Miscarriage of Justice

Depo-Provera Case May Insulate Drug Makers

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Justice was not done in Upjohn v. MacMurdo. Anne MacMurdo lost a 12-year legal struggle to result-oriented jurisprudence in the first state appellate court decision on the unapproved contraceptive use of Depo-Provera. Upjohn, the drug’s manufacturer, won an undeserved legal victory that may insulate pharmaceutical manufacturers from future products liability suits—but may serve as a lightning rod for medical negligence actions.

Depo-Provera, the drug given to MacMurdo, is a three-month injectable progestosterone-based contraceptive used worldwide by 11 million women. The drug, however, is not approved by the Food and Drug Administration (FDA) for contraceptive use in the United States because it is suspected to be a carcinogen. Nevertheless, Upjohn has marketed Depo-Provera and physicians throughout the United States have prescribed it widely as a contraceptive since 1963 because it has been approved by the agency for other purposes, principally the treatment of endometrial cancer. This off-label use received no substantive appellate judicial attention until the 1990 Upjohn v. MacMurdo decision.

This litigation has a long history that began in 1974 when MacMurdo received two injections of the drug for contraception. The first injection was given by Dr. Donald Levy, a New Orleans gynecologist, with no adverse effects. The second injection, by Dr. Arthur Shapiro, a Miami gynecologist, produced heavy and prolonged menstrual bleeding, which Dr. Levy terminated by performing a hysterectomy on MacMurdo.

The case against Upjohn began in 1978 when MacMurdo sued the drug company and Dr. Shapiro. Her day in court, however, was delayed eight years and became Broward County’s longest-running lawsuit by the time it went to trial in 1986. The delay was due in part to defendants’ summary judgment motion. Dr. Shapiro’s motion was granted by a Broward judge but reversed on appeal in 1980.

A Broward County judge also granted Upjohn’s motion, finding that the package-insert warnings were adequate as a matter of law. However, his comments on his lack of faith in the jury system revealed the subjective basis for his decision. "The reason I love to give a summary judgment is, when you put six people in the [jury] box, God knows what they’ll come out of the [jury] room with.""4

A divided Fourth District Court of Appeals in the 1983 MacMurdo v. Upjohn Co. decision reversed and remanded for trial. Judge Walden, speaking for the court, declared, "It is not for judges, but it is for the jury to determine if a particular warning is adequate under the circumstances."5 In Tampa Drug Co. v. Wait,6 he said, the Florida Supreme Court had held that the adequacy of the prescription drug warning was a jury question. In fact, Judge Walden emphasized that the court of appeals had held in Lake v. Konstantinos that "This issue above all others must certainly be submitted to a jury."7

In 1985 MacMurdo voluntarily dismissed her suit against Dr. Shapiro, leaving Upjohn as the sole defendant, but her day in court was further delayed. After new counsel was secured and granted time to prepare the case, her suit finally went to trial in Broward Circuit Court on December 3, 1986. Michael Eriksen, MacMurdo’s counsel, argued that the Depo-Provera package-insert negligently failed to warn Dr. Levy about the drug’s side effects in 1974 and led him to perform a hysterectomy to relieve her bleeding in 1975. David Covey, representing Upjohn, argued that MacMurdo was contributorily...
negligent. Her use of an illicit drug during the late 1960s and early 1970s, he argued, was related to the prolonged bleeding and, along with the stillbirth of an acephalic child in 1970 and a subsequent suicide attempt, had led to her snap decision to request a hysterectomy in order to become sterile. After the three-day trial, a six-person jury found Upjohn had negligently failed to provide adequate package-insert warnings but also found MacMurdo 49 percent contributorily negligent and awarded her $188,700.9 Upjohn appealed and MacMurdo cross-appealed.

A unanimous court of appeals on December 21, 1988, affirmed the trial court on liability, reversed it on contributory negligence, and remanded with instructions to enter a judgment for MacMurdo for the full amount of her damages: $370,000.9

Judge Anstead, speaking for the court, first rejected Upjohn's argument that the evidence was insufficient for the Broward court judge to submit the negligent warning issue to the jury. He cited Judge Walden's statement in MacMurdo v. Upjohn (1983) regarding the legal standard announced in Lake and concluded that the record disclosed that "while there was considerable evidence presented that may have supported a verdict for Upjohn, there was also substantial evidence presented that the drug...caused MacMurdo's bleeding problem, that the warnings were insufficient to alert her physicians of this risk, and that her hysterectomy was performed to treat the bleeding condition."10

Judge Anstead then upheld on cross-appeal MacMurdo's claim that she was entitled to a directed verdict on the issue of contributory negligence. He disposed of what plaintiff's attorney called the "marijuana defense," observing that Upjohn's counsel had conceded at oral argument the lack of evidence connecting her illicit drug use to her bleeding condition.

