

January 1993

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Recommended Citation

Rebecca VVeisman, *Reforms in Medical Device Regulation: An Examination of the Silicone Gel Breast Implant Debacle*, 23 Golden Gate U. L. Rev. (1993).
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REFORMS IN MEDICAL DEVICE REGULATION: AN EXAMINATION OF THE SILICONE GEL BREAST IMPLANT DEBACLE

Rebecca Weisman*

I. INTRODUCTION

On January 6, 1992, the Food and Drug Administration (FDA) called for a forty-five-day moratorium¹ on silicone gel breast implants.² While the moratorium exacerbated the current debate over the implant's safety,³ health questions remain unan-

* Golden Gate University School of Law, Class of 1994. Thanks to my editors, Monica McCrary, Rosanne Calbo-Jackson, Jessica Rudin, and Brian Paget, for their invaluable comments on earlier drafts. I also wish to thank LeRoy Hersh for making available non-confidential information relating to silicone gel breast implants.

1. FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, Pub. No. P92-I (1992) (H.H.S. News).

2. Silicone gel breast implants are elasticized silicone pouches filled with silicone gel. 21 C.F.R. § 878 (1990). Medically known as mammoplasty, over two million women have had the surgery. J. Douglas Peters & Margaret M. Aulino, *Breast Implants: Science and Litigation*, TRIAL, Nov. 1991, at 26. According to FDA estimates, twenty percent of breast implants follow a mastectomy and eighty percent are performed exclusively for cosmetic reasons. FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, Pub. No. T91-18 (1991) (Talk Paper). Recently, juries have awarded large sums to plaintiffs. *Hopkins v. Dow Corning Corp.*, No. C-91-2132, 1991 U.S. Dist. LEXIS 8580 (N.D. Cal. May 27, 1992) (verdict for plaintiff for \$7.3 million). In December 1992, a jury awarded a Houston woman \$25 million in damages which included \$20 million as punitive damages against silicone gel breast implant manufacturer Bristol-Myers Squibb. Gautam Naik, *Woman Receives \$25 Million Judgment in Bristol-Myers Breast Implant Suit*, WALL ST. J., Dec. 24, 1992, at A1, A3.

3. A variety of medical problems have been associated with silicone gel breast implants. Complications include fibrous capsular contracture (painful hardening of the breast), silicone gel leakage (all silicone gel-filled implants are thought to leak small amounts of silicone) and migration, silicone gel rupture, infection, interference with early tumor detection, degradation of polyurethane foam covered breast prosthesis, human carcinogenicity (cancer), human teratogenicity (disturbed growth processes involved in the production of a malformed fetus), autoimmune disease, and calcification. Breast implants have been linked to scleroderma, rheumatoid arthritis, and lupus (which can be

swered.⁴ On February 20, 1992, after three days of hearings on the safety of silicone gel breast implants, an advisory panel recommended to the FDA that silicone gel breast implants remain on the market, but with substantial new restrictions.⁵ On April 16, 1992, the FDA adopted the panel's recommendations, permitting the availability of silicone gel breast implants only under controlled clinical studies.⁶ Women desiring silicone implants for reconstruction after cancer surgery or because of severe deformity will have access to the devices, while the FDA will limit the number of women receiving implants for cosmetic reasons to the amount required to answer safety questions.⁷

This article will consider the regulatory policies of the FDA in protecting the health of the nation's women, particularly its handling of silicone gel breast implants and its policing of the leading implant manufacturer, Dow Corning Corporation.⁸ While this article recognizes the various difficult problems which the FDA must address in protecting consumers from unsafe food, drugs, and medical devices, it also recognizes the need for reform. This article will describe what resulted from the tragedies

fatal). 55 Fed. Reg. 20,570-71 (1990) (to be codified at 21 C.F.R. § 878). The implants may cause changes in nipple sensation. Children who nursed from mothers with silicone gel implants have experienced problems allegedly attributed to the implants. FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, UPDATE ON SILICONE GEL-FILLED BREAST IMPLANTS (1992).

4. FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, Pub. No. P92-35 (1992) (Talk Paper).

5. The advisory panel recommended, after hearing evidence from plastic surgeons, cancer specialists, rheumatologists, implant makers, nurses, breast cancer survivors, implant users, and others, that

1. Implants should remain available to women who have had breast cancer surgery or severe deformity.
2. Use should be restricted in yet unspecified ways to women seeking breast augmentation for cosmetic purposes.
3. All women who receive implants will be registered and monitored in studies in order to collect long-term data on the devices.

FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, Vol. X, No. 2 (1992).

6. FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, Pub. No. P92-11 (1992) (H.H.S. News). Under the new guidelines, before a woman may receive silicone gel breast implants, a physician must certify that saline-filled implants are an inappropriate alternative. *Id.*

7. *Id.* The FDA is also requiring silicone gel breast implant manufacturers to conduct laboratory studies under an FDA-imposed timetable. *Id.*

8. Dow Corning Corporation is a 50-50 joint venture between Corning, Inc. and Dow Chemical Co. Naik, *supra* note 2, at A3.

of diethylstilbestrol (DES) and the Dalkon Shield. With these failures in mind, this article will examine present FDA policies, describe social forces outside of the agency which affect women's health as well as regulatory decisions, and propose reforms that will enhance the effectiveness of protections for the women of this country.

II. BACKGROUND

A. THE DEVELOPMENT OF THE FDA AND ITS ROLE IN REGULATING SAFETY

In 1938, Congress passed the Food, Drug, and Cosmetic Act⁹ as a result of growing concern about the safety of food and drugs.¹⁰ This legislation authorized the FDA to regulate food, drugs, and therapeutic devices sold or transported in interstate commerce.¹¹ The underlying policy was to ensure the safety of food and drugs¹² and to promote honesty and fair dealing for the benefit of consumers.¹³

Congress has continued to make amendments to the Food, Drug, and Cosmetic Act of 1938 to allow the FDA to more effectively protect consumers and to keep current with technological, economic, and social realities.¹⁴ To address the problem of the

9. 21 U.S.C. § 301 (1987).

10. Wallace F. Janssen, *The U.S. Food and Drug Law: How it Came, How it Works*, FDA CONSUMER MAGAZINE, Pub. No. 92-1054, May 1992, at 1, 4. The death of over 100 people from a poisonous drug, elixir sulfanilamide, prompted this legislation. The drug manufacturer was guilty only of mislabeling its product. PETER ASCH, CONSUMER SAFETY REGULATION: PUTTING A PRICE ON LIFE AND LIMB, 18-19 (1988).

11. 21 U.S.C. § 301 (1987).

12. The term "drugs" includes: any article recognized in the official U.S. Pharmacopoeia, Homeopathic Pharmacopoeia or National Formulary; any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; articles other than food intended to affect the structure or function of the body; or articles intended for use as a component in any of the foregoing. 21 U.S.C. § 321(g) (1987).

13. Janssen, *supra* note 10, at 4.

14. *Id.* The Pesticide Amendment in 1954, the Food Additives Amendment in 1958, and the Color Additive Amendment in 1960 provide that manufacturers cannot legally put substances falling into these categories into the stream of commerce absent a prior determination of their safety. 21 U.S.C. §§ 342, 321, 409 (1992). In an attempt to tighten control over prescription, new, and investigational drugs, Congress passed the Drug Amendments of 1962, which require drug manufacturers to demonstrate a drug's safety and effectiveness prior to immersion into the marketplace. Drug manufacturers are required to provide the FDA with any instances of adverse reactions to their products and to inform doctors of the risks as well as the benefits. Since the passage of these amend-

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FDA's limited resources, the FDA required manufacturers to perform adequate research to prove the safety of any substance they wished to market.¹⁵ For the first time, the FDA policy was one of prevention through regulation, rather than prosecuting violations after the damage had occurred.¹⁶

In 1976, Congress passed the 1976 Medical Device Amendment,¹⁷ amending the Food, Drug, and Cosmetic Act of 1938 to authorize the FDA to regulate medical devices.¹⁸ The amendment gave the FDA the authority and the responsibility to assure consumers that medical devices are safe and effective.¹⁹ The FDA is required to classify²⁰ all devices for human use marketed in the United States into one of three regulatory classes²¹ so that the FDA can appropriately control each device.²²

In 1990, Congress passed the Safe Medical Devices Act of 1990,²³ requiring medical device user facilities²⁴ and manufactur-

ments, the FDA has removed from the market thousands of drugs for lack of safety or effectiveness. Many other drugs have required a labeling change to accurately reflect medical facts. *Janssen*, *supra* note 10, at 7; *L & M Indus. v. Kenter*, 321 F. Supp. 1131 (E.D.N.Y. 1971) (FDA detained plaintiff's goods because of labeling misrepresentation); *Dietary Supplemental Coalition, Inc. v. Sullivan*, 978 F.2d 560 (9th Cir. 1992) (FDA initiated seizure proceedings of plaintiff's food products because of unsafe food additives); *Weinberger v. Hynson, Westcott, & Dunning, Inc.*, 412 U.S. 609 (1973) (FDA withdrew approval from the drug Lutrexin because of an insufficient showing of its effectiveness for its intended purpose).

