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## BEYOND THE DALKON SHIELD: PROVING CAUSATION AGAINST IUD MANUFACTURERS FOR PID RELATED INJURY

Intrauterine devices (IUDs)<sup>1</sup> have been linked to a wide variety of injuries to women, ranging from severe cramping, to spontaneous abortion, to sterility, to death. This Comment will focus on the problem of proving that scarring of the fallopian tubes, resulting in sterility or partial sterility, is causally linked to use of the IUD, and therefore, a provable element in a plaintiff's cause of action against a manufacturer for such injuries.

In spite of sketchy guidance from case law as to what will constitute a winning causation argument, a number of medical findings can establish that, more likely than not, plaintiff's IUD was a cause in fact of her injury: (1) medical studies showing a greatly increased risk of pelvic inflammatory disease for women who use IUDs, (2) testimony as to the pattern of development of the infection, (3) the condition of the device itself when it was removed from plaintiff's uterus, (4) the type of bacteria that caused the infection, and (5) the wicking action of the device's string.

### I. HISTORY OF THE IUD

The theory behind the IUD is an ancient one. Arabian and Turkish camel drivers are thought to have placed pebbles in the uteri of their animals to prevent pregnancy on long journeys.<sup>2</sup>

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1. IUDs are small plastic devices of various shapes and sizes. The IUD is inserted into the uterus by a doctor or nurse practitioner to prevent pregnancy.

Exactly how an IUD prevents pregnancy is unknown, but the following mechanisms have been proposed:

(1) The IUD prevents the egg which has been fertilized in the fallopian tube from attaching to the uterine wall. The IUD probably accomplishes this by irritating the lining of the uterus by rubbing against the uterine walls.

(2) The IUD may cause the egg to move more quickly through the fallopian tube so there is less time for fertilization to occur.

(3) The inflamed or irritated condition caused by the device creates an increased amount of white blood cells which may ingest, or prove toxic to sperm.

THE BOSTON WOMEN'S HEALTH COLLECTIVE, *OUR BODIES, OURSELVES* 196 (2d ed. 1979) [hereinafter cited as *OUR BODIES, OURSELVES*].

2. Schmidt, *IUDs, Inflammation, and Infection: Assessment after Two Decades of*

The Hippocratic oath decrying the use of a pessary to cause abortion, suggests that such devices were used to affect womens' reproductive systems even then.<sup>3</sup> Diamond studded IUDs are reported as early as the late 1800's.<sup>4</sup>

Throughout their long history, IUDs have been surrounded by controversy. Periods of popularity were followed by periods of rejection. In 1936 the Japanese government prohibited their use completely.<sup>5</sup> In 1980 there were an estimated 6 million IUDs in use throughout the world.<sup>6</sup>

In 1909 a precursor to the modern IUD was made from silk-worm gut. By the 1930's this model had developed into a silk-worm gut ring held in shape by a wire of silver and copper.<sup>7</sup> By the late 1930's and early 40's the device was associated with such a high rate of infection and complications that it was overwhelmingly condemned by the medical community<sup>8</sup> even though it reportedly had a respectable failure rate of only 2.5 per 100 women per year.<sup>9</sup>

Independent articles published in 1959, one by an Israeli researcher and one by a Japanese doctor, both reported the IUD to be safe and effective. The Israeli researcher went so far as to call the device "absolutely harmless."<sup>10</sup> These reports spurred a flurry of new research and experimentation in the United States in the early 1960's and led to the development of several new models of IUDs.<sup>11</sup> It was later said that "unfortunately [these] advocates were careless in their reading, for nothing new or revolutionary had been added to the already existent knowledge."<sup>12</sup>

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*IUD Use*, 13 HUM. PATHOLOGY, Oct. 1982, at 878 [hereinafter cited as Schmidt, *IUDs Assessment*].

3. *Id.*

4. *Id.*

5. *Id.*

6. HATCHER, STEWART, STEWART, GUEST, SCHWARTZ, & JONES, *CONTRACEPTIVE TECHNOLOGY* 1980-81 at 53 (rev. 10th ed. 1980). [hereinafter cited as *CONTRACEPTIVE TECHNOLOGY*].

7. *Id.* at 52.

8. G. COREA, *THE HIDDEN MALPRACTICE* 168 (1977) [hereinafter cited as *MALPRACTICE*].

9. *CONTRACEPTIVE TECHNOLOGY*, *supra* note 6, at 52.

10. *MALPRACTICE*, *supra* note 8, at 170.

11. *CONTRACEPTIVE TECHNOLOGY*, *supra* note 6, at 53.

12. *MALPRACTICE*, *supra* note 8, at 170.

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Other evidence points to increased interest in IUDs being spurred not by the Israeli and Japanese papers, but by a perception on the part of family planning and population control experts that underprivileged populations needed low motivation birth control.<sup>13</sup> Birth control programs were considered to be cost effective weapons in the war on “newly discovered” poverty in America.<sup>14</sup> In one ghetto clinic in New York City, 55% of the women were given the Majzlin Spring because it had been developed by the director and he was researching a new model. The FDA later recalled that model as being associated with an undue number of serious complications.<sup>15</sup>

Another factor in the surge of renewed interest was the development of chemically inert plastics.<sup>16</sup> Such plastics are composed of relatively pure substances and can be straightened for insertion; once inside the uterus, they will return to their originally molded shape. Inert plastics may have made it easier to insert and remove IUDs because they don't necessitate dilation of the cervix, but the devices weren't necessarily any safer than the earlier models. In some cases the inert plastic devices disintegrated in utero, requiring a D & C to extract the pieces that didn't pass out in fragments.<sup>17</sup>

It was also in the late 1960's and early 70's that the dangers of the birth control pill were being widely publicized.<sup>18</sup> Women who were accustomed to the pill's convenience but alarmed by its dangers were more willing to try a new product.

By 1975 there were an estimated 15 million IUDs in use around the world. Around that time, the same problems encountered in the 1930's and 40's began to emerge.<sup>19</sup> The Dalkon Shield in particular caused the most damage and became one of the most widely litigated products in pharmaceutical history.<sup>20</sup> The Shield, manufactured by the A.H. Robins Company had a

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13. *Id.* at 169.

14. Sharpe, *The Birth Controllers*, in *SEIZING OUR BODIES* 68 (C. Dreifus ed. 1978)

15. *MALPRACTICE*, *supra* note 8, at 157.

16. Schmidt, *IUDs Assessment*, *supra* note 2, at 878.

17. *MALPRACTICE*, *supra* note 8, at 169.

18. Dowie & Johnston, *A Case of Corporate Malpractice and the Dalkon Shield*, in *SEIZING OUR BODIES*, 89 (C. Dreifus ed. 1978) [hereinafter *SEIZING OUR BODIES*].

19. *MALPRACTICE*, *supra* note 8, at 171.

20. *SEIZING OUR BODIES*, *supra* note 18, at 88.

design and composition that set it apart from other IUDs and caused more medical complications than any of the others. The unique physical characteristics of the Shield and the possibility of fraud on the part of its inventor and manufacturer, make proof of liability much clearer for it than for other types of IUDs. For that reason the Dalkon Shield will be discussed only in a footnote and this Comment will concentrate on IUDs in general, and not on any one in particular.<sup>21</sup>

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21. The Dalkon Shield is an IUD which was developed by an independent inventor and later sold to the A.H. Robins Company in the early 1970's. The Shield differs from most other IUDs in that it has small protrusions intended to reduce the chance of expulsion. The Shield also differs from other IUDs because of its polyfilamented (more than one strand) string. Other IUDs are monofilamented and have only one strand. This string is connected to the IUD and passes through the cervix into the vagina. It has been established that the polyfilamented string creates a "wicking action," drawing bacteria from the vagina through the cervix and into the relatively sterile uterus. Some doctors feel that the presence of any foreign body in the uterus connected by any kind of thread reaching through the cervical canal into the vagina makes it more likely that certain infections will be drawn into the upper genital tract where they can cause serious disease. It is also believed that IUDs tend to exacerbate any infection already present in the uterus. Guilleband, *The Safety of IUDs*, 10 *STUD. FAM. PLAN.* 174,175 (1979) [hereinafter cited as *Safety of IUDs*].