He also rejected Upjohn's argument that MacMurdo made a "snap decision" to have a hysterectomy, not to stop her pain and bleeding but because she wanted to be sterilized. Judge Anstead's review of Dr. Levy's testimony led him to conclude: "[W]e do not believe that there was a sufficient basis in the evidence to hold that reasonable persons could differ on whether MacMurdo voluntarily had a hysterectomy outside the context of treatment for her bleeding condition or that she had other treatment alternatives available to her at the time."11

Upjohn's "snap decision" theory also failed because it permitted "the jury to infer that MacMurdo was negligent by opting to proceed with a hysterectomy without considering available alternatives to treat her bleeding problem." However, she had no legal duty to question her physician's advice or to seek a second medical opinion.12

Upjohn appealed, claiming that the decision conflicted with another appellate court decision in Felix v. Hoffmann-LaRoche, Inc.13 The Florida Supreme Court on May 31, 1990, reversed, 4 to 1. In rejecting the testimony of a pharmacologist with a Ph.D., the Florida Supreme Court has created a precedent-setting standard.

2 with one justice abstaining, and remanded with instructions to enter a judgment for Upjohn. The court did not address the issues of proximate cause or comparative negligence that had been appealed and argued by the parties but limited itself to the issue of Upjohn's negligent failure to warn: "[W]e believe the more crucial question is whether the warnings were adequate to warn a physician of the possibility that Depo-Provera might be causing the condition experienced by MacMurdo."14

Justice Grimes, speaking for the majority, rejected the court of appeal's reliance on Lake, MacMurdo v. Upjohn, and Ricci v. Parke Davis & Co.15 The court of appeals had misread Dr. Levy's testimony of Dr. Benjamin, a pharmacologist who endeavored to clarify what these terms meant to physicians, can be considered probative on this issue.16

Second, the majority did acknowledge that Dr. Levy's testimony came close to concluding that the insert was insufficient to warn him when, as the court reported the physician's testimony, "MacMurdo was suffering from dysfunctional bleeding, which he [Dr. Levy] characterized as anything other than normal bleeding, while the package insert only referred to breakthrough bleeding and change in the menstrual flow."17 Yet Justice Grimes quickly added that Dr. Levy testified that had he "had the insert in front of him when MacMurdo was describing her bleeding, he might have concluded that the drug was causing her problem."18 This tenuous evidentiary support for the sufficiency of a package-insert warning was founded on the court's highly selective use of Dr. Levy's testimony. Justice Shaw criticized the majority for failing to mention that Dr. Levy... testified that the plaintiff complained of abnormal bleeding... that he did not consider that Depo-Provera might have been causing her problem because he expected the drug to have just the opposite effects—amenorrhea (the absence of bleeding), and that abnormal bleeding was not listed on the package insert as an adverse reaction.19

Third, the majority rejected the argument that the insert was inadequate because Upjohn knew the results of a study conducted by its Depo-Provera researcher, Dr. Paul Schwalle, but failed to warn against prolonged bleeding.20 The majority, once again, relegated its justification to a footnote, saying, "While
In rejecting his testimony, the support their broad reading of pharmaceutical show that but not physicians, jamie's testimony the 'adequacy of a prescription drug cite sufficiency accepted mony and hea''Y creation of the factual findings of Supreme Court's held that the expert testimony and scientific evidence on the insulating Depo-Provera's warning was inadequate. Plaintiffs also need to argue that the court's use of the Felix standard does not easily mesh with the expert testimony presented at trial.

As Justice Shaw reminded the court, there was enough conflicting expert testimony about the adequacy or inadequacy of the warnings that the issue should have gone to the jury. Instead, the Florida Supreme Court did what any appellate court should avoid doing: It did not restrict itself to matters of the law. Instead, it reweighed and reevaluated the evidence, rejected without prior notice and without explanation an expert whose testimony was critical to the plaintiff's case, refused to grant the plaintiff a new trial, and then rendered a verdict for the defendant.

Political Implications
Upjohn has also won a political victory. MacMuro will embolden pharmaceutical and other manufacturers who lobby Congress for products liability "reform." From the perspective of the plaintiffs' bar, Congress should enact legislation authorizing the FDA to issue regulations that require—
- nonapproved uses of drugs to be clearly stated in all drug package inserts and advertisements,
- drug manufacturers to maintain a detailed record of drugs with nonapproved uses, and
- physicians to provide each patient with the package insert before the drug is prescribed and to discuss the warning with the patient to ensure informed consent.

These proposed regulations are not newly crafted on the basis of Upjohn v. MacMuro but were proposed at the 1973 Senate hearings on DES and Depo-
Provera, a year before MacMurdo received her injections.\(^3\)

Congress needs to enact this legislation because these regulations still make good sense. They are needed even more now than they were 18 years ago because of the legal victory pharmaceutical manufacturers have won in *MacMurdo*. □

Notes

1 The FDA approved Depo-Provera in 1959 to treat amenorrhea, irregular uterine bleