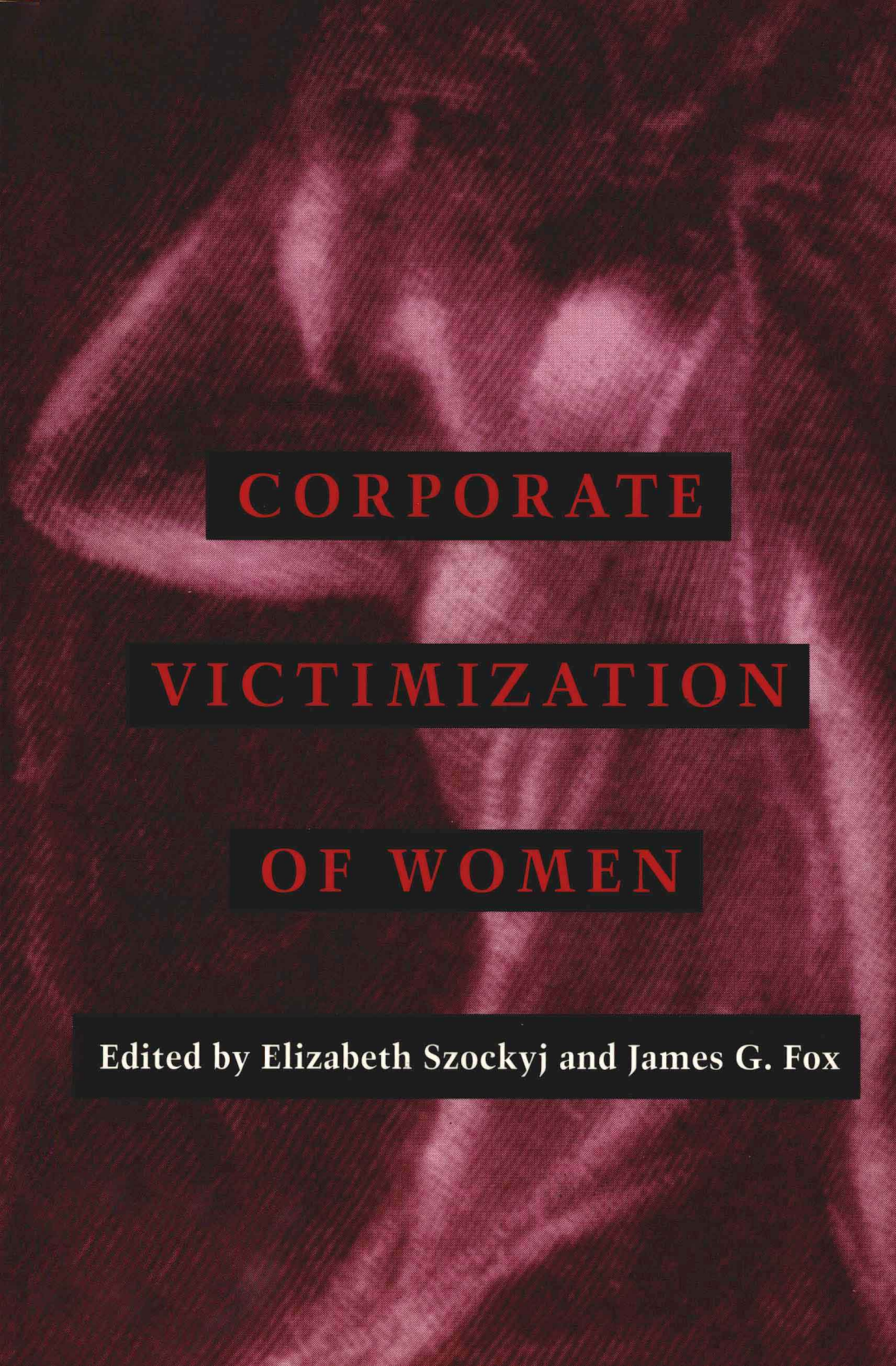
CORPORATE
VICTIMIZATION
OF WOMEN
Edited by Elizabeth Szockyj and James G. Fox

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CONTENTS

it would help while others said it would not, were reluctant to withhold a drug that, even if it did no more than psychologically reassure and relax their patient, could possibly help protect the pregnancy.

