



1975

The Intrauterine Device: A Criticism of Governmental Complaisance and an Analysis of Manufacturer and Physician Liability

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Recommended Citation

Note, The Intrauterine Device: A Criticism of Governmental Complaisance and an Analysis of Manufacturer and Physician Liability, 24 Clev. St. L. Rev. 247 (1975)

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CLEVELAND STATE LAW REVIEW

Volume 24

Spring 1975

Number 2

NOTES

*The Intrauterine Device: A Criticism of Governmental Complaisance and An Analysis of Manufacturer and Physician Liability*¹

OF THE MANY BIRTH CONTROL TECHNIQUES currently in use,² perhaps the most controversial is the intrauterine device (IUD).³ Although not a widely accepted method of contraception until the late 1960s,⁴ the concept of inserting a foreign object into the vagina to prevent conception is by no means novel to our times. For centuries Arabian and Turkish camel drivers have inserted small stones into the uteri of their saddle camels prior to embarking on caravans in

¹ Since there are no reported cases involving intratuterine devices at the present time (although there are numerous actions pending throughout the nation), the discussion in this note will be based primarily on the information brought out at the hearings conducted by the Hon. H. L. Fountain of North Carolina on May 30, 31 and June 1, 12, 13, 1973, *Hearings on Intrauterine Contraceptive Devices Before a Subcomm. of the House Comm. on Government Operations*, 93d Cong., 1st Sess. (1973) [hereinafter cited as *Fountain Hearings*].

² The methods are abstinence; coitus interruptus; the rhythm system; diaphragms; condoms; the pill; the mini-pill; the IUD; tubal ligation; vasectomy; and the many vaginal foams, creams and jellies. Also in use are two so-called "just-in-case measures," the morning-after pill and menstrual extraction.

³ In addition to the extensive examination of the IUD industry conducted by Representative Fountain, *supra* note 1, Senator Edward Kennedy devoted a portion of his hearings on the medical device industry solely to the IUD, *Hearings on Medical Device Amendments, 1973 before the Subcomm. on Health of the Senate Comm. on Labor and Public Welfare*, 93d Cong., 1st Sess. (1973) [hereinafter cited as *Kennedy Hearings*]. Moreover, several women's organizations, including the Coalition for Medical Rights of Women, have petitioned the California Department of Health for stringent regulation of IUD sales in that state, *N. Y. Times*, Sept. 1, 1974, at 14, col. 3. A formal evidentiary public hearing to discuss the Department's proposed draft of regulations relating to IUDs was held in San Francisco on March 5, 1975. Letter from Ms. Erica Black Grubb, attorney for the Coalition for Medical Rights of Women, Feb. 20, 1975, on file in the Cleveland State Law Library. See also Le Roux, *Suits evoke liability juror over birth control IUD*, *BUS. INS.*, Sept. 16, 1974, at 10; Katz, *An IUD, Safety, and 'Sound, Scientific Principles'*, *NAT'L OBSERVER*, Sept. 7, 1974, at 10; *N. Y. Times*, Aug. 22, 1974, at 17, col. 1; *A Plague of Problems*, *FORBES*, Aug. 15, 1974, at 35; *Doubts About IUDs*, *TIME*, July 15, 1974, at 81; Brody, *Birth-Curb Group Acts On IUD Risk*, *N. Y. Times*, May 30, 1974, at 17, col. 1; *N. Y. Times*, May 29, 1974, at 49, col. 1. For a listing of the many discussions on IUDs in the scientific literature, see the extensive bibliographies contained in the *Fountain Hearings* at 67-72, 480-98, 509-14.

⁴ It was at this time that the Advisory Committee on Obstetrics and Gynecology of the Food and Drug Administration made their Report on Intrauterine Contraceptive Devices,

(Continued on next page)

an effort to prevent the animals from copulating.⁵ Moreover, the IUD is mentioned in both the Talmud and the writings of Hippocrates as a potential method of controlling fertility.⁶ However, even in these early historical stages there must have been doubts about the IUD's efficacy and safety, for it is reported that Cleopatra preferred the use of a sponge soaked in vinegar to the insertion of a device.⁷

In the late nineteenth century IUDs composed of metal were first introduced. While these early devices (now termed "first generation")⁸ were at first widely extolled in scientific writings,⁹ by 1930 the medical profession had concluded that the IUD's propensity to to harm far outweighed its utility.¹⁰ From 1930 to 1958 the medical profession expressed little interest in the IUD as a feasible method of birth control; but with the invention, in 1959, of a new polyethelene device¹¹ there grew a resurgence of interest and revitalization of research efforts.¹² Within five years this "second generation" IUD¹³

(Continued from preceding page)

in *Fountain Hearings* at 431. The Advisory Committee found "adequate scientific data attesting the effectiveness and utility of the intrauterine device." *Id.* at 441. See also Hilgers, *The Intrauterine Device: Contraceptive or Abortifacient?*, in *Fountain Hearings* at 499-500 for an historical survey of the tests conducted on, and the medical profession's feeling about, the IUD prior to the 1960's [hereinafter cited as Hilgers].

⁵ Hilgers, *supra* note 4, at 499. The insertion of the stone into the camel's uterus was to "repulse the advances of the male as if the female were pregnant." *Id.*

⁶ ADVISORY COMMITTEE ON OBSTETRICS AND GYNECOLOGY OF THE FDA, REPORT ON INTRAUTERINE CONTRACEPTIVE DEVICES, in *Fountain Hearings* at 431, 436 [hereinafter cited as ADVISORY COMMITTEE ON OBSTETRICS AND GYNECOLOGY OF THE FDA] *A Plague of Problems*, FORBES, Aug. 15, 1974, at 35.

⁷ *A Plague of Problems*, FORBES, Aug. 15, 1974, at 35.

⁸ Ostergard, *Intrauterine Contraception in Nulliparas with the Dalkon Shield*, 116 AM. J. OB. GYN. 1088 (1973). The first generation IUDs were primarily those patterned after the Graefenberg ring, and, as the author points out, were not adaptable to the nulliparous female (women who have never born children).

⁹ The extensive writings on IUDs during this period generally discussed their utility not as a form of contraception or birth control but rather as a method for correction of uterine displacement. ADVISORY COMMITTEE ON OBSTETRICS AND GYNECOLOGY OF THE FDA, *supra* note 6, at 436.

¹⁰ The severe and often fatal pelvic infections associated with the metallic intra-uterine contraceptive devices used in the 1920's and early 1930's led to almost uniform condemnation of this method of contraception.

Marshall, Hepler & Jinguji, *Fatal Streptococcus Pyogenes Septicemia Associated with an Intrauterine Device*, 41 OB. GYN. 83 (1973). See also ADVISORY COMMITTEE OF OBSTETRICS AND GYNECOLOGY OF THE FDA, *supra* note 6, at 431, 436; Hilgers, *supra* note 4, at 499, 500.

¹¹ Japanese scientists were among the first to use inert plastic materials for IUDs, and tests done by Ota and Ishihama, in 1959, helped revive interest. Also, the development of new insertion techniques which did not require dilatation of the cervix helped advance the proposition that this form of birth control was now more feasible. ADVISORY COMMITTEE ON OBSTETRICS AND GYNECOLOGY OF THE FDA, *supra* note 6, at 431, 436.

¹² Hilgers, *supra* note 4, at 499, 500. This was also the year in which Dr. W. Oppenheimer of Israel and Dr. A. Ishihama of Japan published studies showing IUD as safe, reliable and effective, and by so doing "the door was open for a 'reevaluation.'" *Id.* See Ishihama, *Clinical Studies on Intrauterine Rings Especially the Present State of Contraception in Japan and the Experiences in the Use of Intrauterine Rings*, 10 YOKOHAMA MED. BULL. 89 (1959); Oppenheimer, *Prevention of Pregnancy by the Graefenberg Ring Method: A Re-evaluation After 28 Years' Experience*, 78 AM. J. OB. GYN. 446 (1959) (author described experiences over a 28 year period with a silkworm gut ring and concluded that the method was "absolutely harmless").

¹³ Ostergard, *supra* note 8, at 1088.

slowly gained in popularity,¹⁴ primarily through the efforts of the World Population Council in underdeveloped areas of the world.¹⁵ In the United States, the impetus for acceptance was provided by the Senate Hearings on Oral Contraceptives conducted in early 1970.¹⁶ The adverse publicity received by the pill in those hearings engendered such a panic that an estimated one million women ceased using oral contraceptives within the six month period following the hearings.¹⁷ For many of these women the IUD appeared to be the only suitable alternative, especially since testimony in the Nelson Hearings had depicted the IUD as a safe, viable substitute for the pill.¹⁸ Thus, by the end of 1970 over three million American women — and twelve million around the world — were fitted with a device.¹⁹

While undeniably an alternative method of birth control was needed for those women who had foregone the pill, it is indeed questionable that the IUD was the logical choice. Medical scientists even today know neither how the IUD works²⁰ nor the extent or gravity of its possible (or for that matter probable) adverse effects.²¹ Since the reason for the abandonment of the pill by so many women after the Nelson Hearings was the fear of possible adverse effects, it is indeed a curious phenomenon that this method of birth control

¹⁴ See ADVISORY COMMITTEE ON OBSTETRICS AND GYNECOLOGY OF THE FDA, *supra* note 6; Hilgers, *supra* note 4.

¹⁵ The Rockefeller Foundation founded the Population Council in 1952 to study population growth, and in 1962 it held the first International IUD Conference which was attended by representatives from eleven countries. The second conference was held in 1964 and was attended by 500 participants from 44 countries. Hilgers, *supra* note 4, at 500, 501.

¹⁶ *Hearings on Safety of Oral Contraceptives Before a Subcomm. on Monopoly of the Senate Select Comm. on Small Business*, 91st Cong., 2d Sess., pt. 15, vol. 1, at 5921 (1970).

¹⁷ Statement of Russel J. Thomsen, M.D., in *Fountain Hearings* at 143.

¹⁸ Statement of Larry R. Pilot, Director, Division of Compliance, Office of Medical Devices, in *Fountain Hearings* at 249; Letter from John G. Madry, M.D. to Louis M. Wellman, M.D., Sept. 18, 1970, in *Fountain Hearings* at 24.

¹⁹ Statement of Sherwin Gardner, Acting Commissioner, Food and Drug Administration, in *Fountain Hearings* at 198-99.

²⁰ Hilgers, *supra* note 4, at 499, 501. It is unclear whether the IUD should be termed a contraceptive or an abortifacient. If a contraceptive, then the IUD prevents conception; if an abortifacient, then the IUD is an agent which induces abortion after conception. Under either definition there are numerous theories as to how the IUD performs its function, but with the present inadequate data there is no general consensus. It is interesting to note that the World Health Organization, the scientific group which accepted for the medical profession the name IUD, rejected unanimously the name IUCD (intrauterine contraceptive device), thus at least implying their doubts as to its contraceptive propensity. Dr. Thomas Hilgers, a fellow in obstetrics and gynecology at the Mayo Graduate School of Medicine, after an exhaustive review of every available scientific study on human subjects wearing intrauterine devices, has concluded that the IUD is an abortifacient. *Id.* at 508.

²¹ The problem of discovering the scope of the adverse effects lies in the area of reporting, for "gynaecological patients are loyal creatures, and do not like to upset the kind doctors who fitted the device by recounting a failure." Letter from Dr. Dennis F. Hawkins, Institute of Obstetrics and Gynecology, University of London, to the Editor of the British Medical Journal, in *Fountain Hearings* at 314. See Statement of Senator Gaylord Nelson, in *Fountain Hearings* at 46; Note, *The Effectiveness of FDA Medical Device*

became the substitute for the pill and gained such widespread acceptance. This development is especially perplexing in view of the medical profession's universal rejection of first generation IUDs only a few years earlier.

The post-Nelson acceptance of the IUD, when contrasted with the dearth of medical knowledge, becomes more readily comprehensible when the industry's practices are examined; from such an analysis two main reasons explaining the industry's ability to command acceptance of the IUD are immediately discernable. First, since the IUD is classified as a device rather than a drug,²² the Food and Drug Administration (FDA) may not impose any pre-marketing controls on the manufacturing, testing, or distribution processes.²³ Thus an IUD manufacturer need not fear governmental intervention regarding the sufficiency of the testing of the device; a situation that would be encountered if the IUD were classified by the FDA as a drug. Second, the margin of profit available to an IUD manufacturer is enormous. When manufactured in large lots, an IUD is produced for about thirty-five cents, while the price to the physician is three dollars and fifty cents — a mark-up of one thousand percent.²⁴ Added to this sum, the patient must then pay the physician an average of thirty-five dollars for the insertion.²⁵ This potential for profit,²⁶ coupled with the paucity of governmental control, provides little incentive, indeed, for pre-market testing²⁷ and much compulsion for glib over-promotion.²⁸ With this backdrop, then, it is not the least bit surprising that the number of IUD users had risen to an estimated thirty million by 1973.²⁹

²² 21 C.F.R. § 310.502 (1974). See note 72 *infra* for a summary of the regulation's provisions. See also Statement of Sherwin Gardner, Acting Commissioner, Food and Drug Administration, in *Fountain Hearings* at 199.

²³ See text accompanying notes 55-60 *infra*.

²⁴ Statement of Russel J. Thomsen, M.D., in *Fountain Hearings* at 58.

²⁵ *Id.* at 56. Dr. Thomsen's figure was arrived at by surveying physicians in the metropolitan Washington area. He further testified that the actual insertion of the IUD takes about five minutes. See also THE BOSTON WOMEN'S HEALTH BOOK COLLECTIVE, OUR BODIES, OUR SELVES: A BOOK BY AND FOR WOMEN 123 (1973) (stating that the cost of an insertion in the Boston area is \$35-\$50 and \$50-\$100 in the New York City area).

²⁶ IUDs are manufactured and used by the millions. Companies in the United States have produced 30 million IUDs for both domestic and foreign sales since 1959.

Statement of Russel J. Thomsen, M.D., in *Kennedy Hearings*, *supra* note 3, at 368. Further proof of the magnitude of the market is evidenced by the fact that there were, in 1973, over 70 models of IUDs, and the number was still "sprouting." Statement of Louis B. Tryer, M.D., Project Director, Family Planning Division, The American College of Obstetricians and Gynecologists, in *Fountain Hearings* at 384.

²⁷ See text beginning at note 124 *infra*, for a discussion of the importance of pre-market testing.

²⁸ For examples of the promotional literature see *Fountain Hearings* at 73-108. One physician has charged that these promotional tactics have forced American physicians to "unwittingly become participants in a great experiment in population control, utilizing as experimental subjects patients for whom the IUD was not even the prime target for usage." Statement of John G. Madry, M.D., in *Fountain Hearings* at 11.

Statement of Russel J. Thomsen, M.D., in *Fountain Hearings* at 368.

The switch from the pill, however, has not been without adverse consequences to the IUD user. Testimony at the Fountain Hearings³⁰ on IUDs in mid-1973 and complaints received by the FDA in the past several years³¹ have revealed a plethora of untoward reactions experienced by numerous users,³² the most catastrophic of which have resulted in death.³³ Among the more severe effects have been acute pelvic infection,³⁴ perforation of the uterine wall with migration of the IUD into the abdominal cavity or into the intestines necessitating

³⁰ For examples of testimony enumerating the adverse reactions to IUDs see *Fountain Hearings* at 9-10, 42-43, 50-56, 109-114, 440-41, 460-61, 463-65. When reviewing the testimony the terms "adverse effect" and "contraindication" should not be confused. An adverse effect is a result contrary to the one intended or desired and detrimental to the patient's will being. A contraindication refers to a "special symptom or circumstance that renders the use of a remedy or the carrying out of a procedure inadvisable." *STEDMAN'S MEDICAL DICTIONARY* 283 (3d Lawyers ed. 1972).

Contraindications for the IUD are:

Contraindications . . . include evidence of known or suspected pregnancy; acute or subacute pelvic inflammatory disease; history of incapacitating dysmenorrhea or menorrhagia; known or suspected cervical or uterine malignancy; hypoplasia or distortion of the uterine cavity; cervical stenosis; or abnormal Papanicolaou smears.

Kennedy Hearings, supra note 3, at 591.

³¹ Copies of the FDA Complaint File, complete through July 1974, were made available to the *Cleveland State Law Review* by Paul D. Rheingold, Esq. [hereinafter cited as FDA Complaint File]. Copies of the File may be obtained directly from the FDA.

³² "The Cumulated Index Medicus, 1972" has 59 listings under Adverse Effects of IUDs, *Fountain Hearings* at 9-10. In addition to those adverse reactions mentioned in this note are numerous allegations in the FDA Complaint File that the IUD: has caused excessive bleeding; has caused excessive and protracted pain, often necessitating removal; and has embedded in the uterine wall. See also Deming, *Lés Loop; Medicolegal Aspects*, 16 *MED. TRIAL TECH. Q.* 1 (March, 1970).

³³ The mortality rate associated with the use of IUDs is 31.6/100,000, as compared to 3/100,000 for the pill. *Fountain Hearings* at 27-28. Although the exact number of deaths directly attributable to the IUD is unknown, a letter from Raymon B. Wait, M.D., of the Mead Research Center to John G. Madry, Jr., M.D., February 18, 1970 is illuminating for its inclusion of the following table from the May 8, 1969 issue of the *New England Journal of Medicine*:

Risks of Pregnancy Per Million Reproductive Age Women Per Year

Method	Pregnancies	Deaths		
		Due to complications of pregnancy	Due to method	Total deaths
IUD	50,000	12 to 60	24	40 to 80
The pill	10,000	3 to 15	12 to 24	15 to 40

Fountain Hearings at 19. See also Marshall, Hepler & Jinguji, *supra* note 10, at 83; Scott, *Critical Illnesses and Deaths Associated with Intrauterine Devices*, 31 *OB. GYN.* 322, 323-26 (1968); Tsukada, *Ectopic Pregnancy Associated with Use of an Intrauterine Contraceptive Device — Report of Two Cases in which Autopsies Were Performed*, 204 *J.A.M.A.* 331 (1968) (two cases where IUD users died as a result of hemorrhaging that could have been prevented if the correct diagnosis had been made; but suggesting that the difficulty in diagnosis was attributable in part to the presence of the IUD).

³⁴ For two case studies of serious infections (pelvic abscess) caused by an IUD see Wilson & Dilts, *Unusual Complication of an Intrauterine Contraceptive Device*, 112 *AM. J. OB. GYN.* 237 (1972) (two case studies illustrate the potential severe complications that may result from the supposedly "minor" infections commonly associated with the IUD).

surgical removal,³⁵ ectopic pregnancy,³⁶ and septic spontaneous abortion.³⁷ It has also been alleged that IUD users have an average menstrual blood loss more than twice that of non-users,³⁸ a reaction which can lead to secondary anemia and is particularly undesirable among teenagers and nutritionally deficient populations.³⁹ An additionally distressing feature has been the allegation that the pregnancy rate among IUD users may be as high as ten percent⁴⁰ in spite of the fact that manufacturers promise a rate in the area of one or two percent.⁴¹

In addition to the adverse effects attributable to the unknown workings of an IUD on the female physiology, the defects in IUDs *qua* IUDs have not gone without notice. The FDA has received numerous reports of instances in which removal strings have broken upon attempted removal; devices have become disengaged from the inserter before they were completely in place, high in the fundal cavity; devices have broken during insertion or removal; and some devices have been so radiolucent that they could not be located by

³⁵ As with all the data concerning percentages for untoward effects, the recorded percentages for perforation instances varies. The Advisory Committee reported instances varying from .04% to .9%, *Fountain Hearings* at 460. Other reporters have found much higher percentages, one finding that "about two percent . . . may have migration . . . into the abdomen or pelvis . . . and such migration may require immediate surgery for its removal. . . ." Deming, *supra* note 32, at 2. Perforation of the wall apparently occurs in one of three ways: the physician is negligent in his insertion technique and perforates the uterus; the design of the IUD and inserter is such that perforation is caused upon insertion regardless of the physician's due care; or, the IUD migrates after insertion and subsequently pierces the uterine wall. For reports of perforation cases see Sprague & Jenkins, *Perforation of the Uterus with a Shield Intrauterine Device*, 41 OB. GYN. 80 (1973); Deming, *supra* note 32, at 1.