15. *Janssen*, *supra* note 10, at 4.

16. *Id.*

17. 21 U.S.C. § 334(b)(1)(A) (1992).

18. A "device" is any instrument, apparatus or contrivance, including their components, parts and accessories, intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease. 21 U.S.C. § 321(h) (1992).

19. *Janssen*, *supra* note 10, at 4.

20. 55 Fed. Reg. 20,568 (1990) (to be codified at 21 C.F.R. § 878).

21. The three classes are general controls, performance standards, and premarket approval, classes I to III respectively. Only a medical device classified as a class III device requires approval before entering the stream of commerce. However, class III preamendment devices, those devices which were on the market prior to the 1976 Medical Device Amendment, may be marketed without premarket approval until ninety days after the FDA's promulgation of a final rule requiring premarket approval for the device or thirty months after final classification of the device, whichever is later. Thus, after a preamendment device is classified as a class III device, the manufacturer has thirty months to submit appropriate safety data, during which the class III device may be commercially distributed. 21 U.S.C. § 360(c) (1992).

22. FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, REQUIREMENTS OF LAWS AND REGULATIONS ENFORCED BY THE U.S. FOOD AND DRUG ADMINISTRATION, 5 (1985).

23. 21 U.S.C.S. §§ 301(d), 360(i) (1992).

ers to report to the FDA deaths, serious illnesses, and serious injuries related to medical devices.²⁵ Pursuant to this amendment, the FDA may order manufacturers to stop distributing and physicians to stop using a medical device.²⁶ The FDA may also order a recall.²⁷ Further, medical device manufacturers must monitor new patients and warn them directly if serious problems arise.²⁸ However, because the new law is not retroactive, manufacturers do not need to notify patients who had medical devices prior to the law's enactment if serious problems develop.²⁹

The purpose of the FDA and the Federal Food, Drug, and Cosmetic Act of 1938 and its subsequent Amendments is to protect and preserve the public health.³⁰ The FDA decides what is safe and resolves difficult technological questions that have major impacts on the health and welfare of the nation. The FDA's goal is to ensure that consumers are able to make an informed decision, based on appropriate research and scientific studies.

B. FDA ACTIONS AND ITS MONITORING OF SILICONE GEL BREAST IMPLANTS

Although manufacturers have marketed silicone implants since the 1960's, the FDA did not have authority to regulate the implants until the passage of the 1976 Medical Device Amendment.³¹ Manufacturers of devices on the market prior to 1976 were not required to provide the FDA with scientific evidence of safety to continue marketing the implants.³² Although the FDA had authority to request safety data from silicone gel implant manufacturers in 1976,³³ the agency took no action regarding the implants until litigation disclosed potential dangers.

24. "User facilities" include hospitals, nursing homes, ambulatory facilities, doctor's offices, etc. Janssen, *supra* note 10, at 8.

25. 21 U.S.C.S. §§ 301(d), 360(i) (1992).

26. *Id.*

27. *Id.*

28. *Id.*

29. *Id.*

30. 21 U.S.C. § 352 (1992); Desmarais v. Dow Corning Corp., 712 F. Supp. 13, 16 (D. Conn. 1989).

31. 21 U.S.C. § 334 (1992).

32. *See supra* note 21.

33. *Id.*

In 1981, a woman allegedly injured by implants initiated the first breast implant suit against a manufacturer.³⁴ By 1982, the FDA had received sufficient information to determine that silicone gel breast implants presented the potential for unreasonable risks of injury.³⁵ In 1988, internal documents from Dow Corning and the FDA,³⁶ obtained by Public Citizen Health Research Group,³⁷ a consumer advocacy group, revealed that silicone gel breast implants caused cancer in laboratory animals.³⁸ After analyzing the documents, Sidney M. Wolfe, director of Public Citizen Health Research Group, requested that then FDA Commissioner Frank Young ban silicone gel breast implants.³⁹ The FDA took no action.

Various organizations have attempted to either inform women about the potential risks of silicone gel breast implants or inform the FDA of such hazards. Public Citizen Health Research Group has implemented suits⁴⁰ pursuant to the Freedom

34. *Klein v. Dow Corning Corp.*, 661 F.2d 998 (2d Cir. 1981) (plaintiff filed suit for \$10 million in damages when her silicone gel breast implant ruptured).

35. In 1982, the FDA published in the Federal Register that silicone gel breast implants should be considered Category III medical devices, those devices which pose risks and are in need of further study. The FDA expressed concern about the hazards of leakage and the long term toxic effect of silicone gel breast implants. 47 Fed. Reg. 2,820 (1991) (to be codified at 21 C.F.R. § 878). The FDA, however, did not put silicone gel breast implants into the most restrictive category until 1988. 55 Fed. Reg. 20,568 (1990) (to be codified at 21 C.F.R. § 878). Evidence suggests that Dow Corning knew as early as the 1970's that implants had adverse health risks. Stuart A. Schlesinger, *Products Liability: Concealment of Critical Information*, N.Y. L. J., Mar. 18, 1992, at 3-5. Dow Corning has disclosed that in 1971 it had information revealing that silicone could leak and cause damage to surrounding tissue and other areas of the body. Dow Corning also knew that if the gel migrated to other areas of the body, serious medical problems could arise. Daniel Wise, *Bar Besieged with Queries on Breast Implant Claims*, N.Y. L. J., Jan. 30, 1992, at 1, 1-2.

36. Internal memorandum from Tom Talcott, Dow Corning Corp., *Bleed of Mammary Prosthesis* (May 13, 1975); Internal documents from J. Cooper, Dow Corning Corp., *Biosafety Testing Concerns* (Jan. 8, 1985) (on file with the *Golden Gate University Law Review*).

37. *Teich v. FDA*, 732 F. Supp. 17, 20 (D.D.C. 1990).

38. *Id.*; see also Boyce Rensberger, *Silicone Gel Found to Cause Cancer in Laboratory Rats; Citizens' Group Calls for Ban on Breast Implants*, WASH. POST, Nov. 10, 1988, at A3.

39. Rensberger, *supra* note 38, at A3. Wolfe revealed that the Dow Corning documents had been debated by the agency for months and that some FDA scientists thought that the evidence was alarming enough that the agency should issue a public warning and inform past and potential patients of any adverse risks posed by the implants. *Id.*

40. *Teich*, 732 F. Supp. at 17 (responding to Public Citizen's request for safety data, both the FDA and Dow Corning claimed that the requested information was "confidential" commercial information and would cause Dow Corning substantial harm and impair

of Information Act (FOIA)⁴¹ to obtain safety information on the public's behalf. Because of the lack of information available to the public, Command Trust Network, Inc.⁴² attempted to intervene in breast implant litigation for the purpose of vacating protective orders imposed by implant manufacturers.⁴³ The organization's goal was to educate both the public and the FDA of potential health hazards of silicone gel breast implants.⁴⁴

Despite years of complaints and suspicions that silicone gel breast implants posed significant health risks to wearers, the FDA did not place them in the most restrictive regulatory class until 1988.⁴⁵ The same year, the FDA heard allegations that implant manufacturers had falsified data and delayed reporting adverse effects of the implants.⁴⁶ Consequently, the FDA advised the public to delay implantation procedures until the agency assessed the risks of the implants.⁴⁷ On April 10, 1991, the FDA published a regulation requiring silicone breast implant manufacturers to submit data proving that the implants are safe and effective.⁴⁸

On November 15, 1991, an FDA advisory panel⁴⁹ recom-

the FDA's ability to access safety data in the future). *See also* Teich v. FDA, 751 F. Supp. 243 (D.D.C. 1990) (holding that the FDA must release all data submitted to it by Dow Corning and sharply criticizing the agency for failing to adequately exercise its authority).