29. These estimates are reported in Dutton, *Worse than the Disease,* 56–57, and are drawn from O. P. Heinonen, "Diethylstilbestrol in Pregnancy: Frequency of Exposure and Usage Patterns," *Cancer* 31 (1973): 576. It is difficult to derive exact reports on DES usage, because many medical records or prescription forms are no longer available due to passage of time or deliberate destruction, and many pregnant women were not told what pill they were prescribed, or cannot remember whether they took a drug during a long-ago pregnancy.

30. A. L. Herbst, H. Ufelder and D. C. Poskanzer, "Adenocarcinoma of the Vagina: Association of Maternal Stilbestrol Therapy with Tumor Appearance in Young Women," *New England Journal of Medicine* 284 (1971): 878–81.

31. P. Greenwald, J. Barlow and P. Nasca, "Vaginal Cancer After Maternal Treatment with Synthetic Estrogens," *New England Journal of Medicine* 285 (August 12, 1971): 390–92.

32. Dutton, *Worse than the Disease,* 71.

33. Despite these warnings, some U.S. doctors continued to prescribe DES to pregnant patients into the mid-1970s. Dutton (ibid., 74) reports that in 1974, U.S. physicians issued an estimated 11,000 DES prescriptions to pregnant patients. When I conducted interviews with several DES mothers and DES daughters, two of the mothers I interviewed had been given DES while pregnant in 1972 and 1973. One of these women had no prior history of miscarriage but reported that her doctor thought her first, normal, healthy child weighed too little at birth, so he gave her DES in the hope that her second baby would weigh more. The mother reported to me that her daughter weighed in two ounces less than her firstborn. "I guess my body just normally produces five and half pound babies, no matter what you try to do to it," she said. And, the only thing wrong with her second child is the reproductive tract abnormalities caused by DES.

DES also continued to be used throughout the 1970s, especially at college health services, as a "morning after" pill, with no warning to women about the risks if they turned out to be pregnant despite the contraceptive effort. While DES is no longer used for pregnancy in the United States, there are reports that even in the mid-1990s, some doctors in Eastern European countries are prescribing DES to pregnant women. And there is little or no monitoring by international health organizations of how it is being used in Third World countries.

34. One brand of DES, marketed under the name DESPlex, was mixed with vitamins B and C and aggressively marketed as "recommended for routine prophylaxis in ALL pregnancies" (emphasis in original). For a photo-

graphic reproduction of this ad as it appeared in obstetrics-gynecology journals, see R. Apfel and S. Fisher, *To Do No Harm: DES and the Dilemmas of Modern Medicine* (New Haven, CT: Yale University Press, 1984), 26.

35. For a moving first-person account of what it is like for a young woman who is just becoming sexually active, still sexually insecure, and not yet used to pelvic exams, to go in for a checkup about a bleeding problem and emerge with a clear cell adenocarcinoma diagnosis, see J. Bichler, *DES Daughter* (New York: Avon, 1981).

36. There is growing evidence of harm to DES sons, as well. There has been much less research on the sons of DES mothers, perhaps because men do not regularly go to the equivalent of a gynecologist to have their reproductive systems checked and because even fewer men than women know they were exposed to DES. DES researchers and activists also report that men are more defensive and more likely than women to deny that something may be wrong with their sexual organs, which in men's minds are more bound up with sex and masculinity than with reproduction. The research that has been done suggests higher than average rates of testicular cancer and malformations such as small penises, undescended testicles, or enlarged testicular veins; and reduced sperm production, which can lead to impaired fertility.

37. A. Herbst, S. Anderson, M. Hubby et al., "Risk Factors for the Development of Diethylstilbestrol-Associated Clear Cell Adenocarcinoma: A Case Control Study," *American Journal of Obstetrics and Gynecology* 154 (1986): 814–22.

38. Dutton, *Worse than the Disease*, 86–87. The differing rates of these conditions in the various studies may be attributable to the fact that the women in each study group were exposed to different amounts of DES.