Before the Shield went on the market, only one study was done by its inventor to determine the pregnancy rates to be used in future advertising of the product. His results were published in the American Journal of Obstetrics and Gynecology in February 1970 and showed an impressive 1.1% pregnancy rate. The article received widespread press attention, since it was at about this time that the dangerous side effects of the birth control pill were being discovered and publicized. It was later uncovered that the inventor had told many of the women in his study to use spermicidal foam during part of their cycles, a fact which makes his pregnancy rate questionable at best. It also turned out that less than half of the women in the study used the device for a full year. *SEIZING OUR BODIES*, *supra* note 18, at 91. Later, when the Robins Company was negotiating to buy the rights to the Shield, the pregnancy rate was discovered to be 6%. Advertisements in medical journals beginning in December 1970, however, contained the original 1.1% rate. *Id.* at 90. Robins did additional testing and claimed that the Shield permitted only a 3% pregnancy rate, which it duly reported in its ads. *Id.* Private studies performed in Boston and Sacramento at the same time and which were sent to Robins, produced pregnancy figures of 10.1% and 5.6% respectively. *Id.* at 97. These reports were not investigated further by Robins, nor were its advertising figures changed. *Id.*

In 1971, a physician working in another division of the Robins Company discovered that the multifilamented string displayed wicking qualities, which she predicted might lead to serious infection. *Id.* at 96. When she reported her findings to the IUD division of Robins, she was told that her findings would be investigated further by the company's microbiologist. *Id.* at 97. No further action was taken, and when outside doctors inquired about whether the infections they were seeing could have been caused by this wicking action, Robins replied that as far as it knew, the problem did not exist. *Id.* at 96.

Between 1970 and 1973, Robins received numerous complaints from doctors across the country that its product was causing PID and other problems. See Note, *The Intrauterine Device: a Criticism of Government Complaisance and an Analysis of Manufacturer and Physician Liability*, 24 *CLEV. ST. L. REV.* 247, 274 (1975) [hereinafter cited

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## II. PELVIC INFLAMMATORY DISEASE: THE MEDICAL VIEW

Damage to the fallopian tubes may be caused by pelvic inflammatory disease (PID) or as it is otherwise known, salpingitis, which is an infection of the fallopian tubes and ovaries caused by one or more of a number of different bacteria. These infections cause the tubes to abscess or scar, which in many cases cause them to become blocked so that the unfertilized egg cannot travel through the tube to the uterus where fertilization takes place, thus rendering the woman totally or partially infertile. The most reliable way to determine whether the tubes have been completely blocked is a painful surgical procedure called a hysterosalpingogram, where a dye is forced through the tubes and then x-rayed to determine the configuration of the tube.<sup>22</sup>

There are an estimated half million cases of first time PID each year in the United States.<sup>23</sup> If PID is diagnosed early enough, it can be controlled with high doses of antibiotics, and the damage will be limited to partial or no tube scarring. If the PID has sufficiently progressed before it is diagnosed, however, it may cause sterility. In some cases it may be necessary to remove one or both tubes and the ovaries, or perform a total hys-

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as Note, *Criticism*]. In addition to burying findings that it did not want anyone to know about, and failing to advertise accurate pregnancy rates, there is evidence that Robbins made certain misstatements in brochures that went to doctors and patients. These misstatements include "but we do know it's harmless," and "the Food and Drug Administration is kept informed about the progress with these devices." These same brochures virtually ignored the serious side effects and complications of IUDs. See generally *Hearings on Intrauterine Contraception Devices Before a Subcomm. of the House Comm. on Government Operations*, 93d Cong., 1st Sess. 80-108 (1973).

When the dangerous effects of the Shield were widely publicized in 1973 as a result of Congressional hearings, *id.*, the Robins Company sent a letter to all doctors advising them of the possible dangers associated with the device, and for the first time included complete warnings in their package inserts. *SEIZING OUR BODIES*, *supra* note 18, at 99. Robins also informed doctors at that time that if their patients currently using the device were not having any problems, then it was safe for them to leave the device in place and rely on it for contraception. (From interview with a Dalkon Shield plaintiff, San Francisco, California (March 1982).) No general recall of the device has ever been made.

22. Barbot, Parent, & Dubuisson, *Contact Hysteroscopy: Another Method of Endoscopic Examination of the Uterine Cavity*, 136 AM. J. OBSTETRICS & GYNECOLOGY 721, 723 (1980). Even though no cutting is involved, a hysterosalpingogram is considered to be a surgical procedure since it is performed in an operating room under general anesthesia. See also WHITEHOUSE, *GYNECOLOGICAL RADIOLOGY*, 20, 73-86, 151-52 (1981); BENSON, *CURRENT GYNECOLOGIC TREATMENT*, 929-30 (1980).

23. *Digest-IUD Users Have Higher Risk of Contracting PID, Studies Find; Pill May Have Protective Effect*, 12 FAM. PLAN. PERSP. 260, 260 (1980) [hereinafter cited as *Digest IUD*].

terectomy in order to prevent the infection from spreading.<sup>24</sup>

One of the major problems of treating PID in order to prevent major damage is that it is often difficult to diagnose. Its symptoms, such as nausea, fever, and severe cramping, are vague and easily attributable to a number of conditions. Doctors often respond to those symptoms by testing a complaining patient for gonorrhea and/or pregnancy, and it may be several weeks before a test for PID is made.<sup>25</sup> Many doctors feel that the only way to tell definitely if a patient has PID is to perform a laparoscopy.<sup>26</sup> Physicians are understandably hesitant to perform surgery every time a patient complains of nausea and cramps, and as a result, injuries from PID advance and worsen because the infection is not caught in its early stages.

“It appears that the IUD itself makes the bearer more susceptible to PID, other factors notwithstanding.”<sup>27</sup> Incidence of PID correlates more closely with the use of IUDs than with the use of any other method of birth control. PID is an increasingly prevalent health problem, and “the increasing use of the IUD as a means of fertility control almost certainly also contributes to the problem.”<sup>28</sup> In the past few years results from numerous medical studies have indicated a greatly increased incidence of PID in women who have IUD’s.

“Nevertheless, studies are remarkably consistent in estimating the increased risk of PID in IUD users as between roughly 3 and 9 fold overall; the

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24. OUR BODIES, OURSELVES, *supra* note 1, at 175.

25. This presents a classic case of the medical profession refusing to believe that women are medically informed and that they know what is going on with their bodies. One woman interviewed for this paper, *supra* note 21, said that she went to the emergency room with severe cramps, dizziness and nausea, that she told the doctor she had an IUD and that he ought to remove it. He kept her waiting for a number of hours and tried to convince her that she was either pregnant or had gonorrhea, even though she insisted that both were physically and medically impossible as she had not had intercourse for four months.

26. Golden, *Better Diagnosis Could Aid Against Pelvic Inflammatory Disease*, 243 J.A.M.A., June 27, 1980, at 2471, 2472. A laparoscopy is a procedure whereby an instrument called a laparoscope is inserted through the abdomen so that the doctor can observe the tubes and uterus directly. A dye is introduced through the uterus to help in the viewing.