41. 5 U.S.C. § 552(a)(4)(B) (1992). Exemption 4 provides that confidential commercial information which is likely to cause substantial harm to a manufacturer's competitive position will be shielded from public disclosure pursuant to a request under the FOIA. Other information may be disclosed. *Id.*

42. Command Trust Network, Inc., a non-profit organization co-founded by Sybil N. Goldrich, who has suffered various medical complications from implants, is an organization that attempts to educate women as well as the FDA about the potential health hazards associated with silicone breast implants. *Mirak v. McGhan Medical Corp.*, 142 F.R.D. 34, 35 (1992).

43. *Id.*

44. *Id.*; *see also* Sybil N. Goldrich, Remarks at the General & Plastic Surgery Devices Panel Meeting, North Auditorium, Wilbur J. Cohen Building, 330 Independence Avenue, S.W., Washington, D.C. (Nov. 22, 1988).

45. 55 Fed. Reg. 20,568 (1990) (to be codified at 21 C.F.R. § 878).

46. *Peters & Aulino*, *supra* note 2, at 31.

47. *Id.*

48. FDA Talk Paper, *supra* note 2.

49. Advisory panels, consisting of members from both the private and public sector, provide the government with expertise in a variety of areas. Michelle Nuszkievicz, Note, *Twenty Years of the Federal Advisory Committee Act: It's Time for Some Changes*, 65 S. CAL. L. REV. 957, 957 (1992).

mended to the FDA that the implants remain on the market.⁵⁰ However, the same advisory panel voted against approving the devices, claiming that the manufacturers needed to perform further studies to demonstrate the device's safety.⁵¹ On December 13, 1991, Dr. Norman Anderson, a 1988 FDA advisory panel member, delivered previously unseen documents⁵² along with a personal letter requesting that the FDA take silicone gel breast implants off the market.⁵³ On January 6, 1992, the FDA called for a temporary moratorium on the implants.⁵⁴

On February 18, 1992, the FDA began hearings to assess the implant's safety.⁵⁵ The advisory panel again concluded that there was insufficient information to determine the safety of the implants.⁵⁶ The panel recommended to the FDA that the implants remain on the market, but with substantial new restrictions on their use.⁵⁷ The panel concluded that doctors should explicitly warn women seeking the device about the alleged design limitations of the device and should inform the women that at some point, they may have to have the implants removed.⁵⁸

On April 16, 1992, the FDA announced that silicone gel breast implants would be available under controlled clinical studies.⁵⁹ Women desiring silicone implants for reconstruction after cancer surgery and for correction of severe deformities may

50. FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, Pub. No. T91-72, PANEL ISSUES BREAST IMPLANT RECOMMENDATIONS (1991) (Talk Paper).

51. *Id.* The previous day, the panel rejected safety data presented by Dow Corning, claiming that the data was insufficient to prove the product's safety. *Id.*

52. Don J. DeBenedictis, *FDA Action Spurs Implant Suits*, A.B.A. J., Mar. 1992, at 1, 20. The FDA had not previously seen these documents because of court protective orders. *Id.*

53. *Id.*

54. *See supra* note 1.

55. *See supra* note 5.

56. *See supra* note 1.

57. *See supra* note 5.

58. Malcolm Gladwell, *Panel Urges Limited Use of Implants; FDA Asked to Curb Cosmetic Applications of Breast Devices*, WASH. POST, Feb. 21, 1992, at A1. The FDA maintains that the devices should not be considered "lifetime" devices. UPDATE ON SILICONE GEL-FILLED BREAST IMPLANTS, *supra* note 3. Under the learned intermediary doctrine, an adequate warning by manufacturers to physicians will eliminate the need for manufacturers to warn patients directly. The physician acts as a "learned intermediary" between the manufacturer and the ultimate consumer. *Desmarais v. Dow Corning Corp.*, 712 F. Supp. 13, 16 (D. Conn. 1989).

59. *See supra* note 5.

obtain them without limitations on availability.⁶⁰ The FDA will allow only a limited number of implants for cosmetic purposes,⁶¹ permitting access only to the number of women required to answer safety questions.⁶²

Many observers believe that litigation over the implants spurred the FDA to finally take some action.⁶³ When announcing the moratorium, FDA Commissioner David A. Kessler claimed that new information about implants amplified the agency's concerns about their safety.⁶⁴ Specifically, Kessler claimed that much of the new information came from court files of two federal lawsuits, *Hopkins v Dow Corning Corp.*⁶⁵ and *Cardinal v. Dow Corning Corp.*⁶⁶

As of June, 1992, over 10,000 women have filed implant related suits.⁶⁷ An FDA spokeswoman revealed that over 8,000 reports of problems alleged to be associated with the implants have been reported to the agency.⁶⁸ More complications and law suits are expected because the latency period for the development of problems associated with the implants ranges from two to twenty-five years.⁶⁹ In addition, with the publicity of litigation, many women are for the first time making the connection that their medical problems may be linked to the implants.⁷⁰

60. *Id.*

61. H.H.S. News, *supra* note 6.

62. *Id.*

63. DeBenedictis, *supra* note 52, at 20. Some observers credit the moratorium to congressional pressure, FDA embarrassment at keeping a product on the market while questioning its safety, and fear of manufacturer liability. *Id.*

64. *Id.*

65. *Hopkins v. Dow Corning Corp.*, No. C-91-2132, 1991 U.S. Dist. LEXIS 8580 (N.D. Cal. May 27, 1992).

66. *Cardinal v. Dow Corning Corp.*, 1991 U.S. App. LEXIS 6517 (M.D. Ala. July 30, 1991) (federal jury in Alabama awarded \$5.4 million, later halved by a judge, in *Toole v. McClintock*, 778 F. Supp. 1543, 1545 (M.D. Ala. 1991)). The national litigator for Dow Corning claimed that the alleged new information was previously disclosed in a 1984 case, *Stern v. Dow Corning Corp.*, where a jury awarded the victim \$1.7 million, as well as to an FDA advisory panel in 1988. DeBenedictis, *supra* note 52, at 20.

67. Sandra G. Boodman, *Breast Implants; Now Women are Having a Hard Time Getting Them Out*, WASH POST, June 23, 1992, at Z10.

68. *Id.*; see *supra* note 4.

69. DeBenedictis, *supra* note 52, at 20.

70. *Id.*

C. PREVIOUS FDA FAILURES AND THE LITIGATION WHICH FOLLOWED

Continued use of silicone gel breast implants for years after it was known that silicone was dangerous⁷¹ and that silicone leaked from the breast area into other parts of the body raises serious questions concerning physician liability, manufacturer liability, and the effectiveness of the FDA concerning women's health and safety. The FDA has on other occasions failed to act responsibly when dealing with products affecting women's health and safety. The FDA's failure to assess the safety of silicone gel breast implants is horrifyingly familiar to the diethylstilbestrol (DES) litigation and the Dalkon Shield litigation.⁷²

1. *Diethylstilbestrol (DES)*

DES is a synthetic estrogen ingested by women to prevent miscarriages,⁷³ which doctors began prescribing in the late 1940's.⁷⁴ The FDA approved the drug for this purpose in 1947 and was convinced of its safety by 1952.⁷⁵ Hundreds of pharmaceutical manufacturers marketed the drug and millions of pregnant women ingested it during the 1950's and 1960's.⁷⁶ In 1971,

71. The FDA had informed the State Public Health Department that silicone was considered dangerous for use in human body tissue. In 1965, the FDA had obtained an injunction prohibiting transportation of silicone across state lines. Silicone was then classified as a "new drug" that could be used only under scientific circumstances after an application for the use had been approved. *Nelson v. Gaunt*, 178 Cal. Rptr. 167, 168 (Ct. App. 1981).

72. Denise Dunleavy, a sole practitioner who represents over twenty clients claiming injuries from implants and who recently won a \$4.45 million jury verdict in *Livshits v. Natural Y Surgical Specialties*, No. 87 Civ. 2403, 1989 U.S. Dist. LEXIS 11347 (S.D.N.Y. 1989), fears that breast implant litigation will be a repeat of the "DES debacle" and believes the physical problems caused by implants are just beginning to emerge. Andrew Blum, *Publicity Sparks Interest in Breast Implant Suits*, NAT'L L. J., Apr. 29, 1991, at 14.

73. ASCH, *supra* note 10, at 120.

74. *In re DES Cases*, 789 F. Supp. 552, 557 (E.D.N.Y. 1992).

75. *Id.* Discussions and word-of-mouth information which circulated among medical specialists and doctors contributed to widespread acceptance of DES as safe and effective in preventing miscarriages. *Id.* Although animal studies conducted in 1938 had revealed that DES caused cancer, these studies were dismissed as irrelevant to humans. Peters & Aulino, *supra* note 2, at 26.