39. One 1980 study showed a successful pregnancy rate of only 66.7 percent among DES-exposed women and their partners who were trying to have children, compared with a 90 percent rate among a similar unexposed group (M. J. Berger and D. P. Goldstein, "Impaired Reproductive Performance in DES-Exposed Women," *Obstetrics and Gynecology* 55 [1980]: 25–27). Another 1980 study by Dr. Herbst and colleagues, following the daughters of women in the Dieckmann study from the University of Chicago, found that DES daughters had four times as many miscarriages, stillbirths, and ectopic pregnancies as the unexposed women's daughters. Only 47 percent of the DES-exposed daughters had full-term, healthy live births, as against 85 percent of the unexposed daughters (A. Herbst, M. Hubby, R. Blough and F. Azizi, "A Comparison of Pregnancy Experience in DES-Exposed and DES-Unexposed Daughters," *Journal of Reproductive Medicine* 24 [1980]: 62–69). An additional Herbst study found a 21 percent miscarriage rate for those exposed to DES, compared with an 11 percent rate among those without DES exposure (Meyers, *DES: The Bitter Pill*, 127).

40. *Sindell v. Abbott Labs*, 26 Cal.3d 588, 607 P.2d 924 (1981); *Hymowitz v. Eli Lilly & Co.*, 73 N.Y.2d 487, 539 N.E.2d 1069 (1989); *Abel v. Eli Lilly & Co.*, 418 Mich. 311, 434 N.W.2d 164 (1984); *Collins v. Eli Lilly & Co.*, 116 Wis.2d, 342 N.W.2d 37 (1984); *Martin v. Abbott Labs*, 102 Wash.2d 581, 689 P.2d 368 (1984).

41. *Hymowitz v. Eli Lilly & Co.*

42. *It is virtually impossible to sue enough companies to represent over 60 percent of the market, and market share estimation tables prepared in New York and California cannot account for almost 40 percent of the market in key years. If the companies a woman has sued together represent 50 percent of the total market for DES in the year she was born, then she will recover half of her damages. Most drug companies, thanks to the market share principle, have had to pay less than 8 percent of the verdicts or settlements. Eli Lilly has been assigned the largest market share, ranging from approximately 30 to 40 percent depending on the year and the pill dosage.*

43. *This principle is known as the no preconception duty rule. See, for example, Enright v. Eli Lilly & Co.*, 77 N.Y.2d 377, 570 N.E.2d 198 (1989).

44. As a 1968 FDA advisory committee report on intrauterine devices so tactfully put it, in enumerating the advantages of IUDs, "the underprivileged woman is more effectively served when the need for recurrent motivation, required in most other forms of contraception, is removed" (N. Grant, *The Selling of Contraception* [Columbus, OH: Ohio State University Press, 1992], 23, quoting from U.S. Food and Drug Administration, Advisory Committee on Obstetrics and Gynecology, *Report of Intrauterine Devices*. GPO Doc. No. 290-137-0-68-3 [1968], 1).

45. K. Hicks, *Surviving the Dalkon Shield IUD* (New York: Teachers College Press, 1994), 19, quoting from C. Tietze and S. Levitt, eds. *Proceedings of the First Conference on the IUCD*, April 30–May 1 (New York: Excerpta Medica, 1962), 3.

46. Grant, *The Selling of Contraception*, 25.

47. H. J. Davis, "The Shield Intrauterine Device: A Superior Modern Contraceptive," *American Journal of Obstetrics and Gynecology* 106 (1970): 455–62. Nowhere in the article did Davis reveal that he was one of the developers of the Shield or that he had a financial stake in its success. If he had divulged this information, it might have been apparent to readers that this supposedly objective medical research report was little more than elaborate sales promotional literature.

48. Hicks, *Surviving the Dalkon Shield IUD*, 27.

49. See Mintz, *At Any Cost* (New York: Pantheon Books, 1985), 13, 107; Hicks, *Surviving the Dalkon Shield IUD*, 27–33; Grant, *The Selling of Contraception*, 130–31.

50. J. Braithwaite, *Corporate Crime in the Pharmaceutical Industry* (Boston: Routledge, 1984); Mintz, *At Any Cost*.

51. S. Perry and J. Dawson, *Nightmare: Women and the Dalkon Shield* (New York: Macmillan, 1985).

52. Mintz, *At Any Cost*, 55–56.

53. This IUD, too, turned out to very dangerous to women, producing a high rate of infection, perforation, and septic abortion. It generated extensive litigation, during which lawyers for plaintiffs proved that, like the A. H. Robins Company, Searle had suppressed evidence of dangers, submitted misleading information to the FDA, and made false advertising claims. See, for example, *Kociemba v. G. D. Searle Co.*, 707 F. Supp. 1517 (D. Minn. 1989).