27. Schmidt, *IUDs Assessment*, *supra* note 2, at 878.

28. Eschenback & Holmes, *Acute Pelvic Inflammatory Disease: Current Concepts of Pathogenesis, Etiology, and Management*, 18 CLINICAL OB/GYN, March 1975, at 35.

lower figure for older parous [those who have already had a child] women, and the higher figure to younger, nulliparous [those who have not yet had a child] women. . . . The consistency of these reports strongly suggests that the association is causal . . . ."<sup>29</sup>

One often-cited study whose authors claim to represent the first large cohort study<sup>30</sup> to examine the relationship between PID and IUDs, found that hospital admission rates for PID were 1.5 per 1000 women per year among those women currently using an IUD and 0.14 per 1000 women per year among those using other forms of birth control. That is, PID was over 10 times more common in women with IUDs than in women who used some other form of birth control. Another study found that women who had used an IUD for 5 years had a 12.9 times greater risk of contracting PID than women who did not use the device, and those who used an IUD for less than 5 years had a 5.7 times greater risk than non users.<sup>31</sup>

Some studies have indicated that women who become sexually active at an earlier age, and women with multiple partners, have a higher risk of PID.<sup>32</sup> This is generally thought to be a result of increased exposure of these women to harmful bacteria in general, and more specifically to increased exposure to gonorrhea. Defense attorneys have relied on these facts in an attempt to establish that plaintiff's PID was in fact caused by her "immoral" sex life, and not by the defendant's IUD.<sup>33</sup> Previous gonorrhea is also statistically correlated to subsequent PID and to the recurrence of PID. Gonorrhea has been found to cause fallopian tube damage which often doesn't manifest itself until years later when the women experience difficulty in becoming pregnant. It is hypothesized that unrecognized tubal damage as a result of gonorrhea might have the effect of impairing the bacterial balance in the tube, predisposing the patient to the higher rate

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29. *Safety of IUDs*, *supra* note 21, at 175.

30. Vessey, Yeates, Flavel, & McPherson, *Pelvic Inflammatory Disease and the Intrauterine Device: Findings in a Large Cohort Study*, 282 BRIT. MED. J., March 14, 1981, at 885. A cohort study is one which follows a group of experiment subjects over a period of years.

31. *Digest IUD*, *supra* note 23, at 207.

32. *Id.* at 206.

33. Interview with Dennis Conklin, plaintiff's personal injury attorney, San Francisco, California (April 1982).



of PID.<sup>34</sup> A study that compared a group of women with gonococcal PID, to a group suffering from nongonococcal PID, however, established no significant difference between the groups in frequency of intercourse per week or in number of sex partners in the six months preceding the study.<sup>35</sup> More importantly, the researchers found that IUD users were four times more likely to develop PID than non-users.<sup>36</sup>

Several theories have developed to explain how the IUD can cause a pelvic infection or how it can severely aggravate an existing pelvic infection in its early stages. One commonly held theory is that the IUD prevents conception by causing a slight inflammation of the uterus, thereby creating a hostile uterine environment which prevents the fertilized egg from implanting and developing.<sup>37</sup> The inflammation caused by the IUD, it is reasoned, renders the uterus more susceptible to a full-blown infection.

PID can be caused by a doctor's negligence in inserting the device despite medical contraindications. If a doctor decides to insert an IUD in a woman who has had previous pelvic infections or ectopic pregnancies,<sup>38</sup> s/he is seriously increasing the patient's chances of contracting PID again<sup>39</sup> because IUDs aggravate already infected or inflamed tissue.

34. Eschenback, Harnisch, Holmes, *Pathogenesis of Acute Pelvic Inflammatory Disease: Role of Contraception and Other Risk Factors*, AM. J. OBSTETRICS & GYNECOLOGY, August 15, 1977, at 838, 847 [hereinafter cited as *Pathogenesis*].

Of 253 women studied, "some form of salpingitis was found in 54% of the IUD group and in only 6% of the control group . . . As the IUD and control group were comparable in all investigated parameters, the inflammatory reaction must be caused by the method of contraception." Beerthruzen, Van Wyck, Eskes, Vermeulen, & Vooijs, *IUD and Salpingitis: A Prospective Study of Pathomorphological Changes in the Oviducts of IUD Users*, 13 EUR. J. OBSTETRICS, GYNECOLOGY, & REPRODUCTIVE BIO., February 13, 1982, at 31, 31.

35. See *Pathogenesis*, *supra* note 34, at 840.

36. *Pathogenesis*, *supra* note 35, at 847.

37. When the sperm and the egg meet in the fallopian tube, they form a zygote (fertilized egg) which travels into the uterus and becomes implanted on the uterine wall. The zygote divides and develops into a fetus.

38. An ectopic pregnancy is one in which the fertilized egg implants itself, not in the wall of the uterus, but most often in the fallopian tube, or much more rarely in the abdominal cavity, the ovary, or the cervix. OUR BODIES, OURSELVES, *supra* note 1, at 324.

39. Interview with Jack Futeron, M.D., OBGYN, San Francisco, California (April 1982).

A second theory linking the IUD with PID is that the infectious organisms enter the uterus when the IUD is inserted. This may occur if the IUD is not properly sterilized before insertion. It can also occur if care is not taken to ensure that organisms from the vagina aren't pushed through the cervical canal along with the IUD.<sup>40</sup>

PID has also been associated with the wicking action of the string that is attached to the device and passes through the cervix into the vagina.<sup>41</sup> Other theories, however, link the presence of any foreign body in the uterus connected by any kind of thread reaching through the cervical canal with increased likelihood of infections being drawn into the upper genital tract. It is also suggested that IUDs tend to cause any pre-existing infection in the uterus to become more serious, and that stringless IUDs do not have infection rates any lower than those with strings, monofilamented or otherwise.<sup>42</sup>

It is possible to determine that PID is IUD related by examining the manner in which the infection spread.<sup>43</sup> Classic PID in the absence of a device is bilateral—both tubes are infected. PID caused by an IUD is usually unilateral, with only one side infected. When it is apparent that the infection is only present on one side, or that the infection started on one side and then spread, it is clear that the infection was IUD related.<sup>44</sup> This usually happens when the device becomes embedded in one side of the uterus and then aggravates an infection.<sup>45</sup>

The type of bacteria which created the infection should also be examined. *Actinomyces Israelii* is an organism that can cause PID and is not sexually transmitted.<sup>46</sup> "It is our belief that the recognition of *actinomyces* in the vaginal smear is *always* associ-

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40. Information handout written by the Women's Needs Center, San Francisco, California (1981).

41. See *supra* note 21.

42. *Safety of IUDs*, *supra* note 21, at 175.

43. Interview with Jack Futeron, M.D., *supra* note 39; See Schmidt, *IUDs Assessment*, *supra* note 2, at 879.

44. *Id.*

45. Interview with Jack Futeron, M.D., *supra* note 39.

46. See Brenner & Gehring, *Pelvic Actinomycosis in the Presence of Endocervical Contraceptive Devices*, 29 AM J. OBSTETRICS & GYNECOLOGY, January 1967, at 71.

ated with a foreign body, most commonly an IUD."<sup>47</sup> New research linking uterine *actinomyces* to IUDs indicates that there is no safe IUD and urges the nearly 3 million American women using intrauterine devices to use another form of contraception.<sup>48</sup>

*Actinomyces*-linked PID "is uncommon unless associated with IUDs and is clearly different from the more usual, bilateral PID."<sup>49</sup> Such PID is almost always unilateral, involves massively destructive tubo-ovarian abscesses, and causes sterility in a large number of cases.<sup>50</sup> Very recent research into this variation of PID suggests that its incidence has nothing to do with the promiscuity of the victim, but rather with the length of time she had an IUD in her uterus, as biodegradation and biotransformation of the surface of the device over time is an essential pathogenic component.<sup>51</sup> *Actinomyces* is such a strong indicator of a disposition towards infection, that doctors recommend immediate removal of an IUD even in asymptomatic women who show *actinomyces* on their pap smears.<sup>52</sup>

Another theory linking PID and IUDs is that use of the device reduces the efficiency of local natural barriers that protect against the spread of bacteria into the upper genital tract.<sup>53</sup> Still another theory is that the device promotes vaginal polymicrobial

47. Gupta & Woodruff, *Actinomyces in Vaginal Smears*, 247 J.A.M.A., Feb. 1982, at 1175 (emphasis added).

48. Gupta, unpublished research as reported in San Francisco Examiner, March 4, 1982, at A16, col. 1.

Recent research shows that *actinomyces* infection can spread throughout the body causing serious problems. In a case study, a woman was found to have a cranial abscess containing *actinomyces* four years after she had undergone a complete hysterectomy to contain her PID. At the time of the hysterectomy, her doctor mistakenly assumed that the removal of the infected organs would end the infection and so did not prescribe any antibiotics. de la Monte, Gupta, & White, *Systemic Actinomyces Infection: A Potential Complication of Intrauterine Contraceptive Devices*, 248 J.A.M.A., Oct. 1982, at 1876-77.