76. *Id.* Although studies in the mid-1950's revealed that DES did not prevent miscarriage, it remained on the market. Terrie B. Brodie, Comment, *Brown v. Superior Court: Drug Manufacturers Get Immunized from Strict Liability for Design Defects*, 19

several physicians linked DES to a rare form of vaginal cancer⁷⁷ in young girls who had been exposed to the drug in the womb.⁷⁸ Shortly thereafter, the FDA halted the marketing of DES;⁷⁹ however, evidence reveals that doctors continued to prescribe it through the early 1970's.⁸⁰

DES litigation has occupied courts throughout the country since the mid-1970's.⁸¹ In *Bichler v. Eli Lilly*,⁸² the jury found that the manufacturers of DES wrongfully marketed the drug because they did not conduct any laboratory tests upon pregnant mice.⁸³ Had the manufacturers performed such tests, pharmaceutical companies would have discovered that DES was capable of causing grave and deadly damage to develop in the female offspring of women who ingested the drug.⁸⁴ With this knowledge, manufacturers presumably would not have marketed the drug for problems of pregnancy.⁸⁵

The DES debacle has many parallels to the current situation with silicone gel breast implants. When DES manufacturers applied for FDA approval of the drug for ingestion by pregnant women, the manufacturers relied on tests by others which did not demonstrate either the drug's safety or effectiveness.⁸⁶ When the FDA approved, on an experimental basis, the use of DES to prevent miscarriages,⁸⁷ the manufacturers marketed and distributed it on an unlimited basis,⁸⁸ in violation of FDA

GOLDEN GATE U. L. REV. 435, 436 (1989); see also R. MEYERS, DES: THE BITTER PILL 17-19 (1983).

77. Besides cancer, DES is said to cause other serious medical problems, including miscarriage, uterine deformities, ectopic pregnancy, and breast cancer. *In re DES Cases*, 789 F. Supp. at 557.

78. MEYERS, *supra* note 76, at 17-19.

79. *In re DES Cases*, 789 F. Supp. at 557.

80. *Id.* In *Payton v. Abbott Lab.*, 780 F.2d 147 (1st Cir. 1985), both Abbott Laboratories and Eli Lilly were accused of violating FDA regulations. *Payton*, 780 F.2d at 149.

81. See *In re DES Cases*, 789 F. Supp. at 557.

82. *Bichler v. Eli Lilly*, 55 N.Y.2d 571 (1982).

83. *Id.*

84. *Id.* at 578. The jury further found that the manufacturers failed to give adequate warnings of potential effects of DES on fetuses, which would have prevented numerous injuries. *Id.* at 571.

85. *Id.* at 571.

86. Manufacturers seeking approval to use DES to prevent miscarriages relied on studies compiled by four pharmaceutical companies, headed by Eli Lilly. *Id.* at 576.

87. *Payton v. Abbott Lab.*, 780 F.2d 147, 149 (1st Cir. 1985).

88. *Id.*

authorization.⁸⁹

Like breast implant manufacturers, those manufacturing DES failed to adequately warn of the drug's potential dangers, failed to prove the drug's safety and effectiveness prior to its use, and continued to distribute the drug after they knew or should have known of the dangers.⁹⁰ Instead of taking a preventative route, the FDA reversed its approval in 1971,⁹¹ only after mounting evidence that DES was ineffective for its intended use and dangerous to the fetus.⁹² Had the FDA exercised its authority at an earlier date, it could have insisted on proof of safety.⁹³ Now, overwhelming evidence exists linking DES to clear-cell vaginal cancer in daughters of women who ingested it while pregnant.⁹⁴ Millions of women ingested DES and thousands of DES cases have clogged the courts for over a decade.⁹⁵

2. *Dalkon Shield*

The A.H. Robins Company, a pharmaceutical manufacturer, distributed more than 4.5 million Dalkon Shields, an intrauterine device used for birth control, in eighty countries between 1971 and 1975.⁹⁶ A.H. Robins failed to adequately test the Dalkon Shield⁹⁷ and conducted no long-term studies on either the device's effectiveness or safety.⁹⁸ As a result of using the

89. Besides marketing and distributing DES to pregnant women on an unlimited basis, manufacturers continued to do so after the FDA pulled DES off the market for such use. *Bichler*, 55 N.Y.2d at 576.

90. *Id.* at 578; see also *Payton*, 780 F.2d at 153.

91. *Bichler*, 55 N.Y.2d at 577.

92. *Id.*

93. *Id.* at 571. Similarly, Judge Stanley Sporkin criticized the FDA for not exercising appropriate authority in accessing and compelling production of safety data regarding silicone gel breast implants. *Teich v. FDA*, 732 F. Supp. 17, 20 (D.D.C. 1990).

94. *Shields v. Eli Lilly & Co.*, 895 F.2d 1463 (D.C. Cir. 1990).

95. See *Bichler*, 55 N.Y.2d at 577.

96. MORTON MINTZ, *Foreword to AT ANY COST: CORPORATE GREED, WOMEN AND THE DALKON SHIELD* (1985). Dalkon Shields were implanted in over two million women in the United States alone. *Id.* at 4.

97. *Id.* at 4.

98. *Id.* at 3. Approximately 110,000, or 5 percent of all users, became pregnant while wearing a Dalkon Shield, despite that A.H. Robins claimed a 1.1 percent pregnancy rate. While some physicians experienced pregnancy rates of less than 5 percent, many others experienced pregnancy rates in multiples of 5 percent. Bradley Post, an attorney who spent almost a decade analyzing Dalkon Shield statistics, believes that a 5 percent pregnancy rate is a reasonable estimate. Some of the most severe health consequences oc-

Dalkon Shield, tens of thousands of women suffered serious injuries, including pelvic infection, sterility, miscarriage, and death.⁹⁹ As of 1985, Dalkon Shield wearers have filed approximately 20,000 claims against A.H. Robbins,¹⁰⁰ forcing the manufacturer to pay \$314.6 million in damages.¹⁰¹

In February 1977, a plaintiffs' lawyer realized the dangers of the Dalkon Shield and wrote a letter to A.H. Robins requesting "immediate removal of devices in use."¹⁰² A.H. Robins did not respond.¹⁰³ Four years later, a sequence of deaths due to the Dalkon Shield were reported.¹⁰⁴ On February 29, 1984, Judge Lord¹⁰⁵ pleaded for the company to recall the Dalkon Shield and to "give consideration to tracing down the victims and sparing them the agony that will surely be theirs."¹⁰⁶ A.H. Robins responded by filing disciplinary proceedings against Judge Lord under the Judicial Conduct and Disability Act of 1980.¹⁰⁷

On August 22, 1972, the first Dalkon Shield related fatal

curred when Dalkon Shield wearers became pregnant. *Id.*

99. *Id.* at 6.

100. *Id.* at 242.

101. *Id.* In April 1985, G.E.R. Stiles, then senior vice-president and financial officer of A.H. Robins, revealed that an outside consultant indicated that the Dalkon Shield had injured approximately 88,000 women, of which approximately 20,000 would file claims. This estimate was done to assess the company's damages. *Id.* The company continued to market the Dalkon Shield abroad after it halted sales in the United States in 1974. Because many countries that have used the Shield have poor medical conditions, injury and death rates were probably much higher than in the United States. Dr. Richard P. Dickey, a former member of the FDA's obstetrical and gynecological devices advisory panel, said that a woman who has developed an infection due to the Dalkon Shield, "where there are no doctors, no antibiotics, she's going to die." *Id.* at 5.

102. *Id.* at 19. Bradley Post's letter to A.H. Robins urged the company to warn wearers to remove the Dalkon Shield. In a subsequent letter, Post repeated his plea, informing the company that the deaths of two young women were undoubtedly related to their use of Dalkon Shields and expressing his concerns for future fatalities. Again, A.H. Robins gave no response. *Id.*

103. *Id.*

104. *Id.*

105. In a prepared courtroom statement, Miles W. Lord, Chief U.S. District Judge for Minnesota, reprimanded three A.H. Robins' top officers for actions relating to sales of Dalkon Shields. *Id.* at 264-69.

106. *Id.* at 269; see generally Carol T. Rieger, *The Judicial Councils Reform and Judicial Conduct and Disability Act: Will Judges Judge Judges?*, 37 EMORY L.J. 45, 67 (1988).