54. R. Sobol, *Bending the Law* (Chicago: University of Chicago Press, 1991), 7; Mintz, *At Any Cost*, 138–39.

55. Mintz, *At Any Cost*, 141.

56. Ibid., 143.

57. Ibid., 143, quoting September 9, 1971, memo from Daniel French to Oscar Klioze.

58. Ibid., 143–44.

59. Sobol, *Bending the Law*, 8.

60. One particularly salient warning came in a June 1972 letter to Robins's sales manager from Dr. Thad Earl, a gynecologist who once had so enthused about the Shield that he invested in the Dalkon Corporation and became a paid consultant to A. H. Robins when it purchased the device. Dr. Earl reported septic abortions in five of his six patients who became pregnant with Dalkon Shields in place, and he urged the company to warn all physicians immediately to remove the device if a woman became pregnant. This dire report was circulated among several high-level company officials, but no corrective action resulted.

61. Mintz, *At Any Cost*, 4.

62. Grant, *The Selling of Contraception*, 56–57, citing R. Shine and J. Thompson, "The In Situ IUD and Pregnancy Outcome," *American Journal of Obstetrics and Gynecology* 119 (1974): 126–27.

63. Mintz, *At Any Cost*, 164–65.

64. Ibid., 6.

65. Ibid., 7; Grant, *The Selling of Contraception*, 68.

66. Grant, *The Selling of Contraception*, 66–67.

67. Those who doubt, in the current political climate of hostility to product liability lawsuits, that punitive damages can help improve safety should contemplate that within six months after the second punitive damages verdict against it, Robins notified physicians to remove Dalkon Shields, and after a few more punitive verdicts the company finally reached out to notify women of the danger implanted in their bodies.

68. Mintz, *At Any Cost*, 195.

69. Hicks, *Surviving the Dalkon Shield IUD*, 52–53.

70. Sobol, *Bending the Law*, 14.

71. Ibid., 129–135.

72. Hicks, *Surviving the Dalkon Shield IUD*, 69–70.

73. T. Lewin, "Dream Contraceptive's Nightmare," *New York Times* (July 8, 1994): A10; H. Little, "No Panacea: Norplant Suit Charges Failure to Educate Patients," *Chicago Tribune* (Oct. 31, 1993): Section 6, 1; G. Kolata, "Will the Lawyers Kill Off Norplant?" *New York Times* (May 28, 1995): Section 3, 1.

74. T. Koenig and M. Rustad, "His and Her Tort Reform: Gender Injustice in Disguise," *Washington Law Review* 70 (1995): 1–90, 44.

75. Cohen,"Truth and Beauty, Deception and Disfigurement," 172.

76. When Public Citizen, a consumer and health advocacy organization, sought release of animal study data that had been submitted to the FDA, Dow claimed that this research was confidential commercial information whose disclosure would cause substantial harm to its competitive position. A federal court rejected this defense and ordered public disclosure, criticizing Dow for erecting "unnecessary roadblocks" to an effort to help give the public crucial information about safety. The fact that the FDA allowed implants to stay on the market should not prevent women from getting all the information necessary for making their own informed decision, the judge observed (*Teich v. FDA*, 732 F. Supp. 17, 20 [D.D.C. 1990]). Dow also sought protective orders in many of the tort cases, which sealed the evidence from public availability. Dow Corning lawyers then invoked those protective orders to try to stop expert witnesses and former employees from complying with FDA requests for information.

77. As one court explained, in affirming a $6.5 million punitive damages award to Mariann Hopkins:

> Given the facts that Dow was aware of possible defects in its implants, that Dow knew long-term studies of the implants' safety were needed, that Dow concealed this information as well as the negative results of the few short-term laboratory tests performed, and that Dow continued for several years to market its implants as safe despite this knowledge, a substantial punitive award is justified (*Hopkins v. Dow Corning Corp.*, 33 F.3d 1116, 1127 [9th Cir. 1994]).