49. Schmidt, *IUDs Assessment*, *supra* note 2, at 879 citing Schmidt, Bedrassian, & Ali, *Actinomyces and Intra-Uterine Contraceptive Devices: The Clinicopathologic Entity*. 2 DIAGN. GYNECOLOGY & OBSTETRICS 165-177 (1980).

50. *Id.*

51. Schmidt, *IUDs Assessment*, *supra* note 2, at 879.

52. Burkman, Schlesselman, McCaffery, Gupta & Spence, *The Relationship of Genital Tract Actinomyces and the Development of Pelvic Inflammatory Disease*, 143 AM. J. OBSTETRICS & GYNECOLOGY, July 1, 1982, at 585, 588.

53. Eschenback & Holmes, *supra* note 28, at 40.

overgrowth, (growth of more than the usual amount of bacteria in the vagina) that later causes upper genito-urinary tract infections.<sup>54</sup>

### III. PROCEDURAL PROBLEMS OF THE STATUTE OF LIMITATIONS

The initial problem confronted by a plaintiff attempting to sue for injuries caused by an IUD is the bar posed by the statute of limitations.

California, for example, has a one year statute of limitations for injuries or death resulting from a wrongful act or failure to act.<sup>55</sup> The statute implicitly establishes that the limitations period begins to run "after the cause of action shall have accrued."<sup>56</sup> Generally, a cause of action accrues when the wrongful act is committed and the plaintiff has sustained injuries for which relief could be granted.<sup>57</sup>

This rule is extremely harsh when applied to IUD related injuries because in many cases the full extent of the damage or the fact that the injuries may be causally connected to the IUD, is not discovered until more than one year after the wrongful act has occurred.<sup>58</sup> To reduce the harshness of the rule on plaintiffs, the California courts have established a number of exceptions to the rule which have the effect of tolling the statute of limitations.<sup>59</sup>

54. See Golden, *supra* note 26, at 2472.

55. CAL. CIV. PROC. CODE § 340(3) (Deering 1972). This section reads "an action for . . . injury to or for the death of one caused by the wrongful act or neglect of another . . . ."

56. CAL. CIV. PROC. CODE § 312 (Deering 1972).

57. *United States Liab. Ins. Co. v. Haidinger-Hayes, Inc.*, 1 Cal. 3d 586, 596, 463 P.2d 770, 776, 83 Cal. Rptr. 418, 424 (1970); See, e.g., 2 WITKIN, CALIFORNIA PROCEDURE § 263 (2d ed. 1970) [hereinafter cited as WITKIN, PROCEDURE]. In California, under a strict accrual theory, two corollary theories exist which reduce the ability of an IUD plaintiff to receive redress for her injuries.

The first theory is that section 340 begins to run even though the plaintiff is ignorant of the fact that she has a cause of action. See *Rubino v. Utah Canning Co.*, 123 Cal. App. 2d 18, 27, 266 P.2d 163, 168 (1954), *c.f.* *Warrington v. Charles Pfizer & Co.*, 274 Cal. App. 2d 564, 80 Cal. Rptr. 130 (1969).

Under the second theory, section 340 will begin to run even if the plaintiff did not sustain any significant injuries at the time. See *Sanburgh v. MacQuarrie*, 112 Cal. App. 2d 771, 773, 247 P.2d 133, 135 (1952), See generally WITKIN, PROCEDURE, *supra* at §§ 264-65.

58. See *supra* note 48.

59. See WITKIN, PROCEDURE, *supra* note 57, at § 266.

The exceptions to the rule are most easily illustrated in the case of *Nelson v. A.H. Robins Co.*,<sup>60</sup> where the Federal District Court of Northern California applied the California statute of limitations.<sup>61</sup> In *Nelson*, a woman who was rendered infertile, allegedly from her IUD, was held not to be barred from suing the manufacturer, despite the fact that the one year statute of limitations was long past. Plaintiff's IUD was inserted in February of 1971.<sup>62</sup> In July, 1971 she experienced fainting and cramps. Her doctor diagnosed PID and removed her IUD immediately.<sup>63</sup> He told her that the IUD was infected and prescribed antibiotics. She had no further problems until January 1973 when she tried unsuccessfully for a year to become pregnant.<sup>64</sup> The doctor informed her that her tubes were scarred from PID.<sup>65</sup> He operated, and told her that he had been able to clear them. In 1977 plaintiff had still not become pregnant. The doctor performed tests and pronounced that her tubes were totally blocked and that she was sterile.<sup>66</sup> Plaintiff then brought suit against the manufacturer of the device—over six years after the apparent date of the onset of the injury.<sup>67</sup>

The *Nelson* court outlined four exceptions which may toll the one year statute of limitations:

- (1) Where there is no single wrongful act, but rather a period of exposure which results in a continuing injury, the statute is tolled until the time plaintiff knew or should have known that she was suffering from a disease that was likely to cause her injury;<sup>68</sup>
- (2) When plaintiff's injury involves pathological effects occurring without perceptible trauma;<sup>69</sup>
- (3) When plaintiff's failure to bring a cause of

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60. 515 F. Supp. 623 (N.D. Cal. 1981).

61. See 28 U.S.C. § 1332(a) (1976). *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938), held that a federal district court, while sitting in diversity jurisdiction, must apply the substantive law of the state of its situs.

62. 515 F. Supp. at 624.

63. *Id.*

64. *Id.*

65. *Id.*

66. *Id.*

67. *Id.*

68. *Id.* at 625 (citing *Velasquez v. Fibreboard Paper Prod.*, 97 Cal. App. 3d 881, 887-89, 159 Cal. Rptr. 113, 117-18 (1979)).

69. 515 F. Supp. at 625.

action is a result of defendant's fraudulent concealment of facts relating to discovery of a potential cause of action;<sup>70</sup>

(4) When a person, although aware that an injury has occurred, has not yet discovered that her/his injury was caused by defendant's conduct or a defective product.<sup>71</sup>

It is this final exception which was at issue in *Nelson*. The *Nelson* court framed the issue as such—when did the plaintiff possess “facts that identified a *conclusive* relationship between her injuries and the defendant's alleged defective product.”<sup>72</sup>

In determining the moment at which the plaintiff sufficiently discovered the source of her injury, the court scrutinized the information that plaintiff received from her doctor when her IUD was removed in July of 1971.<sup>73</sup> When the IUD was removed the plaintiff's doctor informed her that “it [the IUD] was obviously infected and causing her problems.”<sup>74</sup>

The court found that this statement was insufficient to apprise the plaintiff of the source of her injury, and held that as a matter of law,

[T]he information which the plaintiff must possess with respect to the diagnosis relating her injuries to a particular product is meant to be . . . an “informed diagnosis” roughly parallel to “informed consent” in medical malpractice or battery actions. The physician's diagnosis must be such . . . *that the patient knew or should have known* that the defendant's allegedly defective product caused her injuries.<sup>75</sup>

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70. 515 F. Supp. at 625. See e.g., *Warrington v. Charles Pfizer Co.*, 274 Cal. App. 2d 564, 569-70, 80 Cal. Rptr. 130 at 133-34 (1969). This exception includes some “other valid excuse” which plaintiff may be able to produce. *Id.*

71. 515 F. Supp. at 626; *In re Dalkon Shield IUD Products Liability Litigation: Sidney-Vinstein v. A.H. Robins Co.*, 503 F. Supp. 194, 197 (N.D. Cal. 1980); *Warrington v. Charles Pfizer Co.*, 274 Cal. App. 2d at 572-73, 80 Cal. Rptr. at 135 (statute of limitations was tolled because of defendant's false representations to the public and to the medical profession regarding the safety of its products).