107. 28 U.S.C § 372 (1982); see *Gardiner v. A.H. Robins Co.*, 747 F.2d 1180, 1186-90 (8th Cir. 1984).

spontaneous septic abortion occurred.¹⁰⁸ Dr. C. Donald Christian, the doctor in this case and head of OB-GYN at the University of Arizona Medical Center in Tucson, mentioned the incident to another physician, who had seen an almost identical death with another Dalkon Shield wearer.¹⁰⁹ Struck by the similarities of the two deaths, Dr. Christian inquired among his colleagues and discovered that many other physicians' patients were having similar problems with IUD's, especially with the Dalkon Shield.¹¹⁰ Although Dr. Christian reported his adverse findings to the FDA, he claimed that the agency "kept telling [him] to go away."¹¹¹

Under mounting pressure from adverse reports and a threat by Dr. Christian to publish an incriminating article in a medical journal,¹¹² A.H. Robins submitted some limited safety information to the FDA's Bureau of Medical Devices and Diagnostic Products (BMDDP).¹¹³ Subsequently, A.H. Robins sought FDA approval for a warning letter that would go to physicians who distribute the Dalkon Shield.¹¹⁴ The FDA device unit officials refused to approve the letter, calling it an inadequate method of informing physicians about the potential health risks.¹¹⁵ Ten days later, the head of the device unit urged the FDA to seek a court order to enjoin A.H. Robins from distributing more Dalkon Shields and to recall the devices that were on the market.¹¹⁶ The FDA declined to do so.¹¹⁷

In 1974, the FDA became concerned with reports that the Dalkon Shield caused spontaneous septic abortions and requested A.H. Robins to suspend sales.¹¹⁸ The company complied.¹¹⁹

108. *MINRZ*, *supra* note 96, at 157.

109. *Id.*

110. *Id.*

111. *Id.*

112. *Id.* at 160.

113. *Id.*

114. *Id.* at 163. A.H. Robins also felt that the letter would help with defense against lawsuits as it could argue that the company had genuine concerns with women's health.

Id.

115. *Id.*

116. *Id.*

117. *Id.*

118. *Id.* at 151.

119. *Id.*

Litigation disclosed that A.H. Robbins suppressed vital information and adverse reports from various physicians and the medical community at large.¹²⁰ Had there been a medical device law when the Dalkon Shield was introduced into the market, A.H. Robbins would have been required to prove its safety and effectiveness before entrance into the marketplace. Although the FDA had authority to request safety data,¹²¹ the agency did not do so in a timely manner. Similarly, the FDA's delayed response with regard to silicone gel breast implants has caused more health problems and fear of development of future health problems for women.

III. WHY HAS THE FDA BEEN UNSUCCESSFUL IN EFFECTIVELY PROTECTING WOMEN'S HEALTH?

Although there has been relatively lax regulation of women's medical devices in the past decade, especially with medical devices which were on the market prior to the Medical Device Amendments, this author maintains that overwhelming social forces exist which exacerbate the need for stricter regulation. This author contends that because of these forces, the need for consistently enforced regulation, especially regarding disclosure requirements, is mandated. Many women who choose to have breast implants are not capable of making an informed decision simply because accurate information is unavailable to them. Informed decisions are made difficult by corporations who put financial gain before long-term health, physicians who instill a false sense of security, and media images which falsely reflect the demographic composition of female body shapes and sizes.

A. THE CORPORATE DILEMMA: PROFITS V. CONSUMER SAFETY

The Dow Corning Corporation, one of the leading implant manufacturers, has put profit before women's health. For decades, Dow Corning put silicone gel breast implants on the market without conducting long-term safety studies.¹²² Dow Corning

120. *Id.* at 152.

121. 21 U.S.C. § 360 (1992).

122. A Dow Corning internal document reveals a dog study, which consisted of a six month study for short-term effects and a two year study for "long-term" effects. Dow Corning, however, published the six month study as a long term study. In the six-month

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suppressed scientific studies, concealed hazards to consumers,¹²³ and gave a false sense of security to the medical community and the FDA.¹²⁴ Because of this false sense of security, the common belief was that breast implant surgery was a low-risk procedure.¹²⁵

Dow Corning does not stand alone in appearing to have put its financial well-being ahead of the physical well-being of consumers.¹²⁶ Consider the following conduct of corporations in their quest for profits. Automobile manufacturers have knowingly marketed cars which explode in rear-end collisions;¹²⁷ chemical companies have sold pesticides abroad that have been prohibited in the United States;¹²⁸ coal companies have falsified information about the cause of Black Lung disease;¹²⁹ and tampon manufacturers have put tampons on the market with prior knowledge as to the dangers of toxic shock syndrome.¹³⁰ From these illustrations, one can conclude that left on their own, ab-

dog studies, there was very little change in the dogs. After two years, however, the tissue surrounding the implant showed inflammatory reactions and some dogs died. Dow Corning Corp., Summary of Scientific Studies (released to the public Feb. 10, 1992) (discovery documents on file with *Golden Gate University Law Review*).

123. Boyce Rensberger, *Reaction to Silicones was Denied; Despite 1974 Study, Dow Scientist Told FDA No Risk Seen*, WASH. POST, Jan. 18, 1992, at A1. In 1974, a Dow Corning scientist found that silicone can trigger strong reaction of the immune system. Despite this, at an FDA hearing in November 1991, the company denied that silicone could cause any such reaction. *Id.* In 1987, Dow Corning was aware that its employees falsified documents concerning silicone gel breast implants. The company did not alert the FDA until October 1992. Thus, the FDA, during its hearings on silicone gel breast implants, had incomplete and inaccurate information because of the falsified records. Thomas M. Burton, *Dow Corning Employees Falsified Data on Breast Implants, Counsel Concludes*, WALL ST. J., Nov. 3, 1992, at A3.

124. Edward Terino, M.D., Address at the *California Society of Plastic Surgeons*, 26th Annual Meeting (Mar. 3-7, 1976).

125. Judy Mann, *Implanting Corporate Responsibility*, WASH. POST, Feb. 21, 1992, at E3.

126. *FDA's Reality Check*, WASH. POST, Feb. 20, 1992, at A24. A.H. Robins, with its Dalkon shield, also gave a false sense of security to the medical profession. A.H. Robins suppressed information, insisted its product was safe, knowing of its inherent deadly risks, and continued to market the product abroad for eight months after taking it off the market in the United States. MINTZ, *supra* note 96, *Foreword*.

127. *Grimshaw v. Ford Motor Co.*, 174 Cal. Rptr. 348, 358-60 (Ct. App. 1981).

128. MINTZ, *supra* note 96, at 247.

129. *Id.* at 248.

130. *O'Gilvie v. International Playtex, Inc.*, 609 F. Supp. 817 (D. Kan. 1987) (jury awarded \$11 million in damages to the family of a deceased victim of toxic shock syndrome, \$10 million in punitive damages after deciding that Playtex, the manufacturer, had prior knowledge of the risks of its super-absorbent tampons and failed to warn consumers).

sent regulation, the private market may impose unreasonable and unnecessary risks on the public.¹³¹

Corporate executives certainly do not intend harm and their actions and decisions are simply a natural ramification of capitalism. This author does not propose to discuss the merits of capitalism, but simply to say, where the bottom line is profits and the market is left unregulated, consumers will not be adequately protected. Lax enforcement of regulatory laws¹³² combined with the anti-regulation sentiments of the now disbanded White House Council for Competitiveness¹³³ and recently proposed tort reform legislation¹³⁴ may operate to diminish the effectiveness of consumer protection legislation.

B. COSMETIC SURGEONS AND THEIR VESTED INTERESTS

Encouragement from cosmetic surgeons further reinforces the need for stricter regulation where women's health is concerned, especially in the area of informed consent. While cosmetic surgeons provide a service that some women desire, those

131. See ASCH, *supra* note 10.

132. During the Reagan and Bush administrations, FDA enforcement of regulation was lax as the agency was underfunded and operating under a deregulation philosophy. Malcolm Gladwell, *Silicone Breast Implants; After a Decade of Controversy, Key Questions are Unanswered and the Future of the Device is Unresolved*, WASH. POST, Mar. 3, 1992, at Z10.

133. The White House's Council for Competitiveness was established in 1989 to permit businesses more flexibility in order to compete more effectively. When faced with undesirable federal regulation, corporations could turn to the Competitiveness Council for relief. Daniel Isaac, *They Can't Compete*, LEGAL TIMES, Sept. 7, 1992, at 1. On January 22, 1993, President Clinton abolished the Council, criticizing it as a way for powerful corporations to circumvent federal regulation. *Clinton Scuttles Abortion Rights Limits, Puts Raft of Regulations Up for Review*, WALL ST. J., Jan. 22, 1993, at A1, A4.

134. S. 3190, 102d Cong., 1st Sess. § 640 (1991). Senator John D. Rockefeller (D-VA) initially introduced the bill, known as the Product Liability Fairness Act on March 13, 1991. It would limit damages manufacturers could be forced to pay for defective products and would make it more difficult for plaintiffs to sue in state courts. Senator Rockefeller is confident that the tort reform legislation will pass in the 103rd Congress. Supporters of the bill believe that it is good for business and the economy. Critics claim that the law will encourage dangerous products and marketplace fraud and that victims of defective products will not be compensated. *Product Liability, Product Liability Bill Dies in Senate After Supporters Fail to End Filibuster*, DAILY REPORT FOR EXECUTIVES: REGULATION, ECONOMICS AND THE LAW, Sept. 11, 1992, at 177. The National Association of Manufacturers (NAM), a powerful pro-business lobby, has been trying to get such a bill passed for almost a decade. Gary Lee, *Lobbyists Rush to Make Year Count; Recess, Hill Turnover Push Interest Groups Into High Gear*, WASH. POST, Sept. 9, 1992, at A19.

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who perform breast implants for cosmetic purposes may act out of self-serving interests, placing a higher priority on short-term profit than on long-term health consequences. This may ultimately have an impact on women's health and safety.

During the February 18-20, 1992,¹³⁵ FDA hearings concerning the safety of silicone gel breast implants, the FDA heard from every conceivable witness, including cosmetic surgeons.¹³⁶ Generally, cosmetic surgeons have represented to women their belief that the implants are safe.¹³⁷

In 1983, the American Society of Plastic and Reconstructive Surgeons (ASPRS)¹³⁸ initiated a \$4 million public relations campaign¹³⁹ in defense of breast implants,¹⁴⁰ issuing press releases, before and after photos, and education brochures.¹⁴¹ Not only did the ASPRS represent that cosmetic surgery was safe, effective, and affordable, but also that it was essential to women's mental health¹⁴² and that flat-chestedness caused a "total lack of well being."¹⁴³ ASPRS issued a statement that there is medical evidence that "these deformities (small breasts) are really a

135. Gladwell, *supra* note 132, at Z10.

136. *Id.*

137. Boodman, *supra* note 67, at Z10.

138. The ASPRS has 4,000 members and represents over 90 percent of the country's plastic surgeons. Breast enlargement for cosmetic purposes accounts for approximately one-half of the practices of many members, according to Norman M. Cole, the president of the organization. Sandy Rovner, *Implant Safety: Who's Right?*, WASH. POST, Nov. 12, 1991, at Z12.

139. In April 1992, ASPRS established a hot line to inform women seeking implants which plastic surgeons could counsel them. While this may appear altruistic, establishing the hotline was in response to FDA hearings where women testified that they were having a hard time finding physicians who would remove the implants. Boodman, *supra* note 67, at Z10.

140. SUSAN FALUDI, *BACKLASH: THE UNDECLARED WAR AGAINST AMERICAN WOMEN*, 217 (1985). ASPRS has assessed a mandatory \$350 fee from its members each year to help support the campaign. In 1991, the organization brought 400 women with breast implants to Washington to lobby, paying for the women's air fare and lodging. Rovner, *supra* note 138, at Z12.

141. Rovner, *supra* note 138, at Z12.

142. *Id.* At an FDA advisory panel meeting held in November 1991, speakers asserted that breast implants "are vitally important to women who feel their bust is too small for a society that worships . . . 'high, firm, large breasts.'" Physicians groups have claimed that silicone gel breast implants serve a medical need in the psychological rehabilitation of women with low self esteem. Malcolm Gladwell, *Breast Implant Maker Offers to Monitor Safety*, WASH. POST, Feb. 20, 1992, at A1.

143. FALUDI, *supra* note 140, at 217.

disease.”¹⁴⁴

While there are many ethical and devoted plastic surgeons with admirable ideals and principles who sincerely desire to help and heal people, reality suggests that it is unlikely that the AS-PRS will stop encouraging women to undergo unnecessary surgical procedures. Women’s health will be adequately protected only by strengthening regulation. Access to accurate and reliable information, promulgated through government regulation, would help ensure that women considering breast implant surgery are able to make informed and intelligent decisions. Only with accurate information can women adequately evaluate the risks against the benefits of the desired surgery.

C. CREATING THE MARKET

The third and perhaps most pervasive social force illustrating the need for tighter regulation and the availability of accurate information is media images. Advertisers, media,¹⁴⁵ cosmetic surgeons, and manufacturers have created a market which enforces the need for women to have “perfect” bodies.¹⁴⁶ Faced with pressure to look “beautiful” along with assurances that this surgical procedure is safe, it is understandable why over two million women have gone under the knife in an attempt to conform to the “ideal.” That is their choice. Women should not be chastised as being vain in a world that repeatedly assures them that they can safely become the “ideal” beauty.¹⁴⁷ Absent accurate and reliable information, it is impossible to make a knowing, intelligent decision.

144. *Id.* Some cosmetic surgeons refer to small breasts as a disease, micromastia, requiring treatment. *FDA’s Reality Check*, *supra* note 126, at A24.

145. See generally MARTIN A. LEE & NORMAN SOLOMON, *UNRELIABLE SOURCES: A GUIDE TO DETECTING BIAS IN NEWS MEDIA* (1990) (for a general discussion on media biases and influences).

146. A model for a mannequin maker comments that getting breast implants is the only way to get a job because “big breasts are all the [modeling] agencies are hiring now.” The new mannequin will have measurements of 34-23-36. Real women are supposed to follow. FALUDI, *supra* note 140, at 200. Manufacturers who make products for women insist that magazines promote a certain kind of beauty, mainly the one that the manufacturers themselves have created. MARILYN FRENCH, *THE WAR AGAINST WOMEN*, 171 (1992).

147. See generally NAOMI WOLFE, *THE BEAUTY MYTH: HOW IMAGES OF BEAUTY ARE USED AGAINST WOMEN* (1992).

Manufacturer's failure to warn of known risks coupled with the media's bombardment of information, influences, and images reinforces the need for strict federal regulation. Lax regulation has resulted in many women making potentially life threatening decisions without informed consent.¹⁴⁸ Rarely and inconsistently enforced laws send a message to manufacturers that not all laws need to be complied with, while giving consumers a false sense of security. Consistent enforcement of health and safety regulations will help protect consumers from potential misinformation and manufacturers from potential liability.

IV. RECOMMENDATIONS

While the FDA owes the public a duty to protect it to the best of its ability, a balance must be struck between the public's interest in its health and safety and the burden placed on manufacturers as a result of too much regulation. The public has a legitimate interest in the safety of medical products so that it will not have to face medical decisions with misinformation and fear of misrepresentation. Contrarily, too much regulation is not desirable because the manufacturing of life enhancing and life saving new drugs and medical devices would come to a standstill.

Based on the past experiences of women with regard to unsafe medical devices which have been sold for years absent a demonstration of safety and effectiveness, this author recommends that the FDA, Congress, and states take the following actions to alleviate the current silicone gel breast implant debacle and to prevent other such disasters from occurring.

148. Sybil Goldrich, a breast cancer survivor who had both breasts amputated in 1983 as a result of cancer, sought reconstruction following her surgery. Goldrich interviewed four plastic surgeons, whose consensus was that implants would be the simplest and least traumatic solution. No surgeon told Goldrich that this simple operation would turn into five operations, take ten months, require more than fifteen hours of anesthesia, and cause countless days of pain and worry. Goldrich's implants hardened, migrated, and generated one infection after the other. In the end, Goldrich was no closer to restoration than when she began; she simply had more scars. Had she known of the risks, she would have given her decision a lot more thought. Goldrich, *supra* note 44.

A. MANUFACTURERS SHOULD BEAR THE BURDEN OF PROOF FOR DEMONSTRATING A PRODUCT'S SAFETY

According to current law, manufacturers are required to demonstrate the safety and effectiveness of new medical devices before entrance into the stream of commerce.¹⁴⁹ Despite discussion that the burden should be on the FDA to prove a device is unsafe,¹⁵⁰ the burden of demonstrating the safety and effectiveness of medical devices should remain with manufacturers as it would be much too large a burden for a federal agency to be solely responsible for ensuring the safety of foods, drugs and medical devices. The FDA's responsibility is to ensure that manufacturers comply with the law by conducting appropriate safety and effectiveness studies, promptly submitting FDA requested information, and disclosing serious complaints.¹⁵¹

The FDA should require manufacturers to strictly follow appropriate guidelines when conducting safety tests on products so that the FDA can efficiently assess the accuracy and reliability of the studies.¹⁵² The FDA can most efficiently ensure that products are safe for the public when manufacturers comply in good faith, using appropriate guidelines to shoulder their burden of demonstrating safety and effectiveness.

This author argues that for medical devices which are not medically necessary, the FDA should place a higher burden of proof on the manufacturers, one proportionate to the public health need of the product. Arguably, silicone gel breast implants used exclusively for cosmetic reasons fall into this category. Contrast this with orphan drugs¹⁵³ or experimental drugs¹⁵⁴

149. 21 U.S.C. § 334(b)(1)(A) (1992).

150. Sample letters sent to members of Congress and the news media which ASPRS helped mobilize in response to a CBS broadcast by Connie Chung about silicone gel breast implants suggested that the FDA, rather than the manufacturer, should have the burden of proving that a device is not safe and effective for its intended purpose. Rovner, *supra* note 138, at Z12.

151. 44 U.S.C. § 3301 (1992).

152. The FDA regards itself as "the world's leading institution for scientific consumer protection." All FDA actions are to be based on scientific facts. The FDA relies on the *Official Methods of Analysis of the Association of Official Analytical Chemists*, a book of test methods which has been published since 1895 and is an internationally recognized authority for appropriate laboratory methods. Janssen, *supra* note 10, at 7.

153. Orphan drugs are drugs for very rare, serious diseases that manufacturers are permitted to market absent FDA approval because of the grave social need. Because the

for severely ill persons which are sometimes permitted into the stream of commerce despite adverse side effects. In such cases, the burden of proof on the manufacturer is understandably lower, as the side effects are insignificant compared to the life-prolonging therapeutic value.

In addition, the FDA should allot manufacturers a limited time period to demonstrate the safety of a product after legislation is passed which would have required the manufacturer to demonstrate a product's safety and effectiveness prior to its entrance onto the market. Liberal grandfathering policies¹⁵⁵ may defeat the purpose of the law, which is to prevent harm.¹⁵⁶ Both the Dalkon Shield and silicone gel breast implants were grandfathered in. The tragedies which followed may have been diverted or reduced had there not been such liberal grandfathering policies. Thus, stricter grandfathering policies should be developed whenever new safety legislation is implemented.

B. THE FDA SHOULD HAVE DISCOVERY POWERS SIMILAR TO LITIGATORS

The FDA should have the authority to subpoena documents, researchers,¹⁵⁷ and executive decisionmakers. If the goal is to prevent harm rather than compensate those injured, discovery through litigation comes too late.¹⁵⁸ In the case of silicone gel

diseases are so rare, it is not commercially feasible for manufacturers to invest time, money, and resources into development. 21 U.S.C.S. § 360(a)(a) (1992).

154. Because of the overriding social need for the severely ill to obtain potentially life-saving drugs, the FDA and various states have implemented procedures whereby the time-consuming process usually required for approval may be circumvented in cases of life-threatening diseases, such as acquired immune deficiency syndrome (AIDS). Robert C. Waters, *Obtaining Experimental Drugs for Severely Ill Clients; The Dilemma Caused by AIDS*, FLA. BAR J., May 1989, at 7-9.

155. Preamendment devices were grandfathered in. "Grandfathered in" refers to the fact that a new law does not apply retroactively. Thus, since breast implants were on the market prior to the 1976 Medical Device Amendment, implant manufacturers did not have to prove the implant's safety and effectiveness as would be required of a product that was not on the market when the new law was enacted. FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, *BACKGROUND INFORMATION ON THE POSSIBLE HEALTH RISKS OF SILICONE BREAST IMPLANTS*, 1 (1991).

156. 21 U.S.C. § 334(b)(1)(A) (1992).

157. Many researchers and experts who have testified in breast implant litigation are, under court order, prohibited from disclosing valuable public information. Wise, *supra* note 35, at 1-2.

158. See also Koch, *Discovery in Rulemaking*, 1977 DUKE L.J. 295, 345 (suggesting

breast implants, the most valuable and accurate information was disclosed during pre-trial discovery¹⁵⁹ and through consumer advocate groups seeking to accurately inform the public.¹⁶⁰

Protective orders should not apply to the FDA when the agency requests documents solely to assess a product's safety. The compelling government interest of protecting the public from significant danger outweighs the harm of disclosure to the manufacturer. Evidence from breast implant litigation was under court seal throughout the 1980's,¹⁶¹ unavailable to the public, to lawyers with potential clients, and, most significantly, to the FDA.¹⁶² While data which constitutes confidential commercial information is immune from disclosure when it would cause "substantial harm to [Dow's] competitive position,"¹⁶³ an issue so directly affecting women's health should not be suppressed from the federal agency authorized to oversee the public's health and safety.¹⁶⁴ The FDA should have access to this information so that it can assess the importance of it and warn the public if necessary.

C. THE FDA SHOULD USE EXTREME SANCTIONS FOR REFUSAL TO COOPERATE WHEN IT HAS REQUESTED INFORMATION

Under the statutory guidelines for FDA rulemaking,¹⁶⁵ parties are required to use "good faith" and diligence in supplying the FDA with unfavorable as well as favorable information. Although good faith has various meanings to different parties and is difficult to prove, the FDA has had sufficient experience to

that "any improvement in the information gathering process will enhance the policy decision expressed in the rule"); cf. Todd R. Smyth, Note, *The FDA's Public Board of Inquiry and the Aspartame Decision*, 58 IND. L.J. 627, 642 (1983) (suggesting that the FDA should have more liberal discovery policies with regard to its rulemaking functions).

159. *DeBenedictis*, *supra* note 52, at 20; see *Hopkins v. Dow Corning Corp.*, No. C-91-2132, 1991 U.S. Dist. LEXIS 8580 (N.D. Cal. May 27, 1992).

160. Wise, *supra* note 35, at 1-2.

161. *Id.* at 1.

162. *Id.*

163. *Teich v. FDA*, 732 F. Supp. 17, 17 (D.D.C. 1990).

164. *Teich v. FDA*, 751 F. Supp. 243 (D.D.C. 1990) (consumer group Public Citizen sues FDA for release of documents in order to disseminate safety information to the public). The court found Dow Corning's claim that disclosure of the protected documents would cause the company competitive injury unpersuasive. *Id.* at 249.

165. 21 C.F.R. § 13.25 (1981).

make these factual determinations and to set policy regarding what is and is not good faith. Upon discovery that any party did not use "good faith" and diligence in turning over unfavorable data or upon discovery that any party misrepresented or falsified information in any way, the FDA should implement economic sanctions against that party in proportion to its assets.

In addition, the FDA should require manufacturers to disclose any adverse reports from either physicians or patients regarding their product. Refraining from fully cooperating with such a rule would constitute grounds for sanctions on the manufacturer.

D. CONGRESS SHOULD ENACT LEGISLATION WHICH WOULD ELIMINATE OR REDUCE PRESSURE WHICH CORPORATIONS AND GOVERNMENT CAN PUT ON THE FDA

Congress should implement new legislation for campaign financing so that money cannot buy beneficial laws. Currently, corporations can put pressure on the FDA to take certain actions¹⁶⁶ through lobbying members of Congress and giving members large campaign donations.¹⁶⁷ In the past, members of Congress have pressured the FDA to take certain actions,¹⁶⁸ acting on behalf of powerful Political Action Committees (PACS),¹⁶⁹ corporations, or industry representatives.¹⁷⁰ These actions may not always be to the public's benefit. A powerful corporation can

166. After a board decided against aspartame approval, "Searle stepped up pressure on the FDA . . . by threatening to press a lawsuit filed earlier in an attempt to force a final decision." Cf. Smyth, *supra* note 158, at 635.

167. After receiving a \$117,593 contribution from A.H. Robins, Senator Paul S. Trible, Jr. introduced a bill which would cap damages and allow a manufacturer to pay punitive damages only once. Under pressure from women's groups, trial lawyers, and consumer groups, Senator Trible dropped the bill and it did not come up before the Senate. MINTZ, *supra* note 96, at 238-240.

168. For example, the White House's Competitive Council "wooed the biotechnology industry by pushing the FDA to rule that genetically engineered foods are not inherently dangerous." *No Dummies, These Biotechies*, 24 NAT'L J. at 1711 (1992).