78. Whether Bendectin was a teratogen or not has been the subject of intense scientific and legal controversy. Most juries in Bendectin cases have found that Bendectin did not cause a baby's birth defects, or courts have ruled that without conclusive epidemiological evidence plaintiffs did not have sufficient proof based on animal studies and toxicology alone to warrant presenting the case to the jury. While Bendectin may not have caused birth defects, its effectiveness in alleviating morning sickness was also hotly debated. To the extent that it may have helped some women feel bet-

ter, its active ingredients were available in much less costly over-the-counter preparations such as vitamin B-6. Moreover, Merrell-Dow's decision to withdraw it from the market was attributable in large part to significantly declining sales fueled by adverse publicity, for which tort suits were only partially responsible (M. Green, *Bendectin and Birth Defects: Lessons for Mass Toxics Litigation* [Philadelphia: University of Pennsylvania Press, forthcoming]. Thus, the example of Bendectin does not provide a compelling case for concluding that tort suits can drive a totally safe product of unquestioned benefit off the market. Even if it were, it is the only such example that the pharmaceutical industry possibly has. See S. Garber, *Product Liability and the Economics of Pharmaceutical and Medical Devices* (Santa Monica, CA: RAND Institute for Civil Justice, 1993).

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WOMEN IN THE MARKETPLACE

Targets of Corporate Greed

Joan Claybrook

3

As long as there is money to be made, someone will provide products to buy. Bad buys lurk at every turn. Women, first as managers of the home and now as independent wage earners, are no strangers to the dangers of the marketplace. Oddly, the unequal pay ratio between men and women is reversed in the marketplace, where women actually pay more than men for products and services such as cars and car repairs, dry cleaning, and haircuts. In the area of fashion and beauty, women have been particularly vulnerable, pushed to buy rapidly changing and often uncomfortable clothing and footwear.

Bad buys must, however, be distinguished from bad products. Bad buys involve the unfortunate waste of money; bad products compound financial waste with injury to well-being. Sometimes a bad buy is also a bad product. For centuries women have bought and worn high-heeled shoes that place enormous strain on ankles, legs, and hips and distort normal posture. Corsets, also de rigueur for centuries, squeezed women's bodies into unnatural shapes; in fact the corset placed such a strain on the internal organs of women's bodies that it created a collateral market for a second device, the pessary, designed to prevent the prolapse of the uterus that corset wearing sometimes prompted.[1] And in 1994 the Consumer Product Safety Commission (CPSC) issued a recall on sheer chiffon skirts that burned faster than newspaper; approximately 250,000 of the skirts were in circulation, having entered the marketplace at prices ranging from $6 to $80. These skirts, largely imported from India, failed to comply with the federal Flammable Fabrics Act.[2]

Women pay for bad products in three ways. First, many products are manufactured exclusively for, or marketed mainly to, women. In the area of cosmetics, cosmetic devices, and contraceptives, where manu-

facturers have been largely unregulated, or regulated only unsuccessfully, women have been unsuspecting guinea pigs, testing silicone breast implants, the Dalkon Shield, lactation suppressants, and other products with clinical trials at great personal injury.

Women also pay the price for bad products when, as chief purchasing agents for their households, they unwittingly bring dangerous products home to family members, who are subsequently injured. Such products include infant formula, which until the 1980s was not regulated by the government, and became so only after a series of disasters in which nutritionally deficient formula caused serious developmental problems in hundreds of infants. When members of a family are injured, the resulting stress may destroy the family unit; women, as primary caregivers, are also forced to deal with injury recovery.

The third way in which women pay for bad products is when they seek compensation, as only one in ten injured women does, for harm suffered. Undertaking a lawsuit forces the survivor to relive the trauma of injury. Further, the compensation system is biased against women, awarding economic damages based on earning power and, conversely, trivializing noneconomic damages such as pain, suffering, and loss of fertility. The tort system has been under attack for the past fifteen years, with manufacturers fighting to eliminate or severely restrict the availability of compensation for noneconomic damages.

Women understand the full costs that dangerous products exact and have made clear their safety bias in making purchasing decisions. Many manufacturers have been quick to capitalize on this purchasing preference with ads that advertise the safety of their products, even if they don't put much effort into really improving the design of these products. But even if women want to buy safe products, how can they be certain that they are safe? Many people assume that the government protects citizens from dangerous and unsafe products. To some extent, this is true. Regulatory agencies, some independent and some under the umbrella of the executive branch of the federal government, issue performance standards for many consumer products: children's toys, cars, infant formula, and so on. But these agencies cannot be everywhere, and they are often forced to rely upon the good faith of the manufacturers for assurances that products are safe. Furthermore, such agencies are susceptible to political machinations, and for the last fifteen years they have been cast as scapegoats responsible for economic ills. The courts have consistently provided a safety net and have sometimes even acted as a catalyst, forcing manufacturers to take due care in de-