³⁶ An ectopic pregnancy can be described as the development of an impregnated ovum occurring in the cervical canal, the fallopian tube, an ovarian follicle, the peritoneal cavity or any other site outside the uterine cavity. *STEDMAN'S MEDICAL DICTIONARY* 1013-14 (3d Lawyers ed. 1972). Ectopic pregnancies occur in about 1 out of 300 pregnancies when no IUD is in situ and always require major surgery and often require blood transfusions, "and must be considered a threat to the life and future fertility of the woman." *Fountain Hearings* at 51. Approximately one out of twenty pregnancies occurring with an IUD in situ is ectopic, but the Advisory Committee reported that "there is no evidence that the presence of an IUD can cause a conceptus to implant ectopically. The high relative frequency of tubal pregnancies results from the successful prevention of most uterine pregnancies." *Fountain Hearings* at 461. Thus whether or not the presence of an IUD is causative has not conclusively been demonstrated, for as the Advisory Committee states "there is no evidence" to support the hypothesis that IUDs cause ectopic pregnancies. But others disagree. See Hilgers, *supra* note 4, at 507.

³⁷ A spontaneous abortion is one not artificially induced, and a septic abortion is an infected abortion complicated by fever, endometritis, and parametritis. *STEDMAN'S MEDICAL DICTIONARY* 3 (3d Lawyers ed. 1972). Therefore a septic spontaneous abortion is a natural abortion induced by infection.

³⁸ Statement of Russel J. Thomsen, M.D., in *Fountain Hearings* at 54. This is an especially dangerous problem for there is no quantitative methodology for measuring blood loss. Testimony by Jack Freund, M.D., in *Fountain Hearings* at 331.

³⁹ Statement of Russel J. Thomsen, M.D., in *Fountain Hearings* at 54.

⁴⁰ Statement of Louise B. Tyrer, M.D., Project Director, Family Planning Division, The American College of Obstetricians and Gynecologists, in *Fountain Hearings* at 367. Even this high percentage is not conclusive as being the outer limits of failure as shown by the various testimonies and data presented throughout the Fountain Hearings.

x-ray after migration had occurred.⁴² Although these malfunctions appear quite innocuous compared to the aforementioned adverse effects, it must be remembered that in most instances they necessitate surgical procedures which can be as costly as they are dangerous.⁴³

It is difficult to understand how a product so intimately connected with a bodily function and presenting such a potential for serious harm was allowed on the market without pre-market clearances assuring that it had met at least minimum standards of safety. This development is especially distressing since there exists a governmental agency whose sole function is to protect the public interest in precisely this type of situation. Since the law of products liability should not deny a remedy to the unwary consumer whose reliance on the overzealous representations of the manufacturer ended in tragedy, this note will examine the conduct of the FDA and FTC in light of existing legislation and case law in an effort to ascertain whether they have adhered to the mandate of Congress, and analyze the potential liability of the IUD manufacturer and the prescribing physician in light of the present law of products liability.

The Government

The purpose of the Federal Food, Drug and Cosmetic Act⁴⁴ is to protect the health and safety of the American consumer from products falling within certain enumerated classifications that are found to be unsafe. All foods, drugs and cosmetics are covered, as are medical devices, however, the Act grants the FDA more authority to control some classifications than others. While drugs and medical devices are both given treatment under the Act, the breadth of permissible controls accorded the FDA varies greatly between these two categories; the device controls are not nearly as extensive. This variance in FDA powers, dependent on whether a product is deemed a device or a drug, is most critical since the Act's definitions of drugs

⁴² FDA Complaint File, *supra* note 31. Some of the other more prominent complaints, against the device itself, appearing in the FDA files were: calcification of the IUD leading to difficult removal; strings remaining in the uterus after removal; strings become detached while the IUD is in situ; inserters bending on insertion; IUDs not disengaging on insertion; strings disappearing making it impossible to check if IUDs are correctly positioned; often unable to remove the IUD without surgery; if string is multifilament it may contribute to infection. Furthermore, the utilization of x-rays for locating a migrating IUD is itself not without complications. The x-rays, if they show the IUD at all, will show where the IUD was on the day the x-ray was taken, and if the day is not the same as the day of the surgery the IUD's location may be different. Moreover, the possibility of endangering a developing fetus by the use of x-rays is an always present problem. Deming, *supra* note 32, at 5.

⁴³ If the IUD has perforated the uterus and migrated into the abdomen, the "costs of surgical removal and hospitalization covering that event could easily run to \$1,000. The same could be said for an IUD associated tubal pregnancy or incomplete miscarriage." Statement of Russel J. Thomsen, M.D., in *Fountain Hearings* at 57.

⁴⁴ 21 U.S.C. §§ 301-92 (1970)

and devices are barely distinguishable. As will be seen, this situation can often lead to drastic consequences for the consumer.

When the product in question has been classified as a drug, the Act gives a diligent FDA ample authority to ensure that minimal standards of safety have been met before the product is placed on the market.⁴⁵ If the drug is not exempted by the grandfather clause,⁴⁶ the manufacturer must file a new drug application with the FDA.⁴⁷ This application is designed to ensure that, prior to marketing, adequate scientific and medical evidence exists establishing the product's safety and efficacy. The information submitted to the FDA is composed of toxicology studies on animals, human pharmacological studies in controlled populations, and precise formulation and manufacturing information.⁴⁸ Prior to giving formal approval the FDA must also approve all labels,⁴⁹ labelling,⁵⁰ and prospective advertisements.⁵¹

⁴⁵ 21 U.S.C. § 355 (1970).

⁴⁶ The grandfather clause is contained in 21 U.S.C. § 321(p) (1) (1970), quoted in part at note 47 *infra*.

⁴⁷ 21 U.S.C. § 355(a) (1970) gives the FDA authority to monitor new drugs prior to marketing in interstate commerce:

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) of this section is effective with respect to such drug.

A "new drug" is defined in 21 U.S.C. § 321(p) (1970):

(1) Any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for the use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug . . . the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations been used to a material extent or for a material time under such conditions.

⁴⁸ Radzius, *The Federal Food, Drug and Cosmetic Act — Drug or Device?*, 8 WAKE FOREST L. REV. 527, 530 (1972). See Note, *Liability of Birth Control Pill Manufacturers*, 23 HAST. L.J. 1526, 1532-33 (1972). See also Cooper, *Device Legislation*, 26 FOOD DRUG COSM. L. J. 165, 166 (1971) wherein five steps are listed as "accepted scientific practice":

First, new drugs are tested in animals; second, there is limited clinical testing in humans; third, there is broader testing in larger human populations; fourth, developers have their data reviewed informally by their scientific peers through the literature; fifth, data is given formal review by Food and Drug Administration (FDA) specialists under the new drug provisions of the Act. The aim of the process is to protect patient, physician and the public from unsafe and ineffective drugs. Government involvement is based on the notion that the public cannot protect itself alone; that the nature of drug action is too complicated a process for any but experts to judge.

⁴⁹ A "label" is defined in 21 U.S.C. § 321(k) (1970) as "a display of written, printed, or graphic matter upon the immediate container of any article . . ." This definition is applicable to devices as well as drugs.

⁵⁰ 21 U.S.C. § 355(b) (1970). The definition of "labeling," applicable to drugs and devices, is different and more encompassing than "label" is found in 21 U.S.C. § 321(m) (1970) ("The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article"). See also Davis, *Labeling Requirements for Medical Devices*, 27 FOOD DRUG COSM. L. J.

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Even after approval is given, however, the FDA retains a continuing jurisdiction. All adverse reactions experienced by the general population that are brought to the manufacturer's attention must be adequately recorded and are subject to FDA review.⁵² Moreover, every drug manufacturer is required to register with the FDA annually,⁵³ and his establishment is subjected to an inspection at least biennially to ensure his compliance with good manufacturing practices.⁵⁴ Although this policing task is monumental in relation to the number of drugs on the market, when properly performed, it does have the effect of ensuring that minimal health and safety standards are met before a product achieves general distribution.

Medical devices, on the other hand, are controlled by statutory powers that the FDA can exert only after-the-fact.⁵⁵ There are no requirements that a manufacturer of a medical device establish its safety or efficacy prior to marketing. Once the manufacturer has convinced himself and the medical profession that his product is safe and effective, the device can be successfully marketed.⁵⁶ These problems are further complicated by the FDA's lack of authority to police ante or post marketing advertisements for products classified as devices, but this function is within the domain of the Federal Trade Commission (FTC). These restrictions result in the confinement of FDA regulatory efforts to the policing of device labels and labeling.⁵⁷

(Continued from preceding page)

608, 610 (1972) wherein the author, the Director of the Division of Scientific Review, Office of Medical Devices, states:

Labeling also includes oral presentations and reprints of scientific or clinical reports published in professional journals or other scientific publications used for promotional purposes. Reprints used as promotional material constitute labeling for the product. The distributor of promotional material should realize that he, through this use, is assuming the responsibility for the factuality, truthfulness, and scientific validity of the author's report.

⁵¹ 21 U.S.C. § 355(b) (1970); Radzius, *supra* note 48, at 530.

⁵² It is a prohibited act under 21 U.S.C. § 331(e) (1970) for a drug manufacturer to fail to keep adequate records; and, the power to inspect is granted to the FDA under 21 U.S.C. § 374(a)(2) (1970). See also Note, *supra* note 21, at 296.

⁵³ 21 U.S.C. § 360(b) (1970).

⁵⁴ 21 U.S.C. § 360(h) (1970); Radzius, *supra* note 48, at 530.

⁵⁵ Hutt, *What is a Device?*, 27 FOOD DRUG COSM. L.J. 617, 620-21 (1972).

⁵⁶ Radzius, *Medical Devices and Judicial Legislation*, 27 FOOD DRUG COSM. L.J. 639, 641 (1972).

⁵⁷ The provisions of the Food, Drug and Cosmetic Act, applicable to devices, are: 21 U.S.C. § 351 (1970) (adulterated devices — if IUD has been "prepared, packed, or held under unsanitary conditions . . ."; 21 U.S.C. § 352 (1970) (misbranded devices — if IUD has false or misleading labeling; if labeling does not bear "adequate directions for use" or "adequate warnings"; if device is dangerous to health when used with the frequency or duration prescribed, recommended, or suggested in the labeling thereof).

There is an exemption for those prescription devices sold only to physicians, in 21 C.F.R. § 1.106(d) (1974), which enables the manufacturer to direct the "adequate directions for use" not to the patient but rather to the physician, and compliance is met if

The effect of this statutory aberration is that the American consumer may be subjected to untested and unsafe medical devices while the FDA, in its efforts to remove the unsafe devices from the market, is forced to assume the unseemly role of data collector until it has accumulated sufficient evidence to sustain a court action against the manufacturer.⁵⁸ This task is often rendered extremely difficult because manufacturers of medical devices are not required to maintain continuing records of misadventures with their products, nor are they required to report such mishaps to the FDA.⁵⁹

With these distinct advantages accorded the device manufacturer — at the expense of the American consumer — it is understandable why, if given a choice, most manufacturers would prefer to have their product classified as a device rather than a drug. Unfortunately, in all close questions, the existing legislation allows the achievement of just such a result since the manufacturer is allowed to make the initial determination as to the classification of his product; he need simply market the product as a device without prior consultation with the FDA. Since there are no device pre-marketing controls, in those situations where the FDA is unaware of the manufacturer's plans to market, there is no way to stop a manufacturer from implementing his plan. Unfortunately, the only recourse open to the government is an after-the-fact reclassification.⁶⁰

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Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented.

⁵⁸ Hutt, *supra* note 55, at 620-21. The evidence that must be documented is that the device "is being sold or offered for sale under false and misleading claims, that it is adulterated, or that it is unsafe for the intended use." *Id.* at 621.

⁵⁹ Statement of Sherwin Gardner, Acting Commissioner, Food and Drug Administration, in *Fountain Hearings* at 180:

However, the FDA has no statutory authority to require premarket clearance for a product classified as a device regardless of the potential impact of a device on the quality of life. Also, the FDA has no statutory authority to:

- Require registration of manufacturers of devices;
- Compel the disclosure of complaints transmitted to manufacturers;
- Require the maintenance of records and submission of reports (including clinical studies of safety and efficacy) by manufacturers, and has no statutory authority;
- Require the repair, replacement or return of violative devices.

⁶⁰ Radzius, *supra* note 56, at 641. Mr. Radzius, counsel for a device manufacturer, contends that this system should not be changed and more stringent controls should not be afforded to the Food and Drug Administration because "the decision to use most devices is made by the physician, who relies on the manufacturer's information and the medical literature. Anyone demanding stringent regulatory control of devices risks implying carelessness on the part of the physician and the medical journals alike." *Id.* However, if the manufacturer advertises in a medical journal and does so in a manner intending to mislead the physician (*i.e.*, if the data used has been doctored or at least censored by the manufacturer so that only the most favorable tests are used in the advertisement) then

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The problem of distinguishing drugs from devices under the Act evidences both the careless draftsmanship of Congress and the need for new legislation in this area.⁶¹ Under the Act, drugs are defined as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals," or "articles (other than food) intended to affect the structure or any function of the body of man or other animals."⁶² The definition of devices is identical, with the exception that the word "articles" is replaced by the words "instruments, apparatus, or contrivances."⁶³ Hence, the manufacturer of an "article" must secure pre-marketing approval from the FDA, while the manufacturer of an "instrument, apparatus, or contrivance" need not.⁶⁴

Needless to say, this unfortunate phraseology has engendered much litigation, especially with respect to those products whose efficacy and safety might not surpass the minimal standards of a new drug application and hence are deemed, by the manufacturer,

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surely the physician can not be deemed careless for his reliance on such misinformation for he has no other means at his disposal to derive more accurate information. This is a deplorable situation and unless the FDA or the FTC has notice of such misinformation (FDA for labeling; FTC for periodical), then no action will be taken. This situation is unlike the one when the labeling and advertisements for drugs, because of stringent pre-marketing controls, must first be censored by the FDA, and no misstatements will be allowed to reach the physician.

Further, reliance upon the medical press is often erroneous even in the area of drugs. Certain abuses have also been laid at the doorstep of the medical press. Thus, articles which the medical journals carry about new drugs still in their experimental stage, highly influential upon physicians reading them, may at times be more favorable than the intermediate results indicate, or may be the report of but one out of many experiments performed, or one not done according to exacting scientific principles. Even worse, it was recently demonstrated that some medical journals, which by virtue of their ownership are the captives of certain drug houses, have opened their pages to inaccurately platitudinous articles on the "miracle" effects of new drugs.

Rheingold, *Products Liability — The Ethical Drug Manufacturer's Liability*, 18 RUTGERS L. REV. 947, 959 (1964).

⁶¹ The impetus for the drafters of new device legislation was a call by President Nixon in 1969 in his consumer message to Congress for more stringent device standards. Statement of Senator Gaylord Nelson, in *Fountain Hearings* at 46; Link, *Cooper Committee Report and Its Effect on Current FDA Medical Device Activities*, 27 FOOD DRUG COSM. L. J. 624 (1972). Numerous bills have been introduced in both the House and Senate, but at the present time the powerful manufacturing lobbyists have consistently defeated the consumer's rights.

⁶² 21 U.S.C. §321(g) (6) (B), (C) (1970).

⁶³ 21 U.S.C. § 321(h) (1970).

⁶⁴ Davidson, *Preventive "Medicine" For Medical Devices: Is Further Regulation Required?*, 55 MARQ. L. REV. 405, 405-06 (1972):

This definitional dichotomy has caused much confusion and created significant problems of statutory construction for the courts. Moreover, this dichotomy, whereby "new drugs" are subject to premarket regulation but new "devices" are not, provides a loophole permitting people to be directly or indirectly injured or otherwise harmed by medical devices which are unsafe or ineffective (or both) for their intended use.

devices.⁶⁵ A welcome by-product of this often protracted litigation between the FDA and members of the industry,⁶⁶ however, has been judicial interpretation of the breadth of power actually possessed by the FDA to reclassify. It has been held that the purpose of the Act is to be the guiding principle when any determination is to be made as to whether a product is a drug or device.⁶⁷ The FDA, then, must be ever mindful of its *raison d'être*, even though, from the manufacturer's perspective, this might result in some rather perverted classifications. Thus, through utilization of the courts, the FDA has been sustained in its attempts to reclassify as drugs a tampon,⁶⁸ a sterile gauze bandage,⁶⁹ a nylon ligature loop,⁷⁰ and an antibiotic sensitivity disk (a product which never touches the human body).⁷¹

⁶⁵ Classification by a manufacturer of a product as a device rather than a drug will bypass the new drug application requirements unless the FDA challenges the classification and is successful in reclassification. For example of reclassification see notes 67-70 *infra*. For a very good explanation of the methods utilized by the FDA to remove hazardous devices from the market, instead of even attempting to reclassify, see Butts, *Legal Proceedings*, 27 FOOD DRUG COSM. L. J. 601 (1972).

⁶⁶ Litigation against device manufacturers for alleged violations of the Food, Drug and Cosmetic Act can be drawn out almost indefinitely with the American consumer bearing the brunt of the harm for the violation in the interim. United States v. Diapulse Corp. of America, 427 F.2d 25 (2d Cir. 1972) is illustrative. In *Diapulse* the FDA deemed the device a misbranded device and seized it as such in 1965, and in 1967 a jury found the device to be misbranded. United States v. Diapulse Mfg. Corp. of America, 269 F. Supp. 162 (D. Conn. 1967). The petitioner appealed and the lower court's decision was affirmed. United States v. Diapulse Mfg. Corp. of America, 389 F.2d 612 (2d Cir. 1968), *cert. denied*, 392 U.S. 907 (1968). However, because the FDA allowed the petitioner *three years* to comply with the labeling requirements of the Act, it was not until 1971 that a move for active enforcement of the earlier granted injunction was made. Then, in holding that the lower court had considered the correct factors in issuing the preliminary injunction, the injunction was finally enforced. Thus, even utilizing the court system for enforcement it took seven years to force compliance. And during the seven year period the misbranded device was allowed to be marketed, since a seizure action is an in rem proceeding and affects only those specific devices seized. See 21 U.S.C. § 334 (1970); Comment, *U. S. v. The Diapulse Corporation of America*, 8 N. ENGLAND L. REV. 111 (1972).

⁶⁷ Since the only significance in classifying AMP's products as either "drugs" or "devices" is that if they are "drugs" they may be subject to the "new drug" provisions of the Act, we must classify them with reference to the purpose for which Congress enacted those provisions. That purpose was, very clearly, to keep inadequately tested medical and related products which might cause widespread danger to human life out of interstate commerce.

AMP Inc. v. Gradner, 389 F.2d 825, 829 (2d Cir. 1968), *cert. denied*, 393 U.S. 825 (1968). See also *United States v. An Article of Drug . . . Bacto-Unidisk . . .*, 394 U.S. 784, 799-800 (1968):

Furthermore, the legislative history, read in light of the statute's remedial purpose, directs us to read the classification "drug" broadly, and to confine the device exception as nearly as is possible to the types of items Congress suggested in the debates, such as electric belts, quack diagnostic scales, and therapeutic lamps, as well as bathroom weight scales, shoulder braces, air conditioning units, and crutches.

⁶⁸ *United States v. Article of Drug "Mykocert"*, 345 F. Supp. 571 (N.D. Ill. 1972). It should be noted that the tampon was reclassified as impregnated with a drug.