169. ASPRS has formed its own political action committee, PlastyPAC. Rovner, *supra* note 138, at Z12.

170. FDA Commissioner David Kessler endured intense lobbying by both plastic surgeons and manufacturers of silicone gel breast implants when the FDA sharply restricted the use of the silicone gel breast implants. Julie Kosterlitz, *High Wire Act*, 24 NAT'L J. 1289, 1289 (1992). Consumer groups believe that political pressure from industry and the White House will cause FDA Commissioner Kessler to postpone the deadline for industry compliance with recently promulgated food-labeling regulations. *Id.*

have a great deal of influence on legislative decisions. Campaign finance reform¹⁷¹ could help curb the extraordinary influence that large corporations presently have over legislative decisions.

E. ADVISORY COMMITTEES SHOULD BE COMPRISED OF INDEPENDENT SCIENTIFIC EXPERTS

Advisory committees are comprised of experts from both the public and private sector who provide valuable expertise to federal agencies on various problems, from personnel decisions to complex technical difficulties.¹⁷² The Federal Advisory Committee Act¹⁷³ (FACA) requires that advisory committees be composed of members who are "balanced in terms of the points of view represented and cannot be inappropriately influenced . . . by any special interest."¹⁷⁴

Avoiding conflicts of interest, however, can be extremely difficult.¹⁷⁵ Consider silicone gel breast implants. Arguably, those with the most expertise are manufacturers and surgeons, precisely those who derive a pecuniary benefit from the availability of the devices. Clearly, a potential conflict of interest exists. If the committee is to be comprised of a balance of members representing various interests, then there must be experts on the advisory committee who are advocates of regulation and who place a high value on health and safety. The difficulty with this is that members who speak out on behalf of the public are not always experts. Where unavoidable conflicts of interest exist, the FDA should factor into its decisions who was advising and to what degree an expert's conflict of interest may influence his or her judgment.

The FDA should require committee members to submit financial disclosures of potential conflicts of interest and such

171. Soon after his election victory, President Clinton imposed a five-year ban on certain lobbying for major executive branch appointees and a lifetime curb on representing foreign governments. If similar ethical reforms applied to Congress' campaign financing, institutional congressional bribery could be greatly curtailed. Cf. Rob Quartel, *Reform Congress Too*, WASH. POST, Dec. 15, 1992, at A23.

172. Michael H. Cardozo, *The Federal Advisory Committee Act in Operation*, 33 ADMIN. L. REV. 1, 1-2 (1981).

173. 5 U.S.C. §§ 1-15 (1988 & Supp. I 1989).

174. Nuskiewicz, *supra* note 49, at 959.

175. *Id.* at 975.

conflicts should be disclosed to the public. Additionally, if other conflicts of interest exist, they should be published in the Federal Register so that the public has knowledge of such conflicts. Not only may knowledge of publication deter serious conflicts of interest from arising, but it can foster respect for the FDA's credibility concerning important and controversial decisions.

F. SCIENTIFIC DECISIONMAKING BODIES SUCH AS THE BOARD OR ADVISORY PANEL SHOULD DEFINE AN UNACCEPTABLE LEVEL OF UNCERTAINTY OF KNOWLEDGE ON A PARTICULAR QUESTION

Many decisions, especially those involving technical difficulties, are based on conflicting views or on evidence which has not been conclusively proven. In such cases, FDA advisors should factor into their rulemaking decisions the level of uncertainty of knowledge on a particular question. "The regulator can then apply that definition as a factor in making the final decision of a regulatory matter."¹⁷⁶ This would enable the agency more flexibility in its determinations and, because the decision would be based on inconclusive evidence, would constitute constructive notice to the public in the event that the agency gathers more information and changes its policies accordingly.

G. STATES SHOULD IMPLEMENT THEIR OWN SAFETY REGULATIONS TO SUPPLEMENT THOSE PROMULGATED BY CONGRESS AND THE FDA

Although medical devices are federally regulated, states may impose safety regulations on them, provided that such state law requirements are not "in addition to or different from those mandated by the FDA."¹⁷⁷ Thus, if the FDA has not yet imposed restrictions on particular medical devices, such as preamendment devices,¹⁷⁸ a state may establish statutes, regula-

176. Smyth, *supra* note 158, at 640.

177. King v. Collagen Corp., No. 92-1278, 1993 U.S. Dist. LEXIS 432 (1st Cir. Jan. 15, 1993) (holding that regulatory approval of medical devices largely shields manufacturers from liability for injuries to users); *see also* Desmarais v. Dow Corning Corp., 712 F. Supp. 13, 14 (D. Conn. 1989) (holding that agency regulations will preempt state or local legislation only if such legislation is in conflict with the federal law or frustrates its purpose).

178. *See supra* note 21.

tions, or ordinances to regulate them.¹⁷⁹ If, however, the FDA has imposed federal requirements relating to a medical device, the law provides that states may petition the FDA to permit additional state requirements.¹⁸⁰

Because federal regulation, by itself, may provide insufficient protection, states should be encouraged to enact legislation to more effectively protect their citizens. Prior to the FDA's decision to require silicone gel breast implant patients to read and sign a detailed informed consent form,¹⁸¹ Maryland¹⁸² and Nevada¹⁸³ had laws requiring such disclosure. California recently adopted a similar law, requiring surgeons and physicians to inform patients of possible risks which may be linked to silicone gel breast implants.¹⁸⁴

States might also consider legislation requiring corporations to disclose concealed dangers of products. California's new Corporate Criminal Liability Act¹⁸⁵ requires that manufacturers notify California state officials of serious concealed dangers in a product introduced in the state. Punishable by imprisonment and/or a fine, such laws may force corporate decisionmakers to evaluate the dilemma between safety and economic gain more carefully.¹⁸⁶ Presently, the district attorney in Los Angeles is investigating whether Dow Corning violated this law by failing to notify California state officials about the dangers of the company's silicone gel breast implants.¹⁸⁷ Such investigations should continue and prosecutions should proliferate. Policy changes at the state level will earn public approval, which in turn may generate positive reforms at the federal level.

179. 21 U.S.C. § 360(k)(a)(1)(2) (1992).

180. 21 U.S.C. § 360(k)(b) (1992).

181. FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, BACKGROUND INFORMATION: USE OF SILICONE GEL-FILLED BREAST IMPLANTS UNDER STAGE 2 PROTOCOLS (1992).

182. MD. HEALTH-GEN. CODE ANN. §§ 20-114 (1992).

183. NEV. REV. STAT. ANN. § 449.750 (1991).

184. CAL. BUS. & PROF. CODE § 2259 (Deering 1992).

185. CAL. PENAL CODE § 387 (Deering 1992).

186. Corporate officers may face up to three years in a state penitentiary and a \$25,000 fine. *Id.*

187. Mann, *supra* note 125, at E3.

V. CONCLUSION

Industry representatives and consumer advocacy groups have often disagreed over the degree of regulation that governmental administrative bodies should employ. On the one hand, it is costly and inefficient to go through the maze of regulatory procedures which is presently required. On the other hand, consumers should have some assurance that business cannot disregard safety and manufacture products with total disregard for the ultimate consumer. A balance can and must be struck between the needs of industry and the desire for an acceptable degree of safety. Achieving such a balance will require cooperation from Congress, the FDA, industry representatives, consumer advocacy groups, manufacturers, and the public at large. Positive steps have been made toward effectuating more responsible industry, government, and consumer representatives. President Clinton began speaking of government ethics reform and conflict of interest problems shortly after his election victory.¹⁸⁸ Additionally, a variety of consumer groups have emerged, with the goal of gathering and disseminating crucial information for women considering breast implant surgery.¹⁸⁹ Fifty corporations have formed a trade association called Business for Social Responsibility to counter organizations such as the U.S. Chamber of Commerce and the now disbanded White House Competitiveness Council.¹⁹⁰ More importantly, the FDA has made reforms toward tough regulatory enforcement in matters affecting public safety. The travesty of DES, the Dalkon Shield, and silicone gel breast implants must not be ignored or repeated. It is essential for federal regulation to compel manufacturers to comply with safety and disclosure requirements. The FDA should continue to work toward overcoming problems in the current regulatory scheme for all who rely on its expertise.

188. Quartel, *supra* note 171, at A23.

189. Such organizations include Command Trust Network, Inc., Public Citizen's Health Research Group, National Women's Health Network, American Silicone Implant Survivors, and the Breast Implant Information Foundation. Gladwell, *supra* note 132, at Z10.

190. *Capitalism with a Conscience*, 24 NAT'L J. 1422, 1422 (1992). Business for Social Responsibility intends to work for stronger safety regulations and lobby for increased investment in health, education and welfare. Members include Cedar Knolls, Body Shop USA, First Housing Co., Ben & Jerry's Ice Cream, Lotus Development Corp., and Reebok International, Ltd. *Id.*