72. 515 F. Supp. at 626 (emphasis added). It must be noted that the defendant's motion for summary judgment in *Nelson* was made after a single deposition had been taken. *Id.*

73. *Supra* note 63 and accompanying text.

74. 515 F. Supp. at 624.

75. 515 F. Supp. at 626 (emphasis added) (citing as to the parallel to informed con-

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The *Nelson* court reasoned that the doctor's statement to the plaintiff in July, "raises dual inferences as to its effect on the state of mind of the plaintiff's knowledge as to the precise cause of her injuries."<sup>76</sup>

The exceptions outlined in *Nelson* provide the prospective IUD plaintiff with several methods of circumventing the California statute of limitations. While the Dalkon Shield cases are representative of the "fraudulent concealment" exception,<sup>77</sup> *Nelson* clearly illustrates the "discovery" exception. Neither the "pathological effects" nor the "perceptible trauma" exceptions have been at issue with regard to an IUD case. These last two theories, however, are of far less utility to IUD plaintiffs because of the existence of the "discovery" rule which is more flexible and therefore adaptable to the varied fact situations involved in IUD related PID cases.<sup>78</sup>

#### IV. IUDS AND THE SUBSTANTIVE LAW

##### A. *Strict Liability*

Actions premised on the theory of strict liability in tort focus not on the manufacturer's conduct, but on the product itself. The policy basis of strict liability in tort is that the manufacturer, who can absorb the cost through insurance, or spread the cost through a consuming population, is in the best position to pay for injuries suffered by victims of a defective product it put on the market. Strict liability, it has been argued, is an incentive to manufacturers to produce safe products by adequately testing them and insuring against defects prior to putting them into commerce.<sup>79</sup>

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sent. *Velasquez v. Fibreboard*, 97 Cal. App. 3d at 888-89, 159 Cal. Rptr. at 117-118).

76. 515 F. Supp. at 626.

77. See *In Re Dalkon Shield IUD Products Liability Litigation: Sidney-Vinstein v. A.H. Robins Co.*, *supra* note 71. See also *supra* note 21.

78. Both of these exceptions are much better suited to the situation presented where the plaintiff is suffering from injuries received because of long term exposure to harmful substances which cause disease that become more severe with time and eventually incapacitate the plaintiff. See *Velasquez v. Fibreboard*, 97 Cal. App. 3d 881, 159 Cal. Rptr. 113, (continuing wrong theory used).

79. The testing of drugs is closely regulated by the FDA. Therefore before any drug is put on the market, it must conform to that agency's specified amount and kind of testing. When the Dalkon Shield first went on the market (around 1969), however, the FDA did not require testing of medical devices. Because IUDs were classified as such, little testing was done before the device was sold, and the results of that testing were not

A manufacturer is strictly liable in tort in California when an article it places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being.<sup>80</sup> Strict liability in tort was adopted by the Second Restatement of Torts to require that “[o]ne who sells any product in a defective condition unreasonably dangerous to the user . . . or to his property is subject to liability for physical harm thereby caused . . . .”<sup>81</sup> In *Cronin v. JBE Olsen Corp.*<sup>82</sup> and later in *Barker v. Lull Engineering Co.*<sup>83</sup> the California Supreme Court rejected the unreasonably dangerous requirement of the Restatement by saying it would not be part of the plaintiff’s burden of proof to show that the product was unreasonably dangerous as well as being defective, as this would inject an element of negligence into a strict liability theory and would be unduly burdensome for plaintiff to prove.

The *Barker* court went on to define a defectively designed product as one (1) that fails to meet ordinary consumer expectations as to safety in its intended or reasonably foreseeable operation, or, (2) which even if it satisfies ordinary consumer expectations, the jury finds through hindsight to embody “excessive preventable danger” (that is the risk of danger inherent in the design outweighs the benefits of such a design.)<sup>84</sup> Once the plaintiff makes a prima facie showing that the injury was proximately caused by the product’s design, the burden of proof shifts to the defendant to show that the product is not defective.<sup>85</sup> Thus a product can be found to have a defective design if plaintiff proves it did not meet ordinary consumer expectations when used in an intended or reasonably foreseeable manner, or if plaintiff proves that the design proximately caused his/her injuries and defendant fails to establish that the benefits of the design outweigh the risk of danger inherent in that design.<sup>86</sup>

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reported to any government agency. The incentive reasoning behind strict liability in tort applies perfectly to the Dalkon Shield. The Robins Company apparently decided not to try to cut down their future losses.

80. *Greenman v. Yuba Power Prod., Inc.*, 59 Cal. 2d 57, 62, 377 P.2d 897, 900, 27 Cal. Rptr. 697, 700 (1962).

81. See RESTATEMENT (SECOND) OF TORTS § 402 A (1965).

82. 8 Cal. 3d 121, 501 P.2d 1153, 104 Cal. Rptr. 433 (1972).

83. 20 Cal. 3d 413, 573 P.2d 443, 143 Cal. Rptr. 225 (1978).

84. *Id.* at 430, 573 P.2d at 454, 143 Cal. Rptr. at 236.

85. *Id.* at 431, 573 P.2d at 455, 143 Cal. Rptr. at 237.

86. *Id.* at 432, 573 P.2d at 455, 143 Cal. Rptr. at 237.



Applying the first prong of the *Barker* test<sup>87</sup> to the IUD, it is reasonable that the average consumer would expect that after it is inserted, her IUD would safely prevent her from becoming pregnant. IUDs were advertised as being a safe alternative to the birth control pill, and particularly good for women who had not yet had children.<sup>88</sup> The average consumer would certainly not expect her effortless birth control to cause sterility, infection, hemorrhaging, and birth defects.<sup>89</sup>

The second definition of defect in *Barker*<sup>90</sup> involves a balancing of whether the risk of danger inherent in the design outweighs its benefits. Under this test it might be harder to prove that an IUD's design was defective.

If the benefits of the device's design are seen as highly reliable birth control (very low risk of pregnancy) with no user participation needed, then to some reasonable people it would have an extremely high utility, and its benefits might outweigh its dangers. Other reasonable people who might find contraception (especially effortless contraception), a low priority, could find the device to be of very low utility, and then its dangers might outweigh its benefits.

From a systemic, or epidemiological point of view, it may be easier to see how the dangers of IUDs outweigh their benefits. When considering an IUD as an effective and *effortless* method of birth control, it may seem best to prescribe them for young women who have not had children and who will have multiple sex partners. But from a health and safety point of view, IUDs are considered best prescribed to older women who have already

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87. *Id.* at 430, 573 P.2d at 454, 143 Cal. Rptr. at 236. See Note, *Criticism, supra* note 21, at 272, 73.

88. MALPRACTICE, *supra* note 8, at 174; SEIZING OUR BODIES, *supra* note 18, at 95.

89. The consumer's low expectation of problems associated with the device is reinforced by the fact that it must be inserted by a doctor. The consumer's expectations in a medical case are very much colored by what her doctor tells her. When the IUD was first widely marketed, doctors were told of only a few of its dangerous possibilities even though its dangers were known to manufacturers at the time. See Note, *Criticism, supra* note 21, at 273, 288-90. If, as is the case here, the consumer's expectation is very much influenced by the doctor, and the doctor has not been fully informed of the dangers, it is reasonable to believe that the consumer would have no greater expectation of dangerous consequences than the level of danger that was communicated to her by her doctor.