⁶⁹ *United States v. 48 Dozen Packages, More or Less, of Gauze Bandage Labeled in Part Sterilized*, 94 F.2d 641 (2d Cir. 1938).

⁷⁰ *AMP Inc. v. Gardner*, 389 F.2d 825 (2d Cir. 1968), *cert. denied*, 393 U.S. 825 (1968).

⁷¹ *United States v. An Article of Drug . . . Bacto-Unidisk . . .*, 394 U.S. 784 (1968). Other cases concerning classification: *United States v. Article . . . Consisting of 216 Cartoned Bottle, More or Less, Sudden Change*, 409 F.2d 734 (2d Cir. 1969) (face

In light of the broad power possessed by the FDA and the willingness of the judiciary to give full credence to the presumption of agency expertise, it is most peculiar that the FDA has allowed the IUD to be marketed as a device. Not only was the FDA cognizant of the IUD before its entry onto the market, but it made a determination to treat as a "new drug" only those IUDs possessing what it termed "active substances" while classifying as a device the new polyethylene model.⁷² This appears to be a rather cavalier treatment of a serious issue in light of the insufficiency of scientific data proving the plastic model any less lethal than either its predecessor or those IUDs containing active substances.⁷³ Indeed, considering the advice of its counsel that the classification of all IUDs as drugs would be well

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lift preparation deemed a drug based on labeling and promotional material); *United States v. Ellis Research Laboratories, Inc.*, 300 F.2d 550 (7th Cir. 1962), *cert. denied*, 370 U.S. 918 (1962) (galvanometer deemed device); *Orthopedic Equipment Co. v. Butsler*, 276 F.2d 455 (4th Cir. 1960) (surgical nails deemed devices); *United States v. 23, More or Less, Articles*, 192 F.2d 308 (2d Cir. 1951) (phonograph record for insomnia deemed a device); *United States v. Article Consisting of 46 Devices, "Dynamone"*, 315 F. Supp. 588 (D. Minn. 1970) (facial exerciser deemed a device); *United States v. 2000 Plastic Tubular Cases, More or Less, Toothbrushes*, 231 F. Supp. 236 (M.D. Pa. 1964), *aff'd*, 352 F.2d 344 (3d Cir. 1965), *cert. denied*, 383 U.S. 913 (1966) (toothbrush deemed a device); *United States v. Grayce Inc.*, 126 F. Supp. 6 (N.D. Ind. 1954) (vaginal suppositories deemed drugs).

⁷² 21 C.F.R. § 310.502 (1974). A summation of the pertinent provisions of this regulation by Mr. Sherwin Gardner, Acting Commissioner, appears in *Fountain Hearings* at 199:

Intrauterine devices used for the purpose of contraception and incorporating heavy metals, drugs, or other active substances to increase the contraceptive effect, to decrease adverse reactions, or to provide increased medical acceptability, are not generally recognized as safe and effective for contraception and are new drugs within the meaning of section 201(p) of the Federal Food, Drug and Cosmetic Act. A completed and signed "Notice of Claimed Investigational Exemption for a New Drug" . . . must therefore be submitted to cover clinical investigations to obtain evidence that such preparations are safe and effective for this use. An approved new-drug application is required for the marketing of such articles.

Excluded from consideration as new drugs are:

(1) Intrauterine devices fabricated solely from inactive materials (e.g. inactive plastics or metals).

(2) Intrauterine devices with substances added to improve the physical characteristics if such substances do not contribute to contraception through chemical action on or within the body and are not dependent upon being metabolized for the achievement of the contraceptive purpose.

(3) Intrauterine devices that contain a component, such as barium, added exclusively for the purpose of visualization by X-ray.

⁷³ The *Fountain Hearings* are replete with testimony decrying the sufficiency of data which purportedly supports the thesis that second generation IUDs are safer or more efficacious than their predecessors. An excerpt of a letter from Dennis F. Hawkins, M.D., to the Editor of the *British Medical Journal*, May 10, 1969, at 381, in *Fountain Hearings* at 314, summarizes the problem.

Taking a second look at the numerous and comprehensive reports on IUDs, one is struck by two components. The first of these is the almost naive and zealous optimism of the workers in this field, who record incidences of 3% to 30% of expulsions, 1% to 9% of pregnancies, up to 8% of pelvic inflammatory disease, and 2% to 78% of menstrual disorders and then tend to conclude that this is an effective and acceptable contraceptive method.

within FDA authority⁷⁴ and the recommendation of its advisory committee that there was a compelling need for such action,⁷⁵ it may even be alleged that the FDA's inaction bordered on gross abuse of discretion (if in actuality this was a discretionary function).

Even though the FDA of its own volition will not reclassify the IUD, this decision is not dispositive of the issue. The purpose of the Act is to protect the consumer from products which may be harmful; and, untested medical devices which are capable of inflicting injury should fall distinctly within this realm. The IUD is certainly an article that affects the functioning of the human body, whether it operates as a contraceptive or an abortifacient, and as such it fits nicely into the definition of a drug. Under such a classification the consumer would be afforded more adequate protection.

It seems logical that standing would be accorded to organizations such as the Coalition for the Medical Rights of Women or the National Organization of Women (NOW) to petition the FDA for a reclassifi-

⁷⁴ Memorandum from William G. Goodrich, Assistant General Counsel for FDA to James L. Goodard, M.D., Commissioner, March 19, 1968, in *Fountain Hearings* at 206.

I recommend that we issue a general statement of policy, such as the following, and then proceed on a case-by-case basis:

The recent decision of the Court of Appeals in *AMP, Inc. v. Gardner* points out that the "new drug" provisions of the Federal Food, Drug, and Cosmetic Act are not limited to products that are "drugs" in the conventional sense of the word, but cover a much broader range of products. The purpose of the new drug provisions, the Court said, requires that medical and related products which might cause widespread danger, if inadequately tested, be classified as "new drugs."

Accordingly, the Food and Drug Administration will regard therapeutic articles which have such potential for danger as "new drugs", unless they are generally recognized by qualified experts as safe and effective for their intended uses. Any doubts as to classification of an article will be resolved in favor of designating such article a "drug" within the meaning of the Act.

The New Drug Status Branch of the Bureau of Medicine will offer an opinion as to whether an article will be regarded as a "new drug", when requested to do so and when the article, its intended uses, and its labeling are adequately described.

Subsequent to, or contemporaneously with, issuance of such a policy statement, I recommend the intrauterine device manufacturers be called to a meeting with you to discuss the steps to be taken for reasonably prompt filings of new drug applications. The Advisory Committee on Obstetrics and Gynecology Report on Intrauterine Devices clearly establishes that these articles meet the criteria of the AMP case for "new drugs." The Report points out the widespread use of the devices [pp. 12-14], possible serious adverse reactions [pp. 19-22], the need for more stringent procedures for sterilization [p. 25] and sterile pre-packaging with disposable inserters to reduce insertion perforations [pp. 20-23], and, most important, the need for more research and more adequate testing of the products [p. 25a]. The Report amply illustrates the need for regulation of the distribution of IUD's [*sic*] and for control over future developments of such products.

⁷⁵ *Id.* See those sections in the memorandum referring to the Advisory Committee's report and their recommendations. See also the proposed draft of a regulation to reclassify IUDs

cation of the IUD,⁷⁶ for women are the only class to whom such a ruling would be beneficial and the only class for whom such failure to rule would be detrimental. In the event the FDA refuses to reclassify (the FDA voiced the opinion that the task of handling so many new drug applications would be too massive in scope),⁷⁷ the women might

⁷⁶ This review of a women's group petition is apparently taking place at the present time. The Coalition for the Medical Rights of Women, in correspondence to Alexander Schmidt, Commissioner, November 26, 1974, urged the FDA to institute effective regulation of IUDs by repealing 21 C.F.R. § 130.50 (1974); issue a ruling that all IUDs are to be deemed "new drugs" instead of devices; and require labeling directed to patients similar to that required by 21 C.F.R. § 130.45 (1974) for oral contraceptives. Letter from Ms. Erica Black Grubb, attorney for the Coalition, to the *Cleveland State Law Review*, February 20, 1975 (stated that the FDA was treating the correspondence as a formal petition and the Coalition would be allowed "additional time to file a memo of points and authorities").

⁷⁷ This was alluded to as the main reason that IUDs were not reclassified, even in light of *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784 (1968), and *AMP Inc. v. Gardner*, 389 F.2d 825 (2d Cir. 1968), *cert. denied*, 393 U.S. 825 (1968). Testimony by Peter B. Hutt, General Counsel, Food and Drug Administration, in *Fountain Hearings* at 258. However, in a memorandum from Mr. Hutt to Dr. Davis, Director of the Division of Clinical Devices, October 30, 1970, Mr. Hutt listed several other possible reasons for the FDA's failure to reclassify:

If the IUD's are to be considered drugs, we can anticipate the following:

(a) Legal action to prevent us from making such a move since we have always considered them as devices; for example, see 21 CFR, section 3.49 on Pessaries.

(b) Criticism of FDA for not revising or updating the 1968 Report on IUD's where the experts clearly classify them as devices.

(c) Need for a demonstration on our part of the severity of the problem which would require such an extreme departure.

(d) Damaged relations with the device industry and medical profession who have sought to cooperate in contributing to a solution which would clarify the confusion created by AMP and Bacto-Unidisk.

(e) This would seriously hamper prospects for device legislation since this effort could demonstrate a lack of good faith on the part of FDA and stimulate increased resistance on the part of industry to support future device legislation.

(f) Creation of a difficult regulatory program to administer since products would have to be withdrawn from market if it could be successfully argued these are drugs requiring an NDA.

(g) Lastly, confusion in the nomenclature since the descriptive term intra-uterine devices would create an unusual anomaly.

If the IUD's are to remain as devices, I believe a much more prudent course of action could be followed which would result in less confusion. This could encompass the following:

(a) Calling together of industry to discuss problems and seek appropriate solutions by voluntary action — e.g., this was illustrated by our recent meetings with Pacemaker industry.

(b) Convening of Committee on Obstetrics and Gynecology to again review the status of IUD's.

(c) Collection of additional scientific data on hazards.

(d) If regulatory action is necessary, expansion of our regulatory authority by promulgation of regulations under Section 502 of the Act on the basis that certain — or all — products are so unsafe that they cannot be labeled with adequate directions for the use even under professional supervision.

By retaining authority over IUD's as devices, we preserve some distinction between drugs and devices, avoid unnecessary public and legal battles, and retain, for the purposes of legislation, one of our better justifications for additional regulatory authority over devices. If it is necessary to take action based on the scientific data accumulated, I believe we could expect voluntary cooperation from the industry and perhaps additional support from the Ob-Gyn Committee. If regulations are necessary, we would seek new ways to expand our authority under the present Act.

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then petition for a thorough review of all labeling accompanying IUDs onto the market in an effort to ascertain if the many abuses brought out at the Fountain Hearings are still extant.⁷⁸ Where these violations are prevalent, the women could then request the FDA to utilize its statutory authority to deem such illicit IUDs as misbranded and enjoin the manufacturer from selling the products until the requisite modifications in labeling have been made.⁷⁹ If this request is not acted upon, the women should then turn to the courts.⁸⁰

The Administrative Procedure Act (APA)⁸¹ confers standing to sue on any party who is aggrieved by agency action if the interest they espouse is arguably within the zone of interests to be protected by the statute in question (*i.e.*, they are of the class which Congress intended to be benefited by the statute).⁸² The refusal by the FDA to reclassify the IUD as a drug, or at least adequately police the industry, may be considered as a final administrative action. The women would then be the aggrieved parties of the agency's final decision since they are in effect relegated to the status of guinea pigs;⁸³ a result directly

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The decision to classify IUD's as drugs should come only as a last resort and must be the direct result of a convincing accumulation of data to the effect that IUD's are unsafe and hazardous. If the demonstrated problem is this serious and consequently none of the alternatives expressed above are suitable, then this action would not prejudice our future efforts to implement the Cooper Committee Report and probably would support in a most dramatic way the extreme need for new device legislation.

Fountain Hearings at 253-54. The tenor of the memorandum is more fear of the manufacturers and their ability to forestall device legislation than concern for the consumer.

⁷⁸ See references in note 91 *infra* for examples of how physicians have corresponded with the FDA in an attempt to call its attention to improper advertising practices.

⁷⁹ The FDA has statutory authority, under 21 U.S.C. § 334 (1970), to seize the misbranded article and petition the court, under 21 U.S.C. § 331 (1970), for an injunction. *United States v. Wilson Williams, Inc.*, 277 F.2d 535 (2d Cir. 1960). In addition to injunction and seizure, the other methods available to the FDA to force compliance are prosecution and, in the case of minor violations, a suitable notice or warning. Butts, *supra* note 65, at 602.

⁸⁰ In at least one reported case the FDA has been forced to comply with the enabling statute's provisions through third party intervention. In *American Pub. Health Ass'n v. Veneman*, 349 F. Supp. 1311 (D.C. Cir. 1972), a public health association and a senior citizen's group challenged the FDA's procrastination in administering statutes requiring drugs to be as efficacious as their labels represented. The district court granted summary judgment for the plaintiffs and ordered the FDA to perform its function.

⁸¹ 5 U.S.C. § 551 *et seq.* (1970).

⁸² 5 U.S.C. § 702 (1970). See *Barlow v. Collins*, 397 U.S. 159 (1970); *Association of Data Processing Service Organizations v. Camp*, 397 U.S. 150 (1970).

⁸³ Statement of John G. Madry, Jr., M.D., in *Fountain Hearings* at 11:

Because of the prodigious flow of prominent distribution to physicians of reports by population planners, as well as occurrence of friendly news articles in lay publications, American physicians in private practice appear to have unwittingly become participants in a great experiment in population control, utilizing as experimental subjects patients for whom the IUD was not even the prime target for usage. Yet neither physicians nor patients have been provided sufficient facts by researchers or manufacturers to allow for any IUD to have been inserted on the basis of informed advice by the physician or informed consent by the patient.

contrary to the Act's espoused purpose. These women consumers are the class Congress intended to be the beneficiaries of the Act. Although the issue of standing is not easily resolved, because of their unique position women plaintiffs should (as this note will assume) have standing to bring an action seeking judicial interpretation of the statute.⁸⁴

The initial argument that complainants could pose would be that, in light of its legislative history, the FDA has grossly misconstrued the statute, or if the court is inclined to consider classification a discretionary function, that the FDA has grossly abused its discretion. The fact that an IUD comes to the physician in a sterile package⁸⁵ should be sufficient for the court to warrant reclassification (and courts have in the past held that labeling a product as sterile was reason enough to classify the product as a drug)⁸⁶ because only then can the FDA exercise sufficient control over the manufacturing process to ensure that the product actually reaches the consumer in that condition. *A fortiori*, when this fact is coupled with the dearth of scientific knowledge relative to the operation of an IUD in the human body⁸⁷ and the magnitude and extent of the reported injuries,⁸⁸ the reasons for reclassification of the IUD as a drug for greater consumer protection become overwhelming.

In the event the court is disinclined to effect a reclassification, the alternative remedy sought should be in the nature of mandamus to compel the FDA to perform its statutory mandate by stringently policing the labeling violations in the IUD industry.⁸⁹ While it is true

⁸⁴ For a discussion of the intricate problems involved in the issue of standing, see K. DAVIS, *ADMINISTRATIVE LAW TEXT* §§ 22.01-22.07 (3d ed. 1972).

⁸⁵ Statement of Sherwin Gardner, Acting Commissioner, Food and Drug Administration, in *Fountain Hearings* at 199. However, it appears that it was not until the Food and Drug Administration contacted the manufacturers and requested prepackaging in sterile units that such was the case. ADVISORY COMMITTEE ON OBSTETRICS AND GYNECOLOGY OF THE FDA, *REPORT ON INTRAUTERINE CONTRACEPTIVE DEVICES*, in *Fountain Hearings* at 464. Under the present classification, had the manufacturers refused to even consider the request, the FDA would have been powerless.

⁸⁶ Advertising a product as sterile, just as advertising a product as having healing qualities, is sufficient criteria for classification as a drug rather than device. *United States v. 48 Dozen Packages, More or Less, etc.*, 94 F.2d 641 (2d Cir. 1938).

⁸⁷ See Hilgers, *supra* note 4, at 499.

⁸⁸ See text at notes 29-40 *supra*. The reported injuries discussed in this note were, of course, all sustained by women. Only one instance to date, has been reported in which the male was injured by the IUD. In that case the IUD "was caught in [the] husband's uncircumcized foreskin and pulled out." Deming, *supra* note 32, at 2.

⁸⁹ There is no reason to doubt the FDA's ability to force the IUD manufacturer to comply with the Act, for FDA attempts to cure misbranding violations in other industries have been most successful. *United States v. 60 28-Capsule Bottles, More or Less, etc.*, 325 F.2d 513 (3d Cir. 1963) (the burden of proof necessary for the Government in misbranding cases is merely the preponderance of the evidence); *Research Laboratories, Inc. v. United States*, 167 F.2d 410 (9th Cir. 1948) (scientific half-truths used in labeling and promotional literature sufficient to establish misbranding); *United States v. Articles of Drug, etc.*, 263 F. Supp. 212 (D. Neb. 1967) (all of the statements in label need not be false in order to prevail on a charge of misbranding); *United States v. 2000 Plastic Tubular*

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that a court may not substitute its discretion for that of the FDA in determining which individual manufacturer's labeling is illicit, where the FDA has failed to act against *any* manufacturer a court may compel it to do so.⁹⁰ Here the FDA was aware of the often misleading, and at times false, information contained in the patient brochures which accompanied the product.⁹¹ It was at least put on notice by the Fountain Hearings.⁹² Moreover, it was aware that most manufacturer claims as to efficacy and safety were based on the self-serving and scientifically questionable life-table method,⁹³ a method concededly

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Cases, *More or Less, etc.*, 231 F. Supp. 236 (M.D. Pa. 1964), *aff'd*, 352 F.2d 344 (3d Cir. 1965), *cert. denied*, 383 U.S. 913 (1966) (if any claim is misleading the device is misbranded); *United States v. An Actricle of Device, etc.*, 224 F. Supp. 265 (E.D. Pa. 1963).

The word "misleading" in § 352(a) is obviously not intended to narrow the scope of misbranding but to broaden it to cover situations in which, although a claim is not technically false, or even if literally true, the drug or device may nevertheless be misbranded if the total effect of the labeling is to deceive or mislead.

Id. at 268.

⁹⁰ If an agency's discretion is not utilized, or if utilized and is abused, the courts will then intercede. *Safir v. Gibson*, 417 F.2d 972 (2d Cir. 1969); *United States v. Shaughnessy*, 133 F. Supp. 433 (S.D.N.Y. 1955), *aff'd*, 233 F.2d 705 (2d Cir. 1955), *aff'd*, 353 U.S. 72 (1957); *Chavez v. McGranery*, 112 F. Supp. 264 (S.D. Cal. 1953); *Bustos-Orvalle v. Landon*, 112 F. Supp. 874 (S.D. Cal. 1953), *aff'd*, 252 F.2d 878 (9th Cir. 1955); *Savala-Cisneros v. Landon*, 111 F. Supp. 129 (S.D. Cal. 1953).

⁹¹ For examples of correspondence between physicians and the FDA wherein the FDA was put on notice of any alleged violations see *Fountain Hearings* at 13, 21-26, 31-32, 109-12, and 286-89. Also there is testimony by Dr. Thomsen, in *Kennedy Hearings, supra* note 3, at 366-67:

But even the worst of these ads are innocuous compared to some of the patient brochures prepared for potential users of IUD's by the manufacturers or by family planning agencies. These pamphlets are often such an amalgam of promotion, overstatement, omissions, and even lies that the average women [sic] who reads such a pamphlet is in a poor position to give her informed consent for the insertion of an IUD.

