushing the product on women, it may again take a punitive damages wake-up call to stimulate adequate medical research, serious attention to women's reports of problems, and effective monitoring by the FDA.

### III. CONCLUSION

In light of this history of drugs and devices for women, an "FDA defense" from punitive damages has great potential for undermining what few incentives currently exist for manufacturers to elevate safety concerns above marketing and profit concerns. If manufacturers of drugs and medical devices are insulated from punitive damages, the role the tort system has played in helping unearth safety problems, drawing public attention to risks, stimulating increased medical research, and prodding the FDA to respond to growing evidence of dangers that come to light after initial approval will be hampered, to the overall detriment of women's health. As Dr. David Kessler of the FDA has cautioned, "caveat emptor" never should be the policy for drug safety.<sup>141</sup> Yet extending protection from punitive damages to drug manufacturers that received previous approval from the FDA, even though their post-approval conduct meets the legal standard of flagrant indifference to health and safety, will usher in exactly such a principle. Women will have little in the way of effective legal recourse with enough potential financial consequence to force manufacturers to take their health more seriously from the outset. The women's health community should be extremely skeptical about legislative proposals that will leave women at the mercy of the next over-hyped claim about a wonderfully risk free drug or medical device that will give women the flawless body, the painless pregnancy, the perfect baby, or the "immaculate" contraception.

---

140. For these and other unanswered questions and warning signs about Norplant, see SEAMAN, *supra* note 26, at 245-46.

141. Kessler, *supra* note 135, at 1715.