90. 20 Cal. 3d at 430, 573 P.2d at 454, 143 Cal. Rptr. at 236.

had all the children they want, as the risks of infection are lower for the latter group because their uteri and cervixes are larger so the device is more easily inserted and will not cause as much inflammation.<sup>91</sup> Also, the results of infection are possibly less disastrous for an older woman. Sterility, although traumatic, may be less so for a woman who has already had all the children she wants than for a woman who has not yet had any children.

In determining whether IUDs are defective under the second prong of the *Barker* test,<sup>92</sup> their relative benefits and dangers can also be compared with hindsight to the dangers of other modern forms of birth control. The weighing of the burdens and the benefits depends to a large extent on the relative values attached to women's health, safe and easy contraception, and to high profits for pharmaceutical companies. A manufacturer may contend that this test involves a hindsight analysis, and that the courts have never held that manufacturers have a duty to warn about dangers of which they themselves had, and could not have had, any idea at the time of the injury.<sup>93</sup> To require the manufacturer to compose a warning of side effects not suggested by careful laboratory procedures preceding the distribution of the drug would be to require a semantically impossible warning.<sup>94</sup> However, should a manufacturer attempt to apply this to an IUD situation, a court could easily find that manufacturers should have been alerted to dangers they themselves had not found in pre-market testing, by the results of use of IUDs in earlier periods of their history.<sup>95</sup>

### B. *Negligence*

A manufacturer is negligent when it can be shown that it had a duty, that it breached the duty, and that the breach of duty was a cause-in-fact and proximate cause of plaintiff's injury.

Negligence based on a breach of the duty to warn is fre-

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91. Ziff, *The IUD and Pelvic Infection*, 24 AM. FAM. PHYSICIAN, Dec. 24, 1981, at 109, 113.

92. 20 Cal. 3d at 430, 573 P.2d at 454, 143 Cal. Rptr. at 236.

93. *Christofferson v. Kaiser Found. Hosp.*, 15 Cal. App. 3d 75, 79, 92 Cal. Rptr 825, 827 (1971). See also Annot., 53 A.L.R. 3d 292 (1973).

94. 15 Cal. App. 3d at 80, 92 Cal. Rptr. at 827.

95. See *supra* notes 2-54 and accompanying text.

quently asserted in cases where an injury has been caused by a drug or medical device.<sup>96</sup> Courts have held that the manufacturer of a drug has a duty to warn the medical profession if it knew or should have known, of potential dangers of that drug, even if the dangers will injure only a small percentage of the users. However, this duty to warn extends only to the doctor. The manufacturer has no duty to warn the patients directly.<sup>97</sup> As with all negligence cases, the burden of alternative conduct must be weighed against reduction in risks to be achieved by such a warning. It cannot be disputed that the burden of accurate package inserts as a warning to doctors is outweighed by the benefit of increased health and fertility derived from such a warning. A proper warning to doctors could result in fewer IUDs prescribed or at least fewer prescribed to women who run a high risk of developing PID. It is apparent that many women would have IUDs even if told of the dangers, but it is equally apparent that many others would heed the warnings, were they given in a timely fashion.

In IUD cases, as in the case of drugs,<sup>98</sup> the doctor is an intervening party between the manufacturer and the ultimate user of the product, the patient. The doctor is also a necessary intervening party because it is thought that if the average patient were given all of the highly technical medical information necessary to make an informed decision, she would not have the ability to evaluate fully and understand its import. It is also virtu-

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96. One who supplies [a product] directly or through a third person [in our case, the doctor] for another to use is subject to liability to those whom the supplier should expect to use the [product] with the consent of the other . . . for physical harm caused by use of the [product] in the manner for which and by a person for whose use it is supplied if the supplier:

- (a) knows or has reason to know that the [product] is likely to be dangerous for the use for which it is supplied, and
- (b) has no reason to believe that those for whose use the [product] is supplied will realize its dangerous condition, and
- (c) fails to exercise reasonable care to inform them of its dangerous condition or the facts which make it likely to be dangerous.

RESTATEMENT (SECOND) OF TORTS § 388 (1965).

97. See *Love v. Wolf*, 226 Cal. App. 2d 378, 394, 38 Cal. Rptr. 183, 193 (1964). See *McKee v. Moore*, 648 P.2d 21 (Okla. Sup. Ct. 1982) (manufacturer of IUDs has a duty to warn only physicians as to dangers and side effects).

98. See *supra* note 96.

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ally impossible for a manufacturer to reach all of the consumers of its drug, or intrauterine device, thereby necessitating a warning through the doctor instead.<sup>99</sup>

The Food and Drug Administration (FDA) apparently balanced the necessity of a doctor's intervention against the manufacturer's difficulty in warning patients directly when it instituted its 1975 regulation that manufacturers provide patient inserts that include information on use-effectiveness, adverse reactions, directions for use, side effects, warnings, and special warnings about pregnancy with an IUD in place.<sup>100</sup> This regulation shows that the FDA at least, believes it is possible for manufacturers to warn users by using the doctor as a conduit, and that there is value in giving technical information to consumers. It is questionable, however, whether such inserts are written with the consumer specifically in mind. It is also questionable whether merely requiring manufacturers to provide printed patient information to doctors exerts any control over whether the doctor provides the information to the patient before or after the IUD is inserted.

A manufacturer of drugs has a duty to warn the medical profession within a reasonable time after it knew or should have known of the serious side effects of its drug.<sup>101</sup> A manufacturer has a duty to warn of all adverse reactions which it knows or has reason to know are inherent in the use of the drug. Compliance with FDA regulations regarding testing and warnings may not relieve the manufacturer of liability, as such regulations only establish minimum standards.<sup>102</sup> Liability may also be found when the facts disclose that the drug has not been properly prepared

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99. *Fogo v. Cutter Laboratories, Inc.*, 68 Cal. App. 3d 744, 754-55, 137 Cal. Rptr. 417, 423 (1977).

100. Package inserts accompanying IUDs must include warnings that "pelvic infection may occur with the IUD in place and at times result in development of tuboovarian abscesses or general peritonitis." 21 C.F.R. § 801.427 (1975). This section also requires that pelvic infection be listed as an "adverse reaction" in the package insert for the doctor and in the package insert for the patient as well. The section requires that "labeling in sufficient quantities be available to patients who express interest in IUDs, shall accompany each IUD and be made available to the patient." *Id.* The patient brochure need not, however, include pelvic infection symptoms in the "side effects" section, but does include them in the "warnings" section.

101. See *supra* note 93 and accompanying text.

102. *Stevens v. Parke, Davis & Co.*, 9 Cal. 3d 51, 65, 507 P.2d 653, 661, 107 Cal. Rptr. 45, 53 (1973).

and has been placed on the market without adequate and proper warnings.<sup>103</sup>

Even if the manufacturer fulfills its duty to warn adequately, overpromotion of the drug through a vigorous sales program may have the effect of persuading the doctor to disregard the warnings given. If overpromotion has such an effect, the manufacturer can be held liable even if its warnings alone were adequate.<sup>104</sup> Overpromotion could have been "encouraged" by the pill panic<sup>105</sup> that swept the country in the early 1970's, by lack of FDA testing requirements at that time,<sup>106</sup> and by the ability of the manufacturer to make a 1000% profit or more on a device that cost only about \$.35 to produce.<sup>107</sup>

## V. PROVING CAUSATION

A plaintiff must show that the negligence (the breach of the duty owed) was a cause-in-fact and proximate cause of her injury. In a strict liability case, plaintiff must show that the product was defective and that the defect caused her injury.