While virtually ignoring the mention of serious side effects or complications of IUD's, patient brochures wander through a veritable forest of highly questionable assurances of which the following are typical.

"IUD's do not cause abortion." . . .

"But we do know it's harmless" . . .

"Once an IUD has been inserted, it entails no further costs" . . .

The IUD is "Quietly resting in the uterine cavity — 'minding it own business.'" . . .

"It works only inside the uterus — without effects on your body, blood, or brain." . . .

IUD insertion is "a simple, not painful process." . . .

"The Food and Drug Administration is kept informed about the progress with these devices." . . .

⁹² Note particularly the testimony of Dr. Thomsen wherein he proposes that the FDA and FTC "be directed to evaluate all current and future IUD advertising or promotional material." *Fountain Hearings* at 65.

⁹³ Dr. Thomsen. . . . [T]he life-table method . . . is the accepted form of statistical analysis for IUD complications.

It is a study technique for a fluid population — for instance, a population where new patients are added and other patients drop out at any one time. It is a method of evaluating that type of a patient population statistically, and as such, I recognize its advantages. However, it was designed by those who are

(Continued on next page)

unacceptable to the FDA were a new drug application for the IUD to be required.⁹⁴ Were this writ to be granted and the FDA to begin policing the area, the prospective user would then have at least the minimal assurance of being shielded from any false information.

As another tack in attempting to spur the FDA into action, a woman who has sustained injury through the use of an IUD might consider joining the FDA as a party defendant, under the Federal Tort Claims Act,⁹⁵ in her civil suit against the physician and manufacturer.⁹⁶ Although joinder of the government in this type of situation may pose a question of first impression, the likelihood of plaintiff's success should not be summarily discounted.⁹⁷ The argument for the FDA's liability would be that its nonfeasance in failing to adequately police the misleading statements of the IUD manufacturers in their patient brochures and package inserts was a contributing factor to her injuries, for if the manufacturer had been compelled to delete these glib assurances of safety and efficacy she might never have chosen this method of birth control. Furthermore,

(Continued from preceding page)

unabashedly promotional for IUD's and therefore, it leaves out many complications that should have been included.

And so, when the drug company, for instance, says our statistics quoted are legitimate because they are after the life-table method, and that is the recognized form, they are right, only the life-table method has glaring inadequacies.

Mr. Fountain. And it is not a controlled study?

Dr. Thomsen. It is just a method where this type of patient population can somehow be kept in line in gathering statistics.

These statistics, based on the life-table method then, are used to advertise the new device, and often they are projected.

And I want to explain that . . . the original study that got the device on the market might have been based on a short insertion time The average insertion time . . . might have been 5.5 months, but the life-table method allows the person to say the pregnancy rate based on those 5.5 months of observation is a 1.8 per hundred women-years of usage. In other words, as if you were looking at a hundred women who had used it for one year of time; but in fact, that is not what happened.

. . . [T]he life-table method: . . . was originally developed to draw some sense out of IUD research and statistics, but it has now been taken and incorporated into advertising. It was never even designed to be used for that.

These statistics are used to advertise the new device. Then the large number of women fitted with the commercial device actually and unknowingly become the study population for the IUD's. Several years later reports dribble in about the true nature of the IUD and its complications.

Fountain Hearings at 63.

For an in-depth explanation of the life-table method by a noted expert who believes the method to be acceptable, see statement of Professor H. Bradley Wells, in *Fountain Hearings* at 517. But see the "limitations and problems" section of the prepared statement by Professor Wells, in *Fountain Hearings* at 525-26.

⁹⁴ Testimony of Charles Anello, M.D., Director, Division of Statistics, Office of Scientific Coordination, Bureau of Drugs, in *Fountain Hearings* at 419.

⁹⁵ 28 U.S.C. § 1346 *et seq.* (1970).

⁹⁶ See text beginning at note 109 *infra* for a discussion of the basic theories underlying manufacturer liability.

⁹⁷ See generally DAVIS, *supra* note 84, §§ 25.01-25.06 and cases cited therein for an elucidation of the problems likely to arise and an insight into their possible solution.

had the FDA classified the IUD as a drug, the more stringent controls would have applied, and the manufacturer would have had to convince the government of the IUD's suitability prior to marketing. The classification of the IUD as a device and the FDA's failure to police product labeling both appear, at first glance, to be discretionary functions and thus exempt from Federal Tort Claims Act liability.⁹⁸ Considering the difficulties in differentiating between a drug and a device under the Act, and further considering the fact that a conscious decision was made at a planning level to classify the IUD as a device, a court may be prone to determine that the FDA's actions are immunized. However, the exception to the Federal Tort Claims Act that immunizes discretionary functions from liability should not attach to the FDA's nonfeasance in allowing misbranded medical devices to flourish in the market. The FDA's affirmative duty to halt illicit trafficking of misbranded medical devices, a duty delegated to the FDA by congressional mandate, while discretionary to a point, is not discretionary when a complete industry rather than an individual manufacturer thrives in violation of the Act.

In *Indian Towing Co. v. United States*,⁹⁹ the leading Supreme Court case discussing an agency's discretionary function, the Court ruled that once the government, through the United States Coast Guard, had exercised its discretion in putting a navigational aid at a certain location, and reliance was engendered thereon, the government had a duty to make certain that the aid was kept in good working order. The government, said the Court, was not under a duty to put the navigational aid at that particular location, for this was a decision to be made within the discretion of the Coast Guard. But once the government's discretion was exercised, the implementation of that discretionary decision must be adequately and non-negligently performed. The IUD situation is analogous. The preliminary decision by the FDA to abide by the manufacturer's initial determination that the IUD was a device rather than a drug was, again, made at a planning level and enjoyed discretionary immunity. Following this initial decision, the duty of non-negligently implementing that decision directly parallels the duty found in *Indian Towing* of maintaining navigational aids established by the Coast Guard. Arguably the act of *policing* the IUD industry is not planning level activity but rather operational activity — a level of activity the *Indian Towing* Court held did not enjoy exemption under the Federal Tort Claims Act.

⁹⁸ The discretionary exception to governmental liability under the Federal Tort Claims Act is found in 28 U.S.C. § 2680(a) (1970). For an excellent law review article discussing the possibility of governmental tort liability when the FDA approves a new drug application for an unsafe drug see Note, *The Drug Amendments of 1962: How Much Regulation?*, 18 RUTGERS L. REV. 101, 135 *et seq.* (1963).

The FDA negligently performed its policing function. Meager attempts at regulating the industry — for example, taking off the market an IUD composed of active materials for misbranding violations when, conveniently, and of course unknown to the general public, the manufactured supply had all been disposed of —¹⁰⁰ may have engendered reliance by both physicians and the general public that the FDA was in fact monitoring the manufacturers' activities effectively. The reasonableness of this conclusion is further supported by the practical consideration that if the FDA took one product off the market for misbranding, the logical interpretation of that act by the public would be that the others remaining must be in compliance with FDA standards. For such detrimental reliance the plaintiffs must be compensated.

In the event that the FDA qualifies this action against the manufacturers of active substance IUDs and states that it has taken no action against manufacturers of inert IUDs thereby occasioning no reliance, the counter argument is that the general public makes no such distinction. Furthermore, the Court in *Indian Towing*, in discussing the planning and operational level functions relative to the decision of where to place navigational aids, neither said nor even intimated that no aid need be put anywhere. If such were the holding, then the enabling statute would be rendered nugatory.

Since, the Court said, the Coast Guard had a responsibility to decide, in their discretion, where to erect navigational aids to protect mariners, exercise of that discretion was essential. Again, the IUD situation is analogous. The FDA has a responsibility to protect consumers through efficient enforcement of the statutory labeling provisions. The American consumer has grown to depend on governmental agencies for protection in areas where he is ill-equipped to fend for himself, and protection is sorely needed when drugs and prescription devices are involved. The agency decision of whether to

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Mr. Fountain: . . . [I]t seem curious that FDA failed to take any action in 1971 [against the manufacturer of the Majzlin Spring], but acted with apparent vigor 2 or 3 weeks ago during the midst of this subcommittee's investigation.

But the thing that bothers me is that this action didn't come until the Majzlin device had run its course or lived its life cycle. From the evidence in the record of this hearing so far, it would appear the Majzlin Spring's commercial venture began in 1968 with optimistic reports of the IUD's safety and effectiveness. Sales of the IUD reached a peak and then apparently, because of safety questions which arose, the device entered a period of decline, and, finally, the company, apparently because of mounting suits and difficulties, decided to stop producing the units and phased out the stock they had already produced.

It was at this point that the FDA decided to act, at the time the venture was practically at its end point. What FDA appears to have done in this particular instance was to put the finishing touches on its demise by its seizure and recall. But at that point the damage had already been done and many women, it seems to me, had been needlessly injured.

proceed against individual manufacturers, just as the decision of whether to place a navigational aid at a particular location, is discretionary. But allowing a complete industry to thrive unregulated when the government has notice of gross violations of the statutory provisions enacted to protect against such illegal growth should be deemed abuse of discretion through nonfeasance. No planning level discretion has this much breadth. The mandate of Congress is clear, and the duty must be considered absolute. The function of the FDA is to act as an equalizer between the consumer and the manufacturer whose expertise far surpasses the meager knowledge of the average consumer. If discretion comes into play at all, it is in determining whether to proceed against an individual manufacturer for a specific violation or in selecting the appropriate sanction to impose on the offender. There can be no discretion to refrain from action when an entire industry is involved.¹⁰¹ While it is true that the task of ferreting out violations may at times be staggering, nonetheless, when considering the many violations committed by the IUD industry as a whole that were specifically elucidated during the Fountain Hearings, the subsequent failure to act in this instance cannot be condoned by the courts.

The injured plaintiffs might also consider joining the FTC as another possible defendant under the Federal Tort Claims Act, because, in the area of medical devices, it exercises sole jurisdiction over

¹⁰¹ The exception to government liability under the Federal Tort Claims Act that discretionary functions are immune from criticism "accomplishes the legitimate congressional goal of permitting the framers of policy to reach their decisions free from having to consider governmental liability." Hink & Schutter, *Some Thoughts on the American Law of Governmental Tort Liability*, 20 RUTGERS L. REV. 710, 724 (1966). However, for cases holding, in situations akin to the FDA's nonfeasance, that governmental bodies may be liable for failure to perform a function, see *United States v. Gavagan*, 280 F.2d 319, 327 (5th Cir. 1960):

We may assume that non-performance by a government employee of an intra-governmental duty does not give rise to a civil right in the citizen adversely affected. But the fact remains that, on the analogy of private maritime salvage, these government employees had no right, either absolute or qualified, to abandon or withdraw. On the contrary they were bound to continue . . ."

Kunkel v. City of New York, 282 App. Div. 173, 178, 123 N.Y.S.2d 485, 490-91 (1953):

the surrender of the sovereign immunity from liability with respect to a governmental function, is not limited to any acts of misfeasance or nonfeasance — commission or omission. The surrender is broad, general and unqualified. The only test of liability to be invoked now is . . . , namely: Whether upon all the facts in the case an individual or private corporation would be liable for the breach if the governmental duty were imposed upon him or it.

See also *United States v. Muniz*, 374 U.S. 150 (1963); *Beverly v. Morris*, 470 F.2d 1356 (5th Cir. 1972); *Veach v. City of Phoenix*, 102 Ariz. 195, 427 P.2d 335 (1967); *Latimer v. City of Clovis*, 83 N.M. 610, 495 P.2d 788 (1972); *Schuster v. City of New York*, 5 N.Y.2d 75, 154 N.E.2d 534 (1958); *McCrink v. City of New York*, 296 N.Y.

all advertising in magazines and medical periodicals.¹⁰² The argument for liability would be that although the questionable advertising practices of IUD manufacturers were brought to the attention of the FTC through numerous private complaints by physicians,¹⁰³ as well as by the Fountain Hearings,¹⁰⁴ it failed to take any action to terminate such tactics, thereby facilitating the dissemination of misinformation from physician to patient. In this context the physician can be treated as the agent of the patient when receiving information from the IUD manufacturer,¹⁰⁵ and therefore the FTC's nonfeasance in allowing the dissemination of false and misleading information to reach the physician is contributory to the plaintiff's injury.

While the FTC enjoys the same discretionary latitude as the FDA to ignore minor infractions and to selectively prosecute wayward manufacturers, it likewise does not possess the authority to casually ignore an entire industry. The reason proffered at the Fountain Hearings for its nonfeasance in relation to the IUD industry *in toto* was that the FTC lacked the expertise necessary to adequately monitor advertisements relating to any facet of the medical device industry.¹⁰⁶ If this type of inaction had existed for only a short period of time

¹⁰² 21 U.S.C. § 45 (1970); Statement by Gerald J. Thain, Assistant Director for National Advertising, Bureau of Consumer Protection, Federal Trade Commission, *Fountain Hearings* at 388:

The memorandum of understanding between the Federal Trade Commission and the Food and Drug Administration, most recently updated on September 9, 1971, explicitly recognizes . . . a . . . statutory differentiation in allocating responsibility for advertising. The agreement states in part:

(a) With the exception of prescription drugs, the Federal Trade Commission has primary responsibility with respect to the regulation of the truth or falsity of all advertising (other than labeling) of foods, drugs, devices, and cosmetics. In the absence of express agreement between the two agencies to the contrary the Commission will exercise primary jurisdiction over all matters regulating the truth or falsity of advertising of foods, drugs (with the exception of prescription drugs), devices, and cosmetics.

(b) The Food and Drug Administration has primary responsibility for preventing misbranding of foods, drugs, devices, and cosmetics shipped in interstate commerce. The Food and Drug Administration has primary responsibility with respect to the regulation of the truth or falsity of prescription drug advertising.

¹⁰³ Examples of correspondence between physicians and the Federal Trade Commission wherein the FTC was put on notice of alleged violations can be found in *Fountain Hearings* at 7-8, 112-15.

¹⁰⁴ The FTC was represented at the Fountain Hearings by Mr. Gerald J. Thain, Assistant Director for National Advertising, Bureau of Consumer Protection.

¹⁰⁵ See notes 148-53 and accompanying text *infra*.

¹⁰⁶ Testimony of Gerald J. Thain, Assistant Director for National Advertising, Bureau of Consumer Protection, Federal Trade Commission, *Fountain Hearings* at 392:

FTC does have the responsibility under the law for regulation of the advertising of these devices. We have not attempted, to be perfectly honest, to monitor the advertising for these devices under our advertising monitoring program because the advertising which appears in medical journals is of a nature which requires more technical input than we have at our immediate disposal.

perhaps it might be excusable. Likewise, if action were being taken within this period of time to either find another administrative agency whose expertise was capable of handling the problem or at least requesting such assistance from Congress, then the FTC's actions might again be excusable. However, the FTC admitted that this unconscionable deficiency has existed for at least ten years, with no plan or suggestions to correct it in the offing.¹⁰⁷ It is unthinkable that Congress could have intended that the entire medical device industry go unregulated at the whim of the FTC. This situation is further intensified by the fact that these instruments are intimately connected with vital-bodily organs and thus have an exceptional potential to harm.¹⁰⁸

If these two agencies are allowed to escape liability for their gross neglect of an entire industry on the basis that their decision not to act was made at the planning level and was therefore immune from judicial review, the purpose for their very existence is eviscerated. Surely discretion cannot be accorded such great weight that it can be used as a legal excuse for nonfeasance in a situation where regulatory action is mandatory. The American consumer has grown to rely on these agencies to shield him from unscrupulous entrepreneurs — indeed he has nowhere else to turn. Perhaps the imposition of liability for this intolerable ineptitude will cause these regulators to re-evaluate their posture toward the IUD industry and will hopefully impel them into action. As one physician said in correspondence imploring the FTC to utilize its regulatory power to police the advertising of the IUD industry :

In closing — a final appeal for action, as it were — name a commonly used prescription medication which has a yearly complication rate expectancy for the patient of about 20-25 per cent including pain, hemorrhage, pregnancy, disasters

¹⁰⁷ *Id.* at 393-94:

Mr. Fountain. Are you saying that the FTC, which has the responsibility for monitoring advertising and promotional methods, takes the position that it is not essential because you say you don't have the expertise and that it ought to be done as a cooperative venture between FDA and FTC?

Mr. Thain. I think what I am trying to say is that FTC takes the position it is very essential that monitoring and regulation of these devices occur but that it lacks the resources to effectively carry out the monitoring and regulation under its current setup at the Federal Trade Commission.

Mr. Fountain. How long have you known that you lacked that expertise?

Mr. Thain. I suppose that as long as I have been at the Federal Trade Commission, we have not had the resources to develop this kind of monitoring and review and followthrough.

Mr. Fountain. You said you have been there 10 years?

Mr. Thain. Yes, that is correct.

. . . .

Mr. Fountain. Is FTC considering the initiation of monitoring of advertisements for prescription medical devices?

Mr. Thain. At this point in time; no sir, they are not.

leading to surgery and sometimes death, and which in no way is controlled by the government in respect to testing, advertising, and patient disclosure. Name one such pill and I will go find for you a gorgeous camel which smells like a rose and can read a slide rule.¹⁰⁹

The Manufacturer

Before analyzing the potential liability of IUD manufacturers, it would be well to summarize some of the more bothersome practices followed by manufacturers as they vigorously propounded the IUD as the safest and most efficacious method of birth control. It should be noted at the onset that, insofar as possible, every effort will be made to avoid isolating the practices of any one manufacturer (although the tactics of some have been more distressing than those of others). Moreover, it is also necessary to state that, in order to facilitate the analysis, for the purposes of this note the information contained in the Fountain Hearings will be assumed to be true because there are, as of yet, no reported decisions of cases involving injuries caused by IUDs¹¹⁰ and only one manufacturer testified at the hearings.¹¹¹

Prior to the late 1960's the majority of IUDs manufactured in this country were sold abroad, primarily in so-called underdeveloped nations of the world.¹¹² This effort was greatly facilitated by the World Population Council in the belief that the IUD was the most economically feasible of the many birth control methods available;¹¹³ and, especially attractive to these countries, with their masses of economically dependent inhabitants, was the fact that the one-time insertion

¹⁰⁹ Letter from Russel J. Thomsen, M.D. to Mr. Russell Hatchl, Federal Trade Commission, Feb. 26, 1973, in *Fountain Hearings* at 115.

¹¹⁰ The only decision to date is unreported: *Bookout v. A.H. Robins, Inc.*, No. C-28040 (Dist. Ct. of Sedgewick Cty., Kan. 1975). Counsel of record, Mr. Bradley Post, has provided the following information: a jury verdict in the amount of \$85,000 was returned against the defendant manufacturer (comprised of \$10,000 compensatory and \$75,000 punitive) and the defendant physician was not held liable; the allegations in the complaint yielding the compensatory damages were premised on negligent design, causing migration and perforation, and breach of implied warranties; the allegations in the complaint yielding punitive damages were premised on fraud, wilful misrepresentation and gross and wanton negligence. The action complained of wrongful birth and perforation, however for public policy reasons the court would not allow the issue of wrongful birth to go to the jury. Thus the damages were for migration and perforation. Telephone interview with Bradley Post, Feb. 19, 1975.

¹¹¹ Although unquestionably all of the major IUD manufacturers were aware of the Fountain Hearings, the only manufacturer to be commended for its voluntary attendance and testimony was the A. H. Robins Company, the manufacturer of the Dalkon Shield.

¹¹² Hilgers, *supra* note 4, at 499, 500-01; Letter from Raymond B. Wait, M.D. to John G. Madry, M.D., Feb. 18, 1970. *Fountain Hearings* at 19.

¹¹³ An Evaluation of Intrauterine Contraceptive Devices by the Committee on Human Reproduction, American Medical Association, and an Evaluation of Oral Contraceptives by the Council on Drugs, American Medical Association, *Fountain Hearings* at 40, 43-44; Hilgers, *supra* note 4 at 499, 500-01.

cost was minimal compared to the recurring costs of other methods.¹¹⁴ Also, it appears to be a reasonable conjecture that American manufacturers were comfortable in their belief that legal liability for IUD incurred injuries would be avoided since the status of product liability law in those countries, as opposed to that of the United States, had probably not advanced far enough to encompass the wrongs caused by IUDs.¹¹⁵ Given this atmosphere, the impetus for extensive pre-market testing, and the fear of liability for such failure to pre-test, was almost nonexistent. At least ostensibly, the manufacturer was in a position to market his product with relative impunity and at the same time enjoy rather large economic profits.

When the pill panic swept through this country at the turn of the past decade, IUD manufacturers were quick to capitalize on this incipient market.¹¹⁶ The potential for an immediate profit could well have quelled any desire to engage in necessary pre-market testing, and thus the product was promoted to physicians on the basis of a few highly questionable studies of extremely short duration.¹¹⁷

¹¹⁴ *Id.*

¹¹⁵ Since research of the product liability laws of these nations is beyond the scope of this note, this statement is clearly conjecture. However, considering the fact that, in many instances, the manufacturers sold the IUDs to the United States who in turn, through the Agency for International Development supplied the IUDs by the millions to such impoverished nations as India (presumably without any charge to the receiving nation) the conjecture seems reasonable. Letter from Raymond B. Wait, M.D. to John G. Madry, M.D., Feb. 18, 1970. *Fountain Hearings* at 19. Since suit by the injured consumer would presumably have to entail joining the U.S. government as a party defendant, the likelihood of such suit appears minimal. Also, there exists the problem of discovering the injury and tagging it as IUD related, as so pointed out by Dr. Tietze in *Fountain Hearings* at 375.

¹¹⁶ Statement of Russel J. Thomsen, M.D., *Fountain Hearings* at 143.

¹¹⁷ One advertisement, in *Fountain Hearings* at 87, also contained these clinical tests as support for the IUD's safety and efficacy:

The following clinical data from four published studies including net cumulative event rates (life table method) substantiate the low pregnancy and expulsion rates of the Dalkon Shield. In 3,174 insertions and after 17,222 woman-months of use (see chart below) the pregnancy rate ranged from .4% to 1.9% and the expulsion rate from .2% to 2.3%. Note that there were 1,276 nulliparas [*sic*] patients in the four studies.

	Davis ¹	Earl ²	Ostergard ³	Gabrielson ⁴
Pregnancy rate	1.1%	0.5%	1.1%	1.9%
Expulsion rate	2.3%	0.2%	1.0%	1.2%
Medical removals	2.0%	2.7%	9.7%	14.9%
Personal removals*	0.6%	1.9%	Not given	1.8%
Continuation rate	94.0%	94.7%	88.2% **	80.2%
Insertions	640	536	1,242	756
nulliparas	51	142	327	756
multiparas	589	394	915	None
Woman-months of use	3,549	4,633	5,415	3,625
nulliparas	—	—	1,222	3,625
multiparas	—	—	4,193	None
Time period	12 mos.	15 mos.	9 mos.	9 mos.

Furthermore, the product was billed as a panacea in the area of birth control — equally as effective as the pill, but with none of the dangerous side effects.¹¹⁸ From the testimony given at the Fountain Hearings, this now appears to be far from the truth.

Patient brochures, the method primarily used to reach women directly, were not only misleading but in many instances actually contained false information.¹¹⁹ A close reading of this promotional material reveals that every conceivable effort was made to capitalize on the many fears most women had about the pill. Many of the statements made in advertisements aimed at physicians and in patient brochures were directly contrary to information that should have been in the manufacturers' files.¹²⁰ Moreover, any unfavorable experiences that were contained in unpublished studies by private practitioners, even though brought to the manufacturers' attention, were ignored.¹²¹ This is particularly disturbing since in most instances the majority of physicians would never have this information brought to their attention except through revelations by the manufacturer. Furthermore, there was no effort to up-date the information contained in their warnings until the number of reported adverse reactions attained sizeable proportions.¹²² Similarly, with respect to the up-

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1. Davis, Hugh J. *Am. J. Ob. Gyn.* 106 (3) 455-56 (February 1) 1970.
2. Earl, Thad J. *Am. Fam. Phy.* 4 (3) 93 (September) 1971.
3. Ostergard, Donald R. *Contraception* 4 (5) 313 (November) 1971.
4. Gabrielson, Mary O. *Advances in Planned Parenthood*, Vol. 7, Proceedings of the 9th Annual Meeting of the American Association of Planned Parenthood Physicians, Kansas City, Missouri, April 5-6, 1971.

* Includes removals for desired pregnancy and other personal reasons.

** Would be slightly lower if personal removal rates were included in event rates.

Fountain Hearings at 87.

For a discussion regarding the inadequate length of these cited studies and why they were questionable see note 183 *infra*.

¹¹⁸ The advertisements in medical journals and the patient brochures should be ample evidence of the IUD manufacturer's billing the IUD as safer than the pill. See *Fountain Hearings* at 80-108, particularly 80, 86, 90-91, 104.

¹¹⁹ See note 91 *supra* for specific examples of misstatements related by Dr. Thomsen at the Kennedy Hearings.

¹²⁰ See textual discussion in note 123 *infra*.

¹²¹ See text following note 191 *infra*.

¹²² Appearing in the *Fountain Hearings* at 399-402, is an IUD advertisement in which the manufacturer lists warnings, precautions and adverse effects. The date of the advertisement is November 20, 1972, and the listed warnings and adverse effects are almost identical to the ones listed in the package insert for the same manufacturer's IUD — up to October 1973:

Warnings:

1. As with all IUD's, insertion before 8-12 weeks post-partum (or post abortion) may be attended by a higher risk of uterine perforation.

(Continued on next page)

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2. [Our IUD] exhibits a relatively low level of radiopacity because of its thin construction, and in some patients, particularly the obese, soft-tissue technique may be needed to achieve visualization.

3. Spontaneous complete or partial expulsion of this device may occur. Reports indicate that [our IUD] not in its high fundal position may not provide anticipated contraceptive effect.

....

Adverse Effects: Inter-menstrual spotting and prolongation and increase in the menstrual flow, particularly during the first few cycles following insertion. Lower abdominal cramping, usually transient. Post-insertion syncope, particularly in nulliparas. Infection.

However, in October 1973, three months after the damaging testimony in the Fountain Hearings which alleged the numerous adverse reactions, the following comprised the package insert's warnings and adverse effects:

Warnings:

1. As with all IUD's, uterine perforation (partial or complete) is a recognized risk. Great care should be exercised in examining and sounding the uterus, and in inserting the device. Insertion before 8-12 weeks post-partum (or post-abortion) may be attended by a higher risk of uterine perforation. Adhesions have been reported between the perforated [IUD], adjacent omentum, abdominal and/or pelvic viscera. Perforated devices should be removed.

2. Severe sepsis, with fatal outcome, most often associated with spontaneous abortion following pregnancy with [our IUD] *in situ* has been reported. In view of this, serious consideration should be given to removing the device when the diagnosis of pregnancy is made with [our IUD] *in situ*.

3. [Our IUD] exhibits a relatively low level of radiopacity because of its thin construction, and in some patients, particularly the obese, soft-tissue technique may be needed to achieve visualization.

4. Spontaneous complete or partial expulsion of this device may occur. Expulsion may be more frequent among younger women; usually occurs during menses; and particularly occurs during the first few months after insertion. [An IUD] not in its high fundal position may not provide anticipated contraceptive effect.

5. The ratio of ectopic-uterine pregnancies is considerably higher in women who become pregnant with an IUD *in situ* than in women who become pregnant without an IUD. There is no evidence that ectopic pregnancies are caused by IUD's.

6. String breakage or "pull through" of the string at its tie point on [our IUD] has been reported in connection with difficult removals, usually associated with embedment or partial perforation.

7. The proportion of pregnancies which terminate in spontaneous abortion is considerably higher in the presence of IUD's.

Adverse Effects: Major adverse effects include excessive bleeding, pelvic inflammatory disease, and embedment. Less serious effects include irregular bleeding, uterine cramping, pelvic pain, and backache. Increased or irregular bleeding may occur, particularly during the first few cycles following insertion. Uterine cramping is usually transient in multiparous women but may be moderate to severe and last for several days in nulliparas. Postinsertion syncope may occur, particularly in nulliparas. Septic abortion has been reported. Latent infections may be aggravated by an IUD.

Since those testifying stated throughout the Hearings that they had already informed the manufacturer of these problems well in advance of the Hearings, this change in the updating of warnings can not be attributed to the fact that the testimony in the Fountain Hearings first brought these problems to the manufacturer's attention. This particular manufacturer should not be considered as the exception, for numerous manufacturers, as shown by testimony throughout the Fountain Hearings, engaged in the same deceptive practices.

grading of manufacturing practices, it was not until the IUD's propensity to induce vaginal infection became widely apparent that sterility techniques were introduced.¹²³

These questionable practices then, while not meant to be an extensive compilation of the wrongs elucidated in the Fountain Hearings, will form the primary basis of discussion in the remaining portions of this note.

General Legal Principles

When producing an IUD for general consumption, the manufacturer should be required to comply with certain stringent standards of conduct. When considering the complex nature of the IUD, the average layman cannot be expected to evaluate the merits of the product on the basis of his own general knowledge. Therefore, as in the case of drug and chemical product manufacturers, the law should demand that the IUD manufacturer exhibit the skill of an expert in the design and preparation of his product, for only an expert can produce an IUD that is safe and effective.¹²⁴ To ensure that a product is reasonably safe for its intended purpose, the manufacturer must conduct adequate tests prior to marketing to discover any potential hazards.¹²⁵ These hazards must then be disclosed to the intended con-

¹²³ In the 1968 Report of the Task Force on Inflammatory Reactions and Warnings, which is Appendix 3 of the *Report on Intrauterine Contraceptive Devices* by the Advisory Committee on Obstetrics and Gynecology of the Food and Drug Administration, the following statement appears:

[T]hrough the Food and Drug Administration, all of the U. S. manufacturers and distributors of the intrauterine devices were contacted. Information on control of sterility in the manufacture of IUD's instructions to the physicians about insertions, and plans for prepackaging in sterile units was requested.

Thus far the replies have been incomplete. When sterile packaging is practiced, the bacteriologic controls and checks seem adequate; however, no word has been received about plans for sterile prepackaging of the most commonly used device and inserter although some studies are underway.

Fountain Hearings at 464.

If the FDA had controls over the device industry similar to those exercisable over the drug industry, the manufacturer's procrastination would not be tolerated. The manufacturer should have had the same evidence of the need for sterile prepackaging as that found by the Task Force, and this evidence should have existed prior to marketing. Common sense indicates that inserting a foreign, unsterile object into the female's uterus would have a tendency to induce infection. The Task Force, through the FDA, should not have to "request" the manufacturers to take such self-evident steps — the manufacturer should have realized the probable inherent dangers in unsterilized IUDs and acted prior to the injuries.

¹²⁴ See *Wright v. Carter Prods., Inc.*, 244 F.2d 53 (2d Cir. 1957); *Holland v. St. Paul Mercury Ins. Co.*, 135 So. 2d 145 (La. App. 1961); *Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143 (Mo. 1967); *Henderson v. National Drug Co.*, 343 Pa. 601, 23 A.2d 743 (1942).

¹²⁵ See *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132 (3d Cir. 1973); *Parke-Davis & Co. v. Stromsodt*, 411 F.2d 1390 (8th Cir. 1969); *O'Hare v. Merck & Co., Inc.*, 381 F.2d 286 (8th Cir. 1967); *Gober v. Revlon, Inc.*, 317 F.2d 47 (4th Cir. 1963); *Carter Carburetor Corp. v. Riley*, 186 F.2d 148 (8th Cir. 1951); *Toole v. Richardson-Merrell, Inc.*, 251 Cal. App. 2d 689, 60 Cal. Rptr. 398 (1967); *Smith v. Peerless Glass Co., Inc.*, 259 N.Y. 292, 181 N.E. 576 (1932). See also Annot., 6 A.L.R.3d 91 (1966).

sumer so that her awareness of the dangers attendant to the product's use is sufficient to enable her to make an informed choice between competing models, or for the matter, competing methods of birth control.¹²⁶ The information elicited at the Fountain Hearings indicates that the manufacturers in the IUD industry have deviated from these standards.

When an attempt is made to determine whether the IUD should be treated as a drug or a device, it becomes at once apparent that it must be considered something of a hybrid.¹²⁷ Since the IUD is officially classified by the FDA as a medical device, it is not subject to the same pre-marketing clearance requirements as an ethical drug and, hence, it receives no governmental imprimatur.¹²⁸ However, because the nature of an IUD is so similar to that of a drug (*i.e.*, it is designed to interfere with a natural bodily function and its capacity to harm is equally awesome, as evidenced by the many serious injuries experienced by the users of first generation IUDs)¹²⁹ it seems logical to conclude that a diligent IUD manufacturer should have performed substantially the same degree of testing as that required of an ethical drug manufacturer prior to releasing his product for general distribution. Yet this was not the case. In fact, so exiguous is the amount of research data compiled by the IUD industry that one expert has gone so far as to term their general efforts "pathetic."¹³⁰ While there are a few "glowing" reports in the medical literature,¹³¹ these are basically generic studies and should not suffice to relieve an individual manufacturer from the responsibility to test his own product prior to marketing. A product manufacturer may not rely on the work of a third party unless he commissioned the study; the duty to test his product is peculiar to him.¹³²

¹²⁶ The duty to warn may be said to arise whenever the situation is such that a reasonable man would want to be informed of the risk in order to decide whether to expose himself to it. *Borel v. Fibreboard Paper Prods. Corp.*, 493 F.2d 1076 (5th Cir. 1973); *McEwen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522 (1974).

¹²⁷ If IUDs were classified as "hybrids" rather than drugs or devices, they would join the ranks of *in vitro* diagnostic products which are so classified. For a full explanation of this unusual categorization, which in reality is the classification of items that appear plainly to be devices but are treated as drugs to more adequately protect consumers, see Ringuette, *The Future of Diagnostic Kits and Reagents*, 29 FOOD DRUG COSM. L.J. 246 (1974).

¹²⁸ See text at note 45 and following *supra*.

¹²⁹ See note 10 *supra*. Also, now banned under 21 C.F.R. § 3.49 (1974) are intracervical and intrauterine stem and wing type pessaries. These pessaries, in use at the time of first generation IUDs, were utilized not only for contraception but, as the first generation IUDs, for uterine displacement as well.

¹³⁰ Statement of Russel J. Thomsen, M.D., *Fountain Hearings* at 61.

¹³¹ See notes 11 and 12 *supra*.

¹³² A manufacturer may not utilize as an affirmative defense the fact that the product was negligently tested by a third party, RESTATEMENT (SECOND) OF TORTS § 396 (1965). See also *Annor*, 6 A.L.R.3d 91 (1966).

Since the IUD displays many of the same characteristics as a drug, the standards that are imposed on the drug manufacturers with respect to warnings should be applicable to the IUD industry. In the case of drug products, a manufacturer's warnings must be calculated to adequately apprise the intended consumer of the reasonably foreseeable dangers flowing from the use of the product,¹³³ even though the adverse reactions are expected to be experienced by only a small percentage of users.¹³⁴ The warning must incorporate all ill-effects gleaned from the pre-marketing tests conducted by the manufacturer as well as those reported to the manufacturer by physicians who have been prescribing the product.¹³⁵ The manufacturer is also deemed to have constructive knowledge of all discussions relative to his product contained in the medical literature;¹³⁶ and when these discussions are adverse, the continuing nature of the duty should dictate that the warning be up-dated.¹³⁷ Furthermore, the duty exists even though the physician is likely to be aware of the risks involved from sources other than the manufacturer, for as one court stated, "sometimes it is well to have our attention called to those things which we know best."¹³⁸ The rationale for insisting that even the most obvious adverse effects be continually brought to the physician's attention is that only in this manner can it be assured that at the precise moment of prescription the chance for inadvertent error is held to a minimum.

¹³³ See *Parke-Davis & Co. v. Stromsodt*, 411 F.2d 1390 (8th Cir. 1969); *Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978 (8th Cir. 1969); *De Vito v. United Air Lines, Inc.*, 98 F. Supp. 88 (E.D.N.Y. 1951); *Christofferson v. Kaiser Foundation Hosp.*, 15 Cal. App. 3d 75, 92 Cal. Rptr. 825 (1971); *Farley v. Edward E. Tower & Co., Inc.*, 271 Mass. 230, 171 N.E. 639 (1930); *Halloran v. Parke-Davis & Co.*, 245 App. Div. 727, 280 N.Y.S. 58 (1935); *Marcus v. Specific Pharmaceuticals, Inc.*, 82 N.Y.S.2d 194 (Sup. Ct. 1948); *McEwen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522 (1974).

¹³⁴ The rule that the manufacturer need not give a warning where anticipated adverse reactions will only affect a small percentage of users has been replaced by the theory that the number of persons to be affected is only one of the factors to be considered in assessing the adequacy of the warning. Where the potential harm is severe, the manufacturer will be required to warn all prospective users. See *Parke-Davis & Co. v. Stromsodt*, 411 F.2d 1390 (8th Cir. 1969); *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9th Cir. 1968); *Sterling Drugs, Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1966); *Gober v. Revlon, Inc.*, 317 F.2d 47 (4th Cir. 1963); *Wright v. Carter Prods., Inc.*, 244 F.2d 53 (2d Cir. 1957); *Love v. Wolf*, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964); *McEwen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522 (1974); *Crocker v. Winthrop Laboratories*, 514 S.W.2d 429 (Tex. 1974).

¹³⁵ See *Parke-Davis & Co. v. Stromsodt*, 411 F.2d 1390 (8th Cir. 1969); *De Vito v. United Airlines, Inc.*, 98 F. Supp. 88 (E.D.N.Y. 1951).

¹³⁶ See *Schenebeck v. Sterling Drug, Inc.*, 423 F.2d 919 (8th Cir. 1970); *Kershaw v. Sterling Drug, Inc.*, 415 F.2d 1009 (5th Cir. 1969); *O'Hare v. Merck & Co., Inc.*, 381 F.2d 286 (8th Cir. 1967); *Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143 (Mo. 1967); *McEwen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522 (1974).

¹³⁷ *Schenebeck v. Sterling Drug, Inc.*, 423 F.2d 919 (8th Cir. 1970). See generally *Basko v. Sterling Drug, Inc.*, 416 F.2d 417 (2d Cir. 1969); *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9th Cir. 1968); *O'Hare v. Merck & Co.*, 381 F.2d 286 (8th Cir. 1967); *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1966); *Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143 (Mo. 1967).

¹³⁸ *Abbott Laboratories v. Carr*, 178 F.2d 170, 176 (7th Cir. 1935).

The warning need not necessarily be given by the best available means, however, the method selected must be reasonably calculated to "bring the warning home."¹³⁹ Of course, when the possible adverse reactions could be severe, the manufacturer may be required to use *every* available means to ensure that the prescribing physician is conclusively apprised of the danger.¹⁴⁰ For prescription articles in general, such as the IUD, the channels utilized by the manufacturer to transmit information to the physician include detailmen (salesmen who visit the physicians at their offices),¹⁴¹ advertisements in the various medical journals,¹⁴² package inserts,¹⁴³ "dear doctor" letters,¹⁴⁴

¹³⁹ See *Nolan v. Dillon*, 261 Md. 516, 276 A.2d 36 (1971) (the duty is to give a reasonable warning, not the best one possible); *Gielski v. State*, 3 Misc. 2d 578, 155 N.Y.S.2d 863 (Ct. Cl. 1956) (where the duty exists, the necessary corollary is that the warning must be given with care).