In a personal injury action, as in any other civil case, the plaintiff must prove that the wrongful act was more likely than not a substantial factor in causing the injury. One plaintiff's attorney in an IUD case has stated that defense attorneys often attempt to convince judges that the proper burden of proof is "reasonable medical certainty," or clear and convincing evidence that the defendant's product caused the injury, instead of the correct "more likely than not," preponderance test.<sup>108</sup> *Sentilles*

103. *Toole v. Richardson Merrell, Inc.*, 251 Cal. App. 2d 689, 710-11, 60 Cal. Rptr. 398, 413-14 (1967). See also Annot., 29 A.L.R. 3d 988 (1970).

104. 9 Cal. 3d at 65, 507 P.2d at 661, 107 Cal. Rptr. at 53.

105. Note, *Criticism*, *supra* note 21, at 272.

106. The Food, Drug, and Cosmetics Act prohibits the marketing of any new drug until the manufacturer has met strict testing requirements to demonstrate the drug's safety. 21 U.S.C. § 355 (a)(1938 as amended). When IUDs were first put on the market the FDA classified them not as drugs, but as devices. Since 1968 the FDA has had the authority to classify IUDs as drugs and thus subject them to animal and controlled clinical studies. In spite of that authority, the FDA kept them classified as devices and so no pre-market controls on manufacturing, testing or distribution could be imposed.

Since 1976, however, the Medical Device Amendments Act, 21 U.S.C. § 360 (1976) has labeled IUDs as Class III devices requiring pre-market approval to provide reasonable assurances of their safety and effectiveness.

107. Note, *Criticism*, *supra* note 21, at 250.

108. Interview with Dennis Conklin, plaintiff's personal injury attorney, San Fran-

*v. Inter-Caribbean Shipping Corp.*<sup>109</sup> however, established that an expert's testimony does not have to establish causation by a "reasonable medical certainty" standard and that the jury is entitled to consider all possible medical conditions aggravating the plaintiff's injury or impairing her health. *Grinnell v. Charles Pfizer & Co.*<sup>110</sup> made it clear that a plaintiff only has the burden of presenting evidence which affords a reasonable basis for the conclusion that it is more likely than not that the conduct of the defendant was a substantial factor in bringing about the injury suffered by plaintiff.

In medical cases, there is always a problem of possible alternative causes in fact of the injury. This is certainly true in cases of PID, since gonorrhea, independently caused infection, previous PID, and an IUD can all be sources of the infection. Because of the prevalence of alternative causes of PID, "much of the evidence will be circumstantial, based on reasonable probability, and will involve the opinion testimony of experts."<sup>111</sup>

Courts have been sensitive to problems faced by consumers or users of defective products in proving defect and proximate cause . . . the law recognizes that in a product liability case proof of those elements by direct evidence is frequently impossible; a plaintiff may, therefore, satisfy his burden of proving defect and causation by circumstantial evidence.<sup>112</sup>

It is very important that plaintiff have detailed medical records of her illness and in-depth medical analysis of its details,<sup>113</sup> so that her expert witness can analyze this data in her/

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cisco, California (April 1982).

109. 361 U.S. 107, 109 (1959).

110. 274 Cal. App. 2d 424, 435, 79 Cal. Rptr. 369, 374.

111. See Van Dyke, *The Dalkon Shield: A "Primer" in IUD Liability*, 6 W. St. L. Rev. 1 (1979).

112. *Diamond v. Caterpillar Tractor Co.*, 65 Cal. App. 3d 173, 183, 134 Cal. Rptr. 895, 901 (1976).

113. When an IUD is removed because of suspected PID, the device itself is often covered with bacteria. These IUDs are often disposed of immediately without performance of lab tests on the device. Interview with a Dalkon Shield plaintiff, San Francisco, California (March 1982). Even though such lab tests would only show the presence of infection, and wouldn't present the answer to the "chicken or the egg dilemma," that is, help to explain whether the infection arose independent of the device and caused the device to become infected, or whether the infection was caused by the device, such evidence might be very useful to plaintiff. For example, if the string as well as the device

his testimony. As was discussed earlier,<sup>114</sup> facts such as the direction of the spreading of the infection, and which kind of bacteria caused plaintiff's infection, can be of vital importance in proving causation. Plaintiff's attorney must be well-versed in the current medical literature in order to examine effectively her/his experts and effectively cross-examine defendant's experts.

If evidence of sexually transmitted bacteria was found at the time the IUD was removed, and especially if plaintiff is young and sexually active, defense attorneys may try to explore the plaintiff's sex life in an attempt to prove that the infection was related to her sexual activity rather than to her method of birth control.<sup>115</sup> Whether or not such questions can be explored at trial is up to the judge, as s/he determines what lines of questioning are relevant to the case. These questions, however, are also brought up in discovery in the form of interrogatories and deposition questions. Again, it is important that plaintiff's attorney keep up with the latest medical studies in order to be better prepared to argue in favor of her/his refusal to answer such queries. Again, the ultimate decision lies with the judge. It is most important for plaintiff's attorney to be thoroughly familiar with the medical literature in order to effectively refute damaging cross examination at trial.

Plaintiff's attorney must gather the best statistics available on the probability and incidence of PID in women with IUDs, and the number of women with PID who have IUDs, and find an expert who is comfortable using language establishing that the IUD "probably" rather than "possibly" caused the PID.

The use of expert medical witnesses and studies which show statistical links between product and injury fly in the face of the legal requirements. Scientists oftentimes attempt to describe causation in terms of degrees instead of absolutes. They recognize many different causes of any given event or result, and at-

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were infected, this would tend to show that the device caused the infection. Or, if *actinomyces* is found on the device, and the plaintiff had no *actinomyces* in her history, a strong inference could be created that the IUD caused the infection. Obtaining lab reports evidencing the presence of infection on the device, although not medically conclusive, might be very convincing to a jury.

114. *Supra* notes 33-36 and accompanying text.

115. *See supra* note 34 and accompanying text.

tempt, through statistical methods, to isolate the degree to which different factors entered into the result.<sup>116</sup>

One physician, familiar with the problems of proving that tubal scarring was caused by an IUD, stated that doctors do not refuse to say that the infection was caused by the device because they fear being implicated in the suit, but rather because no doctor wants to say that any one event was caused by any other event.<sup>117</sup> There are too many variables involved in any medical result, and the key is isolating the one variable that was most likely to have had the greatest influence in bringing about the result.<sup>118</sup> This is why statistical studies, in addition to detailed medical evidence about a particular case, are also very important in order to prove legal causation.<sup>119</sup>

### Courts in general are hostile to the idea of using statistical

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116. This technique is called multiple regression analysis. It is a device for making precise and quantitative estimates of the effects of different factors on the same variable.

Multiple regression has frequently been used with the development of reliable statistics and computers. "Some of the increasing use of multiple regression and related techniques has occurred in connection with legal proceedings of various kinds, although lawyers and judges have often tended to view such use with general (and occasionally healthy) distrust. "Fisher, *Multiple Regression in Legal Proceedings*, 80 COLUM. L. REV. 702, 702 (1980) [hereinafter cited as *Multiple Regression*]. See also Finkelstein, *The Judicial Reception of Multiple Regression Studies in Race and Sex Discrimination Cases*, 80 COLUM. L. REV. 737 (1980) [hereinafter cited as *Judicial Reception*].

117. Interview with Jack Futeron, M.D., *supra* note 39.

118. When multiple regression is used properly, it is an accurate and reliable method for determining the relationship between two or more variables and can be valuable in resolving factual disputes. *Multiple Regression*, *supra* note 116, at 736.

119. The use of multiple regression models in a legal setting was first suggested in print in 1975 in *Beyond the Prima Facie Case in Employment Discrimination Law: Statistical Proof and Rebuttal*, 89 HARV. L. REV. 387 (1975). Since then its use has caught on very quickly in some areas of the law, mostly those involving discrimination. *Judicial Reception*, *supra* note 116, at 737.

Use of statistical proof in law is a relatively new concept. Since *Judicial Reception*, *supra* note 116, was published, statistics have been used to prove causation more and more in other areas of law—particularly in toxic torts (harm to people from chemical dumping, hazardous wastes, exposure to hazardous substances on the job, etc.), where there is often a latency period between the exposure and the illness, and where there are often many possible alternative sources of the illness. In those kinds of cases statistical proof is more widely accepted, particularly in cases where plaintiff has virtually no direct evidence of causation and must rely entirely on circumstantial statistical proof. Lecture on causation in environmental cases by William Wick, EPA staff attorney, and adjunct professor at Golden Gate University School of Law (March 1983).

In light of all this, one could postulate that lack of the use of statistics to prove causation in products liability IUD cases is more a factor of the newness of the discipline than its inappropriateness to the field.



evidence to prove causation.<sup>120</sup> Statistical proof, however, has been accepted as valid evidence in cases of discrimination in employment, education, and housing.<sup>121</sup> The primary advantage of statistical proof in these kinds of cases is its capacity to describe the general and long run characteristics and effects of a selection procedure.<sup>122</sup> That is, evidence of a small proportion of minorities in a workforce, student body, or housing unit as compared to a higher proportion of such minorities in the surrounding labor pool, student pool, or neighborhood, is valuable to indicate the possible discriminatory effects of a certain hiring, admission, or rental policy.<sup>123</sup> Similar reasoning can be used to support the acceptance of statistical data in proving causation in IUD cases. Statistics can be valuable to show the characteristics and effects of the IUD on the reproductive organs. Statistics will also demonstrate that large numbers of women who use the same device suffer from the same disease, or that large numbers of women with a particular disease use the same method of birth control.<sup>124</sup>

Under the disparate impact model of discrimination, utilized under Title VII of the Civil Rights Act of 1964,<sup>125</sup> proof of a substantial adverse impact triggers a demand for justification, and if sufficient justification is not presented by defendant, s/he is held liable.<sup>126</sup> In proving that defendant's actions were the cause of plaintiff's injuries in discrimination cases, the focus is not on the reasons behind defendant's actions, but rather on whether the disparate results were caused by a rule or procedure that defendant used, or whether those results were created by chance.<sup>127</sup>

A similar procedure might be considered for fulfilling requirements of legal causation in IUD cases. Plaintiff's presenta-

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120. Large and Miche, *Proving that the Strength of the British Navy Depends on the Number of Old Maids in England: A Comparison of Scientific Proof With Legal Proof*, 11 ENVTL. L. 555, 598-606 (1981) [hereinafter cited as *Old Maids in England*].

121. *Id.* at 602.

122. BALDUS & COLE, *STATISTICAL PROOF OF DISCRIMINATION* 4 (1980) [hereinafter cited as BALDUS & COLE].

123. *Old Maids in England*, *supra* note 120, at 602.

124. See notes 22-54 *supra* and accompanying text.

125. 42 U.S.C. § 2000e-e17 (1976).

126. *Griggs v. Duke Power Co.*, 401 U.S. 424 (1971).

127. BALDUS & COLE, *supra* note 120, at 44-45.

tion of a disparately higher incidence of PID in women who use IUDs would trigger a shifting of the burden of proof of causation to the defendant, who would then be required to prove that such impact was caused by chance and not by any characteristic of the product, the way it works, or by the manufacturer's lack of sufficient warnings and/or pre-market testing.

The ordinary citizen who serves on a jury is presumed to, and urged to, use the same standards of probability in deliberating as s/he would use in everyday life.<sup>128</sup> Statistical models are useful to illustrate causal relationships from patterns in data, in order to give the jury a point of reference from which to work. "[S]tatistical findings may correct false impressions and provide assessments when there is no other basis for judgment."<sup>129</sup>

Only one personal injury IUD case against a manufacturer has proceeded beyond preliminary motions, reached the appellate stage, and been reported.<sup>130</sup> In *Terhune v. A.H. Robins Co.*<sup>131</sup> plaintiff alleged that defendant's Dalkon Shield had perforated her uterus. The Washington Supreme Court held that plaintiff had failed to prove that the Shield was defective either in design or in manufacture, and that the principles of Comment K to the Second Restatement of Torts<sup>132</sup> applied to the device. Comment K protects certain products from suit, particularly drugs, by deeming them "unavoidably unsafe" products whose utility outweighs their known dangers.<sup>133</sup> Therefore, the manufacturers of these products are not liable for injuries caused by these dangers as long as such products are accompanied by proper warnings. The court in *Terhune* held that since Comment K applied to IUDs, and plaintiff's doctor had been warned of its dangers, Robins would not be held liable. The court never reached the causation issue. All other reported IUD cases were either tried on different grounds, such as medical malpractice, or foundered on the statute of limitations problem.<sup>134</sup>

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128. COHEN, *THE PROBABLE AND THE PROVABLE* 49 (1977).

129. FINKELSTEIN, *QUANTITATIVE METHODS IN LAW* 7 (1978).

130. As of February 1983, the author was unable to find any reported cases involving the issue of causation in any IUD case.

131. 577 P.2d 975 (Wash. Sup. Ct. 1978).

132. *RESTATEMENT (SECOND) OF TORTS* § 402A(k) (1965).

133. *Id.*

134. See *Simon v. A.H. Robins*, 543 F. Supp. 502 (S.D.N.Y. 1981); *In Re Northern District of California "Dalkon Shield IUD Products Liability Litigation*, 526 F. Supp.

## VI. CONCLUSION

Despite the lack of guidelines as to what exactly will constitute a winning case on the issue of causation, there is solid medical evidence establishing the IUD to be a cause of PID, which often leads to sterility. Recent medical journals have noted the causal link between IUDs and PID and sterility in an effort to alert more doctors to the seriousness of the device's dangers.<sup>135</sup>

In other areas of personal injury litigation, e.g., toxic injuries and environmental injuries, it has been necessary to expand the established rules for proving causation in order to preserve the theories behind personal injury recovery and strict liability, and to provide relief to people injured by the negligence of large industries.

[D]ifficulties in establishing proximate cause stem from the courts' refusal to accept scientific evidence about carcinogenesis as legal evidence of causation. Cancer victims should not be precluded from recovering for their injuries solely because carcinogenesis is described by a statistical correlation rather than by a cause-and-effect mechanism. Rather, the statistical correlation should be incorporated into the causation requirement so that the tort mechanism can effectively deter carcinogen production and prevent future cancer incidence . . . *The mere fact that the etiology of the injuries is complex should not shield . . . producers from legal responsibility.*"<sup>136</sup>

The same should hold true for proving causation in IUD personal injury cases against manufacturers. Complex etiology

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887 (N.D. Cal. 1981); *Nelson v. A.H. Robins*, 515 F. Supp. 623 (N.D.N.Y. 1981); *Rockwell v. Ortho Pharmaceuticals Co.*, 510 F. Supp. 266 (N.D. Cal. 1981); *Miller v. Mobile County Board of Health*, 409 S. 2d 420 (Ala. Sup. Ct. 1982); *Sciacca v. Polizzi*, 403 S.2d 728 (La. Sup. Ct. 1981); *Bayonne v. Hartford Ins. Co.*, 353 S.2d 1051 (La. Ct. App. 1977); *McKee v. Moore*, 648 P.2d 21 (Okla. Sup. Ct. 1982); *Green v. Lilliewood*, 249 S.E. 910 (S.C. Sup. Ct. 1978); *Newberry v. Tarvin*, 594 S.W. 204 (Tex. Ct. App. 1980); *Doyle v. Planned Parenthood*, 639 P.2d 240 (Wash. Ct. App. 1982).

135. *What Price Contraception?*, S. MED. J., May 1981, at 523.

136. Note, *Tort Actions for Cancer: Deterrence, Compensation, and Environmental Carcinogenesis*, 90 YALE L.J. 840, 854 (1981) (emphasis added).

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requiring statistical and circumstantial evidence should not act to misplace the disastrous cost of industry produced sterility.

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