¹⁴⁰ *Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978 (8th Cir. 1969). The circumstances will dictate whether the warning was reasonable. Hence, even though the manufacturer has mailed "Dear Doctor" letters, he may still be required to convey the warning via detailmen where the potential harm is severe, because manufacturers know that physicians don't always read the medical literature with which they are inundated. A warning may be unreasonable if it is unduly delayed, reluctantly given, or lacking in a sense of urgency. Judge Becker in *Yarrow* stated:

Under the circumstances of this case, when the dangers of the prolonged use of this drug . . . became reasonably apparent, it was not unreasonable to find that the appellant should have employed *all its usual means of communication*, including detailmen, to warn the prescribing physicians of these dangers.

Id. at 992 (emphasis added).

¹⁴¹ The reliance by physicians on the accuracy of the detailman's reports cannot be over-emphasized. The detailman is the physician's real link with the manufacturer, for it is the detailman who supplies the physician not only with information concerning new products, but also updates information on the products already on the market. At least one court has specifically held that the failure of a manufacturer to instruct detailmen to repeat warnings of newly found side effects of a drug, even though contained in the manufacturer's literature, breached the manufacturer's duty to give a reasonable warning under the circumstances. *Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978 (8th Cir. 1969).

¹⁴² Examples of advertisements from medical journals are found in *Fountain Hearings* at 82-108.

¹⁴³ The information contained in the package insert generally concerns the following: indication (prevention of pregnancy); contraindications, *see* note 30 *supra*; warnings (*i.e.* spontaneous complete or partial expulsion may occur); precautions (*i.e.* aseptic technique should be used during insertion); insertion procedure; removal procedure; and adverse effects.

¹⁴⁴ The "dear doctor" letter is a letter sent directly to the physician by the manufacturer warning of newly discovered adverse effects of the product. A summation of the scope of information discussed in one IUD manufacturer's "dear doctor" letter is found in *New News*, June 28, 1974, at 2, a publication of the Department of Health, Education and Welfare:

More than 120,000 physicians recently received a letter from the [manufacturer] with details of the company's own findings of possible complications if a patient becomes pregnant while wearing [the IUD]. The letter recommended removal of the [IUD] if pregnancy occurred in spite of the device, and consideration of therapeutic abortion if removal could not readily be accomplished. To date, [the manufacturer] has data on seven deaths and approximately 100 cases of infection associated with spontaneous abortion (miscarriage) in patients using the [IUD]. Most of these cases have occurred in the mid-trimester (4th, 5th, and 6th months) of pregnancy.

the Physician's Desk Reference,¹⁴⁵ and the Medical Pharmacopeia.¹⁴⁶ However, the mere fact that the manufacturer has conveyed his warning to the physician by all of the above channels may not be sufficient to absolve him of liability in the event of serious injury. Should an injury occur, the court will carefully scrutinize the manufacturer's advertising material to ascertain whether it was designed to induce the physician to prescribe the product despite the possible serious consequences. Hence, the manufacturer must be chary with his promotional material lest it be considered to unfairly predominate, and thereby negate, any warning previously given.¹⁴⁷

When considering the sufficiency of a prescription article's warning, it is important to note that, since the warning is directed to the physician rather than the patient, the physician is considered the patient's agent when receiving the warning from the manufacturer.¹⁴⁸ He is a learned intermediary who deciphers the technical jargon in the manufacturer's warning and translates it into terms

¹⁴⁵ The Physician's Desk Reference (PDR) is a compilation of drugs on the market and statements relative thereto by the manufacturer, and therefore is only applicable to those IUD's classified as drugs under 21 C.F.R. § 310.502 (1974). See note 72 *supra*, quoting portions of the text of the regulation.

¹⁴⁶ A medical pharmacopeia is defined as follows:

A work containing monographs of therapeutic agents, standards for their strength and purity, and directions for making preparations. The various national pharmacopeias are referred to by abbreviations . . . *U.S.P.*, the Pharmacopeia of the United States of America (United States Pharmacopeia) . . . The first edition of the *U.S.P.* was compiled in 1820; it has since been revised every ten years, and recently every five years, by the United States Pharmacopeia Convention, composed of physicians, scientists, and pharmacists. The work was made a legal standard by the terms of the National Food and Drugs Act . . .

STEDMAN'S MEDICAL DICTIONARY 952 (3d Lawyers ed. 1972).

Since the pharmacopeia is not concerned with devices, it is only applicable to those IUDs classified as drugs under 21 C.F.R. § 310.502 (1974). See note 72 *supra*, quoting portions of the regulation.

¹⁴⁷ See *Stevens v. Parke-Davis & Co.*, 9 Cal. 3d 51, 507 P.2d 653, 107 Cal. Rptr. 45 (1973); *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 95 Cal. Rptr. 381 (1971); *Love v. Wolf*, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964); *Ducote v. Chevron Chem. Co.*, 227 So. 2d 601 (La. App. 1969); *Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143 (Mo. 1967); *Incollingo v. Ewing*, 444 Pa. 263, 283 A.2d 206 (1971).

¹⁴⁸ See *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974); *Hoffman v. Sterling Drug, Inc.*, 435 F.2d 132 (3d Cir. 1973); *Schenebeck v. Sterling Drug, Inc.*, 423 F.2d 919 (8th Cir. 1970); *Basko v. Sterling Drug, Inc.*, 416 F.2d 417 (2d Cir. 1969); *Parke-Davis & Co. v. Stromsodt*, 411 F.2d 1390 (8th Cir. 1969); *Stottlemire v. Cawood*, 213 F. Supp. 897 (D.D.C. 1963); *Grinnell v. Charles Pfizer & Co.*, 274 Cal. App. 2d 424, 79 Cal. Rptr. 369 (1969); *Love v. Wolf*, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964); *Toole v. Richardson-Merrell, Inc.*, 251 Cal. App. 2d 689, 60 Cal. Rptr. 398 (1967); *Hines v. St. Joseph's Hosp.*, CCH PROD. LIAB. REP. ¶ 7294 (N.M. App. 1974); *Wechsler v. Hoffman-La Roche, Inc.*, 198 Misc. 540, 99 N.Y.S.2d 588 (Sup. Ct. 1950); *Cunningham v. Charles Pfizer & Co., Inc.*, 532 P.2d 1377 (Okla. 1974); *Incollingo v. Ewing*, 444 Pa. 263, 282 A.2d 206 (1971); *Gravis v. Parke-Davis & Co.*, 503 S.W.2d 863 (Tex. Civ. App. 1973).

This method of utilizing the physician to transmit information to the patient was employed by the IUD industry as evidenced by the testimony of a manufacturer's representative in the *Fountain* Hearings at 339.

comprehensible to the patient.¹⁴⁹ There is no duty on the part of the manufacturer to ensure that his warning actually reaches the consumer; once he has made a full disclosure to the physician his duty has been fulfilled.¹⁵⁰ Warning procedures take another tack when the product is sold directly to the consumer or when the product is dispensed to the general public other than by a physician. The manufacturer is then required to convey his warning directly to the ultimate consumer.¹⁵¹ Thus, if the above standards are made applicable to IUD manufacturers, in those instances in which an IUD is prescribed by a paramedic from a family planning clinic, the manufacturer will not have fulfilled his duty merely by transmitting his warning to the clinic; he must also ensure that it reaches the intended user.¹⁵²

In addition to the above general rules, there are two additional theories regarding the "agency" role assumed by the physician in the warning process. The first is that he occupies the position of a dual agent representing both the manufacturer and the patient concomitantly, and the second is that he is solely the agent of the manufacturer. These theories should be considered whenever the manufacturer expressly advises the patient in his brochure to consult the physician for additional information about the product. Such suggestions have the legal import of ascribing an agent's role to the physician and a principal's role to the manufacturer, with liability attaching to the principal for any false or erroneous representations made by the agent.¹⁵³

¹⁴⁹ See *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974); *Schenebeck v. Sterling Drug, Inc.*, 423 F.2d 919 (8th Cir. 1970); *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9th Cir. 1968); *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1966); *Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143 (Mo. 1967); *Gravis v. Parke-Davis & Co.*, 502 S.W.2d 863 (Tex. Civ. App. 1973).

¹⁵⁰ See *Basko v. Sterling Drug, Inc.*, 416 F.2d 417 (2d Cir. 1969); *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9th Cir. 1968); *Nishida v. E.I. DuPont DeMours & Co.*, 245 F.2d 768 (1957); *Karp v. Cooley*, 349 F. Supp. 827 (S.D. Tex. 1972); *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 95 Cal. Rptr. 381 (1971); *Love v. Wolf*, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964); *Magee v. Wyeth Laboratories, Inc.*, 214 Cal. App. 2d 340, 29 Cal. Rptr. 322 (1963); *Mulder v. Parke-Davis & Co.*, 181 N.W.2d 882 (Minn. 1970); *Gravis v. Parke-Davis & Co.*, 502 S.W.2d 863 (Tex. Civ. App. 1973).

¹⁵¹ See *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974) (where there is mass immunization or an ongoing program the prescription drug exception does not apply — the warning must go to the consumer directly); *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9th Cir. 1968) (over-the-counter or mass immunization requires that the warning reach the consumer); *Cunningham v. Charles Pfizer & Co. Inc.*, 532 P.2d 1377 (Okla. 1974) (where there are mass immunizations the duty runs to the public directly).

¹⁵² *Id.* This conclusion is strongly suggested by these cases. The IUD industry is aware that many users receive their device from a paramedic without first engaging in consultation with a physician. Although this is not a mass immunization situation, the manufacturer must ensure that his warning reaches the consumer because there is no physician directly involved in the prescription process.

¹⁵³ For a discussion of these theories see Note, *Liability for the Failure of Contraceptive Devices*, 3 RUTGERS CAMDEN L.J. 489, 497 & nn. 38-44 (1972), and Rheingold, *supra* note 60, at 976 & n. 168.

Although these theories are not extensively utilized, they would be applicable to the IUD situation because the manufacturers' brochures instruct the patient to consult her physician for additional information. See, e.g., *Fountain Hearings* at 79.

When a consumer is injured by a product and is able to show the inadequacy of the manufacturer's warning, the law raises a rebuttable presumption that any warning which might have been given would have been heeded.¹⁵⁴ The burden is on the manufacturer to show that the possible adverse reactions excluded from the warning were so inconsequential or the likelihood of their occurrence so miniscule that, were they to have been included in the warning, the consumer would have nevertheless purchased the product.¹⁵⁵ If the manufacturer successfully rebuts this presumption, the jury will then be instructed to apply an objective reasonable man standard — *i.e.*, if the warning had been complete, would a reasonably prudent person have refrained from purchasing the product?¹⁵⁶

With the foregoing as a foundation, an examination of the specific causes of action in which these principles may be utilized can now be undertaken.

Warranty

The manufacturer's knowledge relative to the safety and efficacy of the IUD is superior to that of the consumer. As in the case of a drug manufacturer, the IUD manufacturer should be held to the standard of an expert in the production of his product,¹⁵⁷ and after production he should not be permitted to engage in any "puffing" during his advertising efforts. This is necessary since, were it otherwise, the likelihood is great that the consumer would be misled into believing these statements comprised express warranties. Consequently, any statements of opinion contained in the promotional material may be considered assertions of fact and thereby incorporated into whatever express warranty the manufacturer actually intended to give.¹⁵⁸ In addition to these express warranties, the manufacturer is held by law to impliedly warrant that his product will be reasonably fit for its intended purpose.¹⁵⁹ These warranties, express and implied, extend to those persons whom the manufacturer intended to be the ultimate consumers of his product, even though they may not have purchased

¹⁵⁴ *Cunningham v. Charles Pfizer & Co., Inc.*, 532 P.2d 1377 (Okla. 1974).

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

¹⁵⁷ See note 124 *supra* and accompanying text.

¹⁵⁸ *Toole v. Richardson-Merrell, Inc., Inc.*, 251 Cal. App. 2d 689, 60 Cal. Rptr. 398 (1967). The court relied on the RESTATEMENT (SECOND) OF TORTS § 542 (1965) in holding that the statements of a party with superior knowledge will be construed as fact and not opinion. See also, UNIFORM COMMERCIAL CODE § 2-313.

¹⁵⁹ UNIFORM COMMERCIAL CODE § 2-315. See also *Tinnerholm v. Parke-Davis & Co.*, 411 F.2d 48 (2d Cir. 1969); *Brown v. Globe Laboratories, Inc.*, 165 Neb. 138, 84 N.W.2d 151 (1957); *Cudmore v. Richardson-Merrell, Inc.*, 398 S.W.2d 640 (Tex. Civ. App. 1965),

the product directly from the manufacturer.¹⁶⁰ Therefore, the IUD manufacturer warrants to the female user, the intended ultimate consumer, that the product will be effective in preventing pregnancy and that its use will not entail unreasonable risks of injury.

For an injured IUD plaintiff to recover under a warranty theory, certain facts must be established: first, the IUD must have been sold to the injured consumer; second, the warranties which ran with the product must have been breached; and third, the manufacturer must have been seasonably notified of the breach. The element most difficult for an injured IUD user to establish will be the sale, for without this requirement the warranties will not obtain and there can exist no breach. Faced with this theory, the manufacturer can be expected to argue that no direct sale occurred; instead the product was supplied to the plaintiff as part of the overall service performed by her physician.¹⁶¹ Hopefully, the courts will reject this specious argument. By virtue of the initial sale the manufacturer has propelled the IUD into commerce. The warranties must logically follow the device on its journey. Once the IUD has reached its ultimate destination, the consumer, it is sheer folly to suggest that the warranties have somehow vanished.¹⁶²

Moreover, there is a distinct possibility that some courts may not impose the sale requirement as a prerequisite to recovery because of the product's similarity to foods and drugs. There is an exception to the sale requirement which has been created for foods and drugs, and the courts have held that when a product is designed to interfere with a natural bodily function or is ingested into the body a manufac-

¹⁶⁰ See *Tinnerholm v. Parke-Davis & Co.*, 411 F.2d 48 (2d Cir. 1969); *Mannsz v. Macwhyte Co.*, 155 F.2d 445 (3d Cir. 1946); *Oressman v. G. D. Searle & Co.*, 321 F. Supp. 449 (D.R.I. 1971); *Peterson v. Lamb Rubber Co.*, 54 Cal. 2d 339, 353 P.2d 575, 5 Cal. Rptr. 863 (1960); *Rogers v. Toni Home Permanent Co.*, 167 Ohio St. 244, 147 N.E.2d 612 (1958). See also UNIFORM COMMERCIAL CODE § 2-318.

¹⁶¹ The situation is likely to be analogized to the case wherein a hospital administers impure blood during a transfusion. Most courts refuse to find the hospital liable for breach of warranty. See *J. WHITE & R. SUMMERS, UNIFORM COMMERCIAL CODE § 9-6* (1972); *Leff, Medical Devices and Paramedical Personnel: A Preliminary Context for Emerging Problems*, 1967 WASH. U.L.Q. 332, 335 n.108; Note *Unwanted Pregnancy and the Pill — The Question of Liability of the Manufacturer*, 41 UNIV. CIN. L. REV. 335, 343 n.37 (1972).

¹⁶² See *Gottsdanker v. Cutter Laboratories*, 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1960). In an action for damages against the manufacturers of the Salk vaccine, the *Gottsdanker* court noted:

While the manufacturer of foods or drugs is not liable as a warrantor unless he has made a sale, we see no reason to hold that he escapes liability because the ultimate consumer, whose use of the product is the essential consideration in its manufacture for the market, is not a purchaser under a contract of sale . . . While a sale is essential to impose liability under the implied warranties, the initial sale to distributor or retailer of pharmaceuticals is sufficient to impose upon the manufacturer the responsibility of fulfilling the implied warranties which run to the benefit of the persons whom the manufacturer intended to be, and who in fact became, the 'consumers'.

turer will not be permitted to escape liability for any harm which the product causes merely because the injured party did not technically purchase the product.¹⁶³ The user will not be penalized simply because the product was acquired by means other than direct purchase from the manufacturer. Within this framework, the warranties extend to the intended ultimate consumer or to those who could reasonably be expected to use the product.

A defective product cannot be reasonably fit for its intended purpose. When a product is sold in a defective condition the warranties are deemed to have been breached and the manufacturer will be liable for any injuries occasioned thereby. A product will be considered defective if it can be shown that the manufacturer has breached his duty to conduct adequate pre-marketing tests or has failed to give sufficient warning of the product's propensity to harm.¹⁶⁴ Thus, to prove the IUD defective, the plaintiff need only show how pathetic were the manufacturer's effort at pre-market testing and how insouciant were the initial warnings when contrasted with the severity of the injuries experienced by many IUD users. Furthermore, recovery will be made all the more certain when the plaintiff contrasts the information presented in the patient brochures with the information contained in the medical literature. As in the case of a drug manufacturer, the IUD manufacturer's status vis-à-vis the consumer being that of an expert, these statements in the patient brochures should attach to the product as part of the express warranty and the consumer should be entitled to rely thereon. If these express statements are shown to be false, the warranty is breached, and the plaintiff should be entitled to recover.

The requirement that the manufacturer be notified of the breach within a reasonable time does not appear to impede recovery. In an action occasioned by an IUD manufacturer's breach of warranty the notification requirement is designed to afford the seller an opportunity to prepare for negotiation and litigation.¹⁶⁵ As such, it is unlikely that a court will dismiss an action for want of notice or unreasonably delayed notice when the filing of the lawsuit itself is sufficient to satisfy this purpose.¹⁶⁶

¹⁶³ *Id.* at 608, 6 Cal. Rptr. at 324.

¹⁶⁴ See *Basko v. Sterling Drug, Inc.*, 416 F.2d 417 (2d Cir. 1969) (breach of duty to warn causes product to be defective); *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9th Cir. 1968) (failure to warn of existence and extent of risk renders drug unfit); *Lewis v. Baker*, 243 Ore. 317, 413 P.2d 400 (1966) (inadequate warning equals breach of warranty).

¹⁶⁵ See UNIFORM COMMERCIAL CODE § 2-607, Comment 4.

¹⁶⁶ Recent courts faced with the issue have suggested that the notice requirement is inapplicable in actions for personal injury and in actions against remote sellers or manufacturers. See *Fischer v. Mead Johnson Laboratories*, 41 App. Div. 2d 737 (1973); *Hickman v. Bross*, 58 Pa. D. & C.2d 137 (C.P. 1972). *Cf. Murphy v. Petrolane-Wyoming Gas Service*, 468 P.2d 969 (Wyo. 1970) (held: notice requirement of § 2-607 inapplicable to manufacturer or retailer in action for property damages). *But see Redfield v. Mead, Johnson &*

Negligence

Action grounded on negligence should encompass negligent failure to test, negligent design, and negligent failure to warn, although, if the conduct of the IUD manufacturers toward the intended user is as reprehensible as suggested by the material presented in the Fountain Hearings, any one ground should be sufficient for recovery.

The failure to adequately warn and the occasionally pernicious designs can be traced initially to the inadequate pre-market testing conducted by the manufacturers. The general rule regarding testing is:

[W]here experiment or research is necessary to determine the presence or the degree of danger, the product must not be tried out on the public, nor must the public be expected to possess the facilities or the technical knowledge to learn for itself of inherent but latent dangers. The claim that a hazard was not foreseen is not available to one who did not use foresight appropriate to his enterprise.¹⁶⁷

This standard should be applicable to the IUD industry. Not only is the IUD a product that is intimately connected with a delicate and complex female organ, but it is also the type of product that the average consumer is unable to assess on the basis of her general knowledge. Therefore, if the testing is shown to be grossly inadequate, the IUD manufacturers cannot then complain that the product's lethal qualities were unknown since the manufacturers did not use the "foresight appropriate to [their] enterprise" to determine the product's propensity to harm.

Nor may an individual manufacturer evade liability on the basis that his conduct comported with that of the industry as a whole, for in light of the above standard it is apparent that the entire industry was negligent. In the words of the late Justice Holmes, "What usually is done may be evidence of what ought to be done, but what ought to be done is fixed by a standard of reasonable prudence, whether it is usually complied with or not."¹⁶⁸ In view of the fact that a multitude of the problems were experienced with the first generation IUDs,¹⁶⁹ prudence would dictate that cautious manufacturers assiduously test

(Continued from preceding page)

Co., 512 P.2d 776 (Ore. 1973) where the court, in reversing and remanding, gave leave to amend the complaint to include an allegation of notice. Although *Redfield* would seem to indicate that the court felt constrained to adhere to the letter of § 2-607, there was no need to do otherwise. Indeed, these cases are alike in their most fundamental aspect — the courts unanimously refused to dismiss the action for lack of notice.

¹⁶⁷ *Dalehite v. United States*, 346 U.S. 15, 51-52 (1953) (dissenting opinion), *quoted with approval in Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132 (3d Cir. 1973). *See also note 172 infra* for cases which have applied this principle to the manufacturer's duty to warn.

¹⁶⁸ *Texas & Pacific Ry. Co. v. Behymer*, 189 U.S. 468, 470 (1903). *See also The T. J. Hopper*, 60 F.2d 737 (2d Cir. 1932) (opinion by L. Hand, J.).

the second generation models prior to releasing them for general distribution. Yet such testing was never performed. On the basis of a few glowing reports, the earlier problems were overlooked, and the market was flooded with the newer models¹⁷⁰ — much to the eventual dismay of many unsuspecting users. This conduct is arguably unreasonable under the circumstances, especially when considering the gravity and magnitude of the injuries which surfaced soon after the products were released. Such maleficients as septicemia inducing multifilament strings and radiolucent devices that necessitate surgery after migration could have been discovered prior to marketing if the testing had even approached sufficiency.¹⁷¹ Where, as should be done here, the manufacturer is held to the standard of an expert in designing and producing his product, he cannot complain that he was unaware of the defects in design when he did not use the requisite degree of diligence in testing his product prior to marketing. Indeed the fact that these defects surfaced so soon after general distribution further suggests this conclusion.

Another consequence of this insufficient testing has been to necessarily render inadequate any warning given by the manufacturer to the physician. The manufacturer cannot plead that the hazards of use were unforeseen when he negligently failed to test his product.¹⁷² If the injury suffered by the plaintiff was not included in the warning, when such injury was reasonably foreseeable or capable of discovery during the testing process, any consent to the insertion of the IUD that was given by the patient is vitiated, and, as a consequence, the manufacturer should be estopped from defending on the basis of assumption of the risk. The patient cannot assume a risk of which she is unaware.¹⁷³ When the warnings given to the physician do not adequately apprise him of the reasonably foreseeable hazards attendant to the product's use, the manufacturer's duty to warn has been breached.¹⁷⁴ When this occurs, the patient is unable to give an informed consent because the physician was not able to adequately instruct and advise,¹⁷⁵ and, since uninformed consent is no consent at all,¹⁷⁶ the

¹⁷⁰ See notes 11-20 and accompanying text *supra*.

¹⁷¹ See note 204 *infra*.

¹⁷² *Kershaw v. Sterling Drug, Inc.*, 415 F.2d 1009 (5th Cir. 1969) (where manufacturer reasonably should have known of the dangers, he must give warning); *Christofferson v. Kaiser Foundation Hosp.*, 15 Cal. App. 3d 75, 92 Cal. Rptr. 825 (1971) (duty to warn applies where manufacturer "has knowledge or by the application of reasonably developed human skill and foresight should have knowledge of the danger").

¹⁷³ *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974) (there can be no assumption of risk where there was inadequate warning or no warning at all).

¹⁷⁴ *De Vito v. United Airlines, Inc.*, 98 F. Supp. 88 (E.D.N.Y. 1951).

¹⁷⁵ For a discussion of the duty of the physician, see text accompanying note 206 *infra*.

¹⁷⁶ *Fogal v. Genesee Hosp.*, 41 App. Div. 2d 468, 473, 344 N.Y.S.2d 552, 559 (1973) ("an uninformed consent to surgery obtained from a patient lacking knowledge of the dangers inherent in the procedure is no consent at all").

patient has assumed no risk. When, thereafter, the patient sustains an injury the possibility of which she was not warned, she is entitled to recover her damages directly from the manufacturer. The physician is deemed to be the agent of the patient for the purpose of receiving the manufacturer's warning, and this agency relationship allows the right to recover for inadequate warning to inure to her benefit.¹⁷⁷

Another method to prove the inadequacy of the warning is to show that what scant warnings were given were canceled by a barrage of promotional material replete with false and misleading information. A product manufacturer may not evade liability for an injury caused by his product merely because the possibility of its occurrence was included in his warning when the overall effect of his advertising campaign induced the consumer to utilize his product in spite of the fact that such use may bode ill.¹⁷⁸ To show motive for such watered down warnings, the plaintiff need only introduce evidence of the huge economic benefits to be gained by the industry from the product's wide-spread acceptance.¹⁷⁹ As previously noted, the staggering profits certainly provide ample inducement for zealous overpromotion.

In addition to effectively canceling any warnings given, these promotional materials appear to have been statutory violations and hence may be considered to be negligence per se.¹⁸⁰ When the labeling accompanying a product contains even one false statement, the product is considered to be misbranded and in violation of the statute designed to prevent such overtly misleading practices.¹⁸¹ The same holds true for advertisements expressing only half-truths.¹⁸² Thus, even though the FTC and FDA have allowed the IUD manufacturers to violate these statutes with relative impunity, a court should not be so indifferent to their actions. Since these statutes were enacted to

¹⁷⁷ Grinnell v. Charles Pfizer & Co., 274 Cal. App. 2d 424, 79 Cal. Rptr. 369 (1969); Weschler v. Hoffman-La Roche, Inc., 198 Misc. 540, 99 N.Y.S. 2d 588 (Sup. Ct. 1950).

¹⁷⁸ See note 147 *supra*.

¹⁷⁹ Love v. Wolf, 226 Cal. App. 2d 378, 38 Cal. Rptr. 183 (1964).

¹⁸⁰ See Gober v. Revlon, Inc. 317 F.2d 47 (4th Cir. 1963) (violation is negligence per se); Orthopedic Equip. Co. v. Eutsler, 276 F.2d 455 (4th Cir. 1960) (violation is negligence per se); Wright v. Carter Prods., Inc., 244 F.2d 53 (2d Cir. 1957) (statutory violation may be the basis of civil liability if injured person is member of class for whose benefit the statute was enacted and the harm resulting from the violation is of the type the statute was designed to prevent); Toole v. Richardson-Merrell, Inc., 251 Cal. App. 2d 689, 60 Cal. Rptr. 398 (1967) (violation raises a presumption of negligence).

¹⁸¹ See United States v. 2000 Plastic Tubular Cases, etc., 231 F. Supp. 236 (M.D. Pa. 1964), *aff'd*, 352 F.2d 344 (3d Cir. 1965), *cert. denied*, 383 U.S. 913 (1966) (if any single claim in the labeling is false or misleading, the device is misbranded). See also Research Laboratories, Inc. v. United States, 167 F.2d 410 (9th Cir. 1948), *cert. denied*, 355 U.S. 843 (1948) (evidence of scientific half-truths used in promotional literature and in label was sufficient to establish charge of misbranding).

¹⁸² Aronberg v. Federal Trade Commission, 132 F.2d 165 (7th Cir. 1942) (the Act forbids dissemination of any misleading advertisement which fails to reveal facts material in view of the consequences of the use of a commodity).

protect the consumer, once the plaintiff is able to show that these statutory violations contributed to her injury by inducing her to purchase the product, the liability of the IUD industry for its negligent failure to warn appears to be ineluctable.

Intentional Misrepresentation

After close scrutiny of the industry's utilization of "test results" for advertising purposes, it should be concluded that the distorted information disseminated to physicians and their patients amounts to a deliberate misrepresentation. The life-table method, for example, was designed solely for use by clinicians in their attempts to statistically evaluate the efficacy and safety of IUDs. Since it utilizes a fluid rather than a controlled study group it is at best a quasi-scientific tool whose results are often conjectural.¹⁸³

¹⁸³ Upon insertion of an IUD, women are permitted to enter the study group at any time during the compilation of data, and for every month they are under observation one "woman month" is tallied and the results recorded. Women are also permitted to leave the study group at any time, in which event these patients are deemed "lost to follow-up," and for statistical purposes are considered to follow the same pattern and yield the same results as those continuing in the study. This is, of course, deceiving because the reasons for dropping out of the study are varied and can encompass pregnancy or removal of the device by physicians not participating in the study. Much criticism throughout the Hearings was directed at this methodology in dealing with lost to follow up patients. One example of such criticism is the testimony of Dr. Madry:

[A]ll "lost" patients are eliminated from consideration in presentation of final results on the basis that "lost" patients are identical to those not lost. I am aware of no other studies related to patient care, in any of its aspects, where such a presumptuous, fallacious, mathematical formula has been applied to evaluation of experimental results obtained in human beings subject to medical treatment of any kind.

Fountain Hearings at 10.

Moreover, while the test data might indicate a greater number of "woman months" over the span of the test, there is no indication of how many women were under observation for only a short period of time. Women who are observed for only a few months following insertion would most probably not become pregnant if the manufacturer's suggestion to use an additional method of birth control during this initial term is followed. As the number of birth control methods used increases the likelihood of pregnancy decreases. Therefore, inclusion in the study of women who start early in the test cycle but leave before completion, or women who enter late in the test cycle, would appear to make the study's credibility doubtful. Supportive of this criticism is a letter from Dr. Thomsen to an IUD manufacturer, December 15, 1972:

The four studies quoted (Davis, Earl, Ostergard, Gabrielson) are probably the best you could find for your advertisement. But, these are pathetically inadequate studies in evaluating the effectiveness and complications of an interuterine device

. . . [The] Davis study covered a time period of 12 months with 640 insertions and 3,549 woman-months of use. This simply means that the study covered 640 insertions with the average of time used by each insertion being only 5.5 months. Earl's study covers a little more time (8.6 months average insertion time), but Ostergard and Gabrielson give pathetic average insertion study times of only 4.3 and 4.9 months respectively. Need I point out that the grand average of your four quoted studies involving 3,174 insertions covering 17,222 woman-months gives an equally pathetic average insertion study time of only 5.4 months.

In your own ad you suggest "A supplemental contraceptive method . . . during a 2-3 month post-insertion adjustment phase." If that three month period is subtracted from the 5.4 months average insertion study time one comes to the startling conclusion that you are selling this product with an add that really makes claims based on a partial guarantee covering only about 2.4 months of average time during which the [IUD] is the only form of contraception recommended

Because of this innate deficiency, the method was never intended to generate statistics which would form the basis of an advertising campaign.¹⁸⁴ The manufacturers knew this, yet they energetically heralded these statistics despite the fact that, when utilized in an advertising campaign, they are insidiously deceptive since their use in an advertisement indicates that they are sufficient, by themselves, to prove safety or efficacy.¹⁸⁵

Another odious advertising practice engaged in by IUD manufacturers was to select from available information only those facts beneficial in propagandizing their product, while disregarding those which would be detrimental.¹⁸⁶ This, of course, is repugnant to even the most rudimentary sense of fairplay, and is especially repulsive when the damaging information concealed relates to an issue of religious or moral belief. Although medical science is not yet certain how an IUD works, there is evidence that it operates not as a contraceptive but rather as an abortifacient.¹⁸⁷ This information was ignored in promotional material, no doubt because, were this fact generally known, the many women who consider abortion as morally unacceptable would never have considered using an IUD.¹⁸⁸ This deceit was further ex-

¹⁸⁴ See note 93 *supra*.

¹⁸⁵ See note 183 *supra*. Furthermore, testimony by Dr. Anello [Director, Division of Statistics, Office of Scientific Coordination, Bureau of Drugs] was that life table studies, by themselves, are not adequate in the FDA's opinion to establish safety or efficacy. *Fountain Hearings* at 419. For an example of one manufacturer's use of the life-table method in an advertisement, see note 117 *supra*.

¹⁸⁶ One example of this deceptive reporting is given by Dr. Thomsen: [One manufacturer's] advertisement assured gynecologists that the large surface area of the device was designed for maximum coverage of the endometrium and, thereby, maximum contraceptive effect. But the ad did not mention that maximum coverage of the endometrium might mean maximum side effects from bleeding and cramping, both known to be related to large surface coverage of IUD's. *Fountain Hearings* at 61.

¹⁸⁷ See note 20 *supra*.

¹⁸⁸ Not only did the manufacturers have to contend with the moral views of American women on the abortion issue, but even prior to extensive marketing in this country the same issue had to be faced in overseas marketing. Religious countries, such as Pakistan, would never condone utilization of an abortifacient; therefore, in the Second International Conference on Intrauterine Contraception held in New York City in 1964,

discussion was begun on the abortifacient capability of IUD's. Candidly expressing that an abortifacient label would be detrimental to promoting the device in underdeveloped countries like Pakistan, where abortion is strongly opposed, the population planners began to redefine abortion and pregnancy.

In considering redefinition, the likelihood that IUD's destroy blastocysts prior to implantation led the planners to consider defining the blastocyst out of existence. Pregnancy, they said, should be redefined to begin at implantation. It seems that all subsequent scientific conferences on the "Preimplantation Stages of Pregnancy" were to be considered mere fiction.

Later, a scientific group of the World Health Organization (WHO) gave careful consideration to the proper name for these devices. After considering such names as "Intrauterine foreign body" (IUFB), "Intrauterine contraceptive device" (IUCD), and "Intrauterine device" (IUD) they unanimously accepted the name "intrauterine device" (IUD) with the recommendation that it be universally used in the medical literature. However, most articles in the

acerbated in at least one instance when a manufacturer made the unqualified statement in his patient brochure that IUDs definitely do not cause abortion.¹⁸⁹

IUD manufacturers also evinced a reluctance to incorporate into their warnings any reports of the many adverse reactions of which they were aware until the number achieved substantial proportions.¹⁹⁰ Moreover, they refused to take cognizance of the many inimical reports which were brought to their attention unless these were published in the medical literature.¹⁹¹ In fact, one example was given wherein the manufacturer went so far as to base his entire advertising campaign on the results achieved during the first nine months of a completed eighteen month study even though the results of the first half were directly contravened by those of the study as a whole.¹⁹² He then defended this tactic on the ground that only the first half of the study was published.¹⁹³ Such an argument is outrageous since the

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literature, written primarily through grants from the Ford Foundation and the Population Council, have ignored this recommendation and continued to use intrauterine contraceptive device. This rhetorical ploy is in direct contradiction to the mounting scientific evidence that the principal mode of action of the IUD as a "contraceptive device" is not the prevention of conception but, rather, the destruction of the human blastocyst prior to implantation.

Hilgers, *supra* note 4, at 501.

¹⁸⁹ Testimony of Russel J. Thomsen, M.D., *Kennedy Hearings*, *supra* note 3, at 167.

¹⁹⁰ See note 122 *supra* and accompanying text.

¹⁹¹ The reason given by the manufacturers for ignoring the unpublished studies in their advertisements was that the unpublished studies had not yet passed the stringent standards demanded by an editorial board of an Ob-Gyn publication. There is logic to this argument. However, there is also limit. When the unpublished studies evidence adverse reactions either different or in greater incidence than the published studies, the manufacturer's obligation to warn the consumer of adverse effects is not fulfilled by ignoring the unpublished studies simply because they are unpublished. The fact of publication is not in issue, the possibility of adverse effects and the need to warn thereof is. The manufacturer must be concerned not from where the adverse information came, but with what steps must be taken to ascertain if the information is accurate, and if accurate, how to warn the consumer.

Furthermore, testimony in the *Fountain Hearings* at 117, by Dr. Thomsen, brought to light the fact that, prior to publishing the advertisement found in note 117 *supra*, the particular manufacturer had other studies in its files which were not utilized in the advertisement because of their less favorable results.

¹⁹² See statement by Mr. Fountain, *Fountain Hearings* at 404-05. Mr. Fountain then stated:

The updated study shows that the pregnancy rate had risen from 1.9 percent, as indicated in the ad, to 5.1 percent for the 18-month study. The medical removals shown in the . . . ad at 14.9 percent had risen to 26.4 percent . . . The dropout rate after 18 months was 31 percent. . . .

The ad also failed to state — that Dr. Gabrielson, after 18 months, had stated in the report

Because of the substantial pregnancy rate found in our series, we are currently advising IUD patients to use a second simple method of contraception from day 9 to day 16 of the month

The overall infection rate noted in our series was 5 percent. Four patients were ill enough to be hospitalized; one required a laparotomy.

Id. at 405.

¹⁹³ *Fountain Hearings* at 303.

manufacturer knows that it is impossible for the physician to ascertain the veracity of the information contained in an advertisement.¹⁹⁴ The physician has grown to rely on the manufacturers' representations concerning his product since the time needed to glean all of the relevant information from the medical journals is simply not available. Furthermore, both physician and patient alike tend to labor under the misconception that the FDA and FTC continually monitor the activities of the prescription drug and device industries in an effort to ensure that the manufacturers' representations are accurate. Albeit, as the Fountain Hearings so demonstrated, such is not the case.

To allow the IUD industry to have capitalized on this situation without regard to the injurious consequences to a substantial number of users would be a travesty of justice. The quest for economic gain cannot be so unfettered as to allow a manufacturer to misrepresent his product under these circumstances; and therefore, any judgment awarded would be incomplete if it did not include a sizeable complement of exemplary damages.¹⁹⁵

Strict Liability

In those states where the doctrine of strict liability in tort has been accepted, the liability of the IUD manufacturer should be virtually assured. Section 402A of the Restatement of Torts instructs that one who sells a product in a defective condition unreasonably dangerous to the consumer will be liable for any injury occasioned

¹⁹⁴ The manufacturer who utilized only the first nine months of an eighteen month study in his advertisement, on the basis that the last nine months was not included in a published study, asserted that the physician did have an avenue for verification of the advertisement. He suggested that since all inquiries by physicians concerning the product were answered by presenting "him with all of the data, published, unpublished, case reports, and even data that wasn't handled appropriately, for comparison," then there can be "no inference, to the best of [his] knowledge, of an intent to mislead anyone." *Fountain Hearings* at 312.

The problem with this manufacturer's reasoning is that it begs the issue. Certainly physicians can not be expected to have to write to manufacturers for information needed to decipher advertisements. The manufacturer's statements in the advertisements should be capable of accurate interpretation (and not misleading) without resort to outside resources. If the physician must use outside materials to weed the false from the true statements, the advertisement cannot be termed other than deceptive.

¹⁹⁵ Malice in fact, once established by the evidence, will ground an award of punitive damages where "there is evidence that the conduct in question is taken recklessly and without regard to its injurious consequences." *Toole v. Richardson-Merrell, Inc.*, 251 Cal. App. 2d 689, 713, 60 Cal. Rptr. 398, 415 (1967). See *Davis v. Hearst*, 160 Cal. 143, 116 P. 530 (1911) (wilful misrepresentation grounds for an award of punitive damages); *Sturges v. Charles L. Harney, Inc.*, 165 Cal. App. 2d 306, 320, 331 P.2d 1072, 1080 (1958) (award of punitive damages sustained due to defendant's wilful and reckless conduct showing an utter disregard of possible injury to others). See generally *Annot.*, 29 A.L.R.3d 1021 (1970) for a discussion of the allowance of punitive damages in product liability cases.

thereby.¹⁹⁶ This rule will apply even though the manufacturer has exercised all possible care in the preparation and sale of his product.¹⁹⁷

To resolve whether the defect rendered the product unreasonably dangerous, it is necessary to determine if the injury occasioned by the IUD was of the type that the ordinary consumer would have contemplated at the time of purchase. If the consumer could not have reasonably foreseen the danger inherent in the defective product and was not forewarned the manufacturer will be held strictly liable.¹⁹⁸ As previously discussed, a product that enters the market with an inadequate warning is *ipso facto* defective.¹⁹⁹ Since this appears to be the case with the IUD, the plaintiff need only show that this inadequate warning rendered the IUD unreasonably dangerous — a task of little effort since the many serious injuries sustained by IUD users were, because of the manufacturer's glib overpromotions, not anticipated by even the most knowledgeable people in the area of birth control, let alone the average consumer.²⁰⁰

Of course, the manufacturer will counter with the argument that the IUD should be exempted from the general rules for strict liability on the basis of the "unavoidably unsafe" exception, provided by

¹⁹⁶ RESTATEMENT (SECOND) OF TORTS § 402A (1965):

Special Liability of Seller of Product for Physical Harm to User or Consumer

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

(a) the seller is engaged in the business of selling such a product, and

(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The rule stated in Subsection (1) applies although

(a) the seller has exercised all possible care in the preparation and sale of his product, and

(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

¹⁹⁷ RESTATEMENT (SECOND) OF TORTS § 402A (2) (a) (1965).

¹⁹⁸ RESTATEMENT (SECOND) OF TORTS § 402A, comment g (1965):

The rule stated in this Section applies only where the product is, at the time it leaves the seller's hands, in a condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him.

RESTATEMENT (SECOND) OF TORTS § 402A, comment j (1965):

In order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warning, on the container, as to its use.

See *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974); *Basko v. Sterling Drug, Inc.*, 416 F.2d 417 (2d Cir. 1969); *Toole v. Richardson-Merrell, Inc.*, 251 Cal. App. 2d 689, 60 Cal. Rptr. 398 (1967); *Grinnell v. Charles Pfizer & Co.*, 274 Cal. App. 2d 424, 79 Cal. Rptr. 369 (1969); *Incollingo v. Ewing*, 444 Pa. 263, 282 A.2d 206 (1971).

¹⁹⁹ See *Basko v. Sterling Drug, Inc.*, 416 F.2d 417 (2d Cir. 1969); *Grinnell v. Charles Pfizer & Co.*, 274 Cal. App. 2d 424, 79 Cal. Rptr. 369 (1969); *Incollingo v. Ewing*, 444 Pa. 263, 282 A.2d 206 (1971). See also note 164 *supra*.

²⁰⁰ The manufacturers should be "the most knowledgeable" of the adverse effects of their product, but because of the inadequate testing done even they were not aware of the inherent dangers. This being the situation, information from the manufacturer to the physician must also be inadequate; and, it therefore becomes impossible for the consumer to be apprised of the possible adverse effects, since none of the "knowledgeable people in the area of birth control" knew the adverse effects.

comment *k* of section 402A.²⁰¹ For comment *k* to apply two requirements must be met: the product must be incapable of being made safe within the present state of human knowledge, and the product must possess such a high degree of social utility that its use is warranted despite this fact.

Under these requirements the IUD should not qualify for exception from the general strict liability provisions for unreasonably unsafe products. The IUD is certainly not the *sine qua non* for birth control as is the Pasteur vaccine for the treatment of rabies.²⁰² With the many alternative methods of birth control available,²⁰³ the IUD can hardly be considered so necessary that women would have to be subjected to its many inherent dangers rather than choose a substitute method. Even more damaging to the manufacturer is that defects in the product, such as infection inducing multifilament strings and migratory radiolucent designs, could have been discovered prior to general distribution if adequate testing had been conducted.²⁰⁴

Moreover, even when a manufacturer meets the requirements of comment *k* and his product is deemed "unavoidably unsafe," one further step must be taken to avoid liability. The manufacturer must give proper warning of the defect.²⁰⁵ Since the IUDs were marketed

²⁰¹ RESTATEMENT (SECOND) OF TORTS § 402A, comment *k* (1965):

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

²⁰² See example in comment *k*, note 201 *supra*.

²⁰³ See note 2 *supra*.

²⁰⁴ Such is the only logical conclusion when other clinicians, testing the manufacturer's product, and utilizing simple experiments, discovered the flaws. See Tatum, Schmidt, Phillips, McCarty, O'Leary, *The Dalkon Shield Controversy, Structural and Bacteriological Studies of IUD Tails*, 231 J.A.M.A. 711 (1975); Thomsen, *IUD Complications — Radiological Aspects of Diagnosis*, 5 CONTEMP. OB. GYN. 77 (1975).

²⁰⁵ *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974); *Borel v. Fiberboard Paper Prods. Corp.*, 493 F.2d 1076 (5th Cir. 1973); *Toole v. Richard-Merrell, Inc.*, 251 Cal. App. 2d 689, 60 Cal. Rptr. 398 (1967); *Grinnell v. Charles Pfizer & Co.*, 274 Cal. App. 2d 424, 79 Cal. Rptr. 369 (1969); *Cunningham v. Mac Neal Memorial Hosp.*, 47 Ill. 2d 443, 266 N.E.2d 897 (1970); *Incollingo v. Ewing*, 444 Pa. 263, 282 A.2d 206 (1971).

with grossly inadequate warnings they cannot, by any stretch of the imagination, be considered as "unavoidably unsafe," and thus the manufacturers should not be permitted to escape liability for the injuries caused by their products.

The Physician

Any discussion of potential physician liability is at once complicated by the fact that a minority in the medical profession consider this method of contraception so hazardous that to prescribe an IUD is malpractice per se.²⁰⁶ Moreover, there is also disagreement as to whether the insertion of an IUD should be considered a surgical procedure, thereby necessitating the completion of written consent forms prior to insertion.²⁰⁷ These differences notwithstanding, in the interest of simplicity, this note will consider only the duty of disclosing information relative to the potential adverse reactions which may be experienced by the patient.

When prescribing an IUD, there are certain duties imposed upon the physician. First, he must obtain the informed consent of his patient, and after consent is procured he must exercise due care in the insertion process. Also, the physician who utilizes the services of a paramedic may be held liable on the basis of respondeat superior. Since these potential sources of liability can logically be separated into discrete functions, they will be discussed *seriatim*.

Informed Consent

Because of its nature, the IUD can be distinguished from the other types of prescription medication dispensed by a physician. There is no question here of a physician, after diagnosing his patient's ills, relying on his many years of education and experience to select the appropriate medication entailing the least risk for the most effective treatment of the malady.²⁰⁸ The patient comes to the physician only for the prescription of a safe and effective method of birth control. Therefore, the duty of the physician is to discuss with his patient all available methods of contraception, delineating the advantages and disadvantages of each.²⁰⁹ Moreover, the disclosure as to possible adverse

²⁰⁶ Letters from Dr. Madry to the FTC, *Fountain Hearings* at 7, in which he stated:

From the medical point of view, recommendation of the IUD as a method of contraception superior to the "Pill", or causative of fewer complications than the "Pill", is per se malpractice.

²⁰⁷ Deming, *supra* note 32, at 1.

²⁰⁸ When a physician is prescribing medication, he may be entitled to withhold information that would have a detrimental effect on the mental or emotional state of his patient. However, for this therapeutic privilege to exist there usually must be some dread disease and the information withheld must be of a character that would jeopardize recovery because it would make the patient unstable or depressed. See *Salgo v. Leland Stanford, Jr. Univ. Bd. of Trustees*, 154 Cal. App. 2d 560, 317 P.2d 170 (1957); *Natanson v. Kline*, 186 Kan. 393, 350 P.2d 1093 (1960).

²⁰⁹ *Fiorin v. Wenger*, 19 N.Y.2d 407, 227 N.E.2d 296, 280 N.Y.S.2d 373 (1967).

reactions must be complete so that the patient has a rational basis upon which to make an informed choice.²¹⁰ The physician may not choose the method which he thinks is best; the final decision must be that of the patient.²¹¹ Of course, the physician must decline to prescribe the method selected if such declination is so indicated by the patient's medical history, but in those instances where there has been a full and fair disclosure of all the information to which he has been made privy by the manufacturer, the physician will be absolved of any liability for the patient's choice.²¹²

Insertion

The insertion of an IUD is an extremely delicate procedure, and because the technique may vary depending upon which brand is chosen, it is extremely important that the manufacturer's instructions be followed carefully. If a perforation occurs, any deviation from such directions may be sufficient to render the physician liable for the injury.²¹³ Moreover, it has even been suggested that because the insertion requires such a high degree of skill, no physician should attempt the procedure unless he has taken a postgraduate course in the subject.²¹⁴ The necessary corollary to this hypothesis, then, is

²¹⁰ *Salgo v. Leland Stanford, Jr. Univ. Bd. of Trustees*, 154 Cal. App. 2d 560, 317 P.2d 170 (1957) (a physician may not minimize known dangers in order to induce a patient's consent); *Fogal v. Genesee Hosp.*, 41 App. Div.2d 468, 344 N.Y.S.2d 552 (1973) (there must be a reasonable disclosure of the known dangers incident to the proposed treatment).

²¹¹ *Natanson v. Kline*, 186 Kan. 393, 350 P.2d 1093 (1960) (the law does not permit the physician to substitute his own judgement for that of the patient).

²¹² The test to be applied by the jury is what a reasonable medical practitioner would have disclosed under the same or similar circumstances. *Aiken v. Clary*, 396 S.W.2d 668 (Mo. 1965). However, the courts are split as to who must supply the standard. The *Aiken* Court, for example, held that the plaintiff must introduce expert medical testimony on this subject. On the other hand, in *Fogal v. Genesee Hosp.*, 41 App. Div. 2d 468, 344 N.Y.S.2d 552 (4th Dept. 1973), the court, after an exhaustive review of the authority, adopted the reasoning set forth in *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972), viz: duty and scope of disclosure arise apart from medical considerations and are not governed by the profession's standards of due care, but by the general standard of conduct reasonable under all the circumstances. Under this theory, the jury may consider evidence of custom but needn't be bound thereby because it is possible that the entire medical community was negligent. *Incollingo v. Ewing*, 444 Pa. 263, 282 A.2d 206 (1971).

²¹³ *Magee v. Wyeth Laboratories, Inc.*, 214 Cal. App. 2d 340, 29 Cal. Rptr. 322 (1963). However, the RESTATEMENT (SECOND) OF TORTS § 447 (1965), provides that the manufacturer will remain liable if the physician's intervening negligence is reasonably foreseeable. Hence, if the manufacturer's insertion instructions are incomplete, a physician who negligently inserts an IUD may not be liable because his conduct should have been reasonably foreseeable.

²¹⁴ Dr. Ostergard testified in the *Fountain Hearings* at 336 as follows:

Mr. Thompson. If you were a doctor, without your particular detailed background in this area, and a patient requested an IUD, what pattern would you follow to determine the proper way to insert this device:

Dr. Ostergard. I am assuming the particular physician in question has had no experience with the uterine devices in the past?

Mr. Thompson. Correct.

Dr. Ostergard. I think that particular physician would be well advised to refer this patient to someone who had had experience in the insertion of

(Continued on next page)

that any physician who attempts to perform an insertion without having taken such a course is *ipso facto* negligent. While this view may not find broad support, it does illustrate the dangers involved in the insertion process and indicate the need for specific physician training. Although a physician who has performed a number of insertions without mishap may escape liability by arguing proven expertise, it would well behoove a novice to refer his patients to an experienced colleague until he has obtained the requisite training, especially since the manufacturer can be expected to argue that a perforation occurs only during the insertion procedure. Of course, the benchmark for the imposition of liability will be provided by the general practices of the medical community,²¹⁵ but where the physician has obtained the necessary expertise and has carefully followed the manufacturer's instructions, the prospect that a jury will find him to have conformed to the required standard of due care seems favorable.

Respondent Superior

In those instances where a physician utilizes the services of a paramedic, the paramedic must conform to the above discussed standards. For deviation, the physician will be held vicariously liable, since such actions were clearly done within the scope of employment.²¹⁶ This doctrine also applies to those family planning clinics which utilize the services of paramedics to perform insertions — indeed it is in this situation that the doctrine will most likely apply since relatively few physicians employ paramedics while the clinics do so extensively. The clinic has the responsibility to ensure that all of its personnel have the required degree of skill to effect error free insertions.²¹⁷ Moreover, it is especially important that the clinic ensures the patient's right to select the method of birth control. Therefore the paramedic, as the physician, may not withhold information of possible adverse side effects of one method in an effort to channel the patient's choice to another. He may advise and counsel based on

(Continued from preceding page)

uterine devices. If he wished to pursue it himself, he would be advised to seek a post-graduate education course that would allow him to be instructed in the best technique in the uterine device insertion, preferably with a structural experience in a clinical population, such as the experience I described through our federally funded grant, as physicians do not have this opportunity to come to a clinic and actually learn this device.

²¹⁵ For a compendium of fairly recent judicial formulations of the malpractice standard, see Leff, *supra* note 161, at 397-99.

²¹⁶ This is no more than a reiteration of the basic principle set forth in the RESTATEMENT (SECOND) OF AGENCY § 243 (1958). For an excellent and thorough discussion of paramedics and the imputation of liability for their negligence to physicians, see Leff, *supra* note 161.

²¹⁷ *Id.* See also *Fiorentino v. Wenger*, 19 N.Y.2d 407, 227 N.E.2d 296, 280 N.Y.S.2d 373 (1967).

the patient's medical history and economic status, but he may not choose. When these standards have been breached, there is no informed consent; consequently, if an injury ensues the clinic will be liable.²¹⁸

Conclusion

This note has endeavored to bring the ills caused by the IUD industry to the attention of those in a position to alleviate them, and further, hopefully illuminate a few of the many arguments which can be made by plaintiff's counsel in a lawsuit against an IUD manufacturer.²¹⁹ Before closing, however, one additional practical thought should be added. Whenever possible, it will generally be preferable to join both the physician and the manufacturer as party defendants in the same suit. Moreover, in those instances in which the injury complained of is perforation of the uterus, it may even be mandatory if the plaintiff is to be successful.²²⁰ When both parties are joined, the plaintiff's overall chance for success will be improved, for both defendants will become plaintiff's ally to the extent necessary to avoid their own individual liability.²²¹

In spite of the potential for success, the tragedy of this entire episode is that for the majority of IUD injuries the culpable manufacturers will never be brought to task. Most women are probably not aware that the law will provide them with a remedy.²²² And when to the number of these women is added those who are reluctant to seek a remedy because they are loath to involve their physician,²²³ the likelihood of the IUD industry being held accountable for the magnitude of the injuries which its reprehensible conduct occasioned appears remote.

²¹⁸ *Fiorentino v. Wenger*, 19 N.Y.2d 407, 227 N.E.2d 296, 280 N.Y.S.2d 373 (1967) (hospital will be derivatively liable if a professional person employed by it commits an act of malpractice under the doctrine of respondent superior or for the malpractice committed by an independently-retained healer, if the hospital knows there is no informed consent to the procedure).

²¹⁹ Most of the evidence offered in the Fountain Hearings, is, of course, inadmissible to prove a point in issue in an actual trial. However, by reviewing the data plaintiff's counsel will be aware of what evidence should be introduced to show culpability. Furthermore, the actual correspondence, referred to in the Fountain Hearings, is available through discovery and *must* be supplied by the manufacturer. *See, e.g., Meyers v. G. D. Searle & Co.*, 41 F.R.D. 290 (E.D. N.Y. 1966) (all correspondence between manufacturer and FDA regarding product); *Henard v. Superior Court*, 26 Cal. App. 3d 129, 102 Cal. Rptr. 721 (1972) (all reports from physicians to manufacturer regarding product); *Bristol-Meyers Co. v. District Court, City and County of Denver*, 161 Col. 354, 442 P.2d 373 (1967) (all documents regarding development and testing of product).

²²⁰ Since perforation occurs in one of two ways, either by negligent physician insertion or migration of the IUD stemming from defective design, non-joinder of both parties may allow the culpable defendant to escape unscathed. In two unreported cases involving only physician-defendants, migration was determined to be the cause of the perforation and no liability ensued. *Johnson v. Ruller*, Cal. Super. Ct., Orange Co., Docket # 174871 (Sept. 7, 1972); *Hines v. Keiser Foundation Hosp.*, Cal. Super. Ct., Alameda Co., Docket # 395620 (Oct. 4, 1973).

²²¹ L. FRUMER & M. FRIEDMAN, *supra* note 108, § 34 A[4][e], at 9A-29.

²²² *Id.* [1], at 9A-5.

²²³ *See* note 21 *supra*.

It is precisely for this reason that the nonfeasance of the FDA and FTC is so outrageous. The consumer will never receive adequate protection unless these agencies assiduously assume their responsibilities and diligently perform their duties. To help ensure that this will come to pass, it is imperative that Congress enact new device legislation requiring that device manufacturers prove to the satisfaction of the FDA that their products are safe and effective prior to general distribution.²²⁴ Only in this way can recurrence of a tragedy such as that caused by the IUD industry be prevented. Common sense demands that never again should a situation be allowed to arise when, after years of distribution and thousands of serious injuries, an investigative committee of Congress must be told about a product:

The IUD of today is reputed to date from some 2,000 years ago when stones were placed by camel drivers into the wombs of their beasts of burden. The camel driver knew not how the stone prevented pregnancy, but he knew that it did work some times. If the animal became sick or died, then the camel driver undoubtedly asked his gods the nature

²²⁴ It is a sad testimonial to the previous bills passed regarding food, drug and cosmetic regulation that in order to establish the necessary impetus for their passage a grave public disaster acted as a catalyst. "Had it not been for the public impact of Upton Sinclair's *The Jungle*, with its description of the horrors of the American meat processing industry . . . , [the 1906 Federal Food and Drugs Act] might not have passed." Davidson, *supra* note 64, at 408. The 1906 Act did not require pre-market testing of drugs, and the "Elixir Sulfanilamide" disaster in which at least seventy-three persons died forced the legislature to enact the 1938 amendments requiring that drugs receive FDA approval prior to marketing. *Id.* at 409-11. The 1962 Amendments broadened the FDA's powers — but these were enacted as a direct result of the public clamor following the Thalidomide tragedy. *Id.* at 412. Will the IUD be the next catalyst?

President Nixon, in his consumer message to Congress in 1969, urged that Certain minimum standards should be established for devices; the government should be given additional authority to require premarket clearance in certain cases.

Statement of Senator Gaylord Nelson, *Fountain Hearings* at 46. "To date there has been no new legislation. The medical device industry is large and powerful, and its lobbying pressures have been felt." Although figures vary, Senator Nelson stated that in 1971 the industry's retail sales topped 3 billion dollars, a figure which will double by 1981. *Id.* The Cooper Committee, a study group commissioned to make recommendations for new device legislation following President Nixon's message to Congress, reported

that there was a medical device hazards problem, and that while its exact magnitude could not be quantified, there were convincing "indicators" of its dimensions. For example, an FDA tally of several hundred articles published since 1963 reporting problems associated with medical devices shows 512 deaths and 300 injuries associated with heart valves, 89 deaths and 186 injuries associated with pacemakers, 47 deaths and several injuries associated with anesthesia machines, 28 deaths and 171 injuries associated with catheters of various kinds, over 8,000 injuries associated with IUD's, over 2,000 injuries associated with radiation equipment, and hundreds of injuries associated with a wide variety of prosthetic and orthopedic devices, dental equipment, sutures, syringes, heating pads and blankets, and contact lenses.

Copper, *supra* note 48, at 170 (emphasis added). The Cooper Committee Report was made public in September 1970, but as yet Congress has not acted. Only prompt action will thwart the established legislative pattern — new device amendments must precede

of the offense he had committed; he certainly had no conception of rates of morbidity or mortality due to "camel stones." We might compare ourselves today with that camel driver of long ago, and asking ourselves the same question, arrive at virtually the same answers.²²⁵

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²²⁵ *Fountain Hearings* at 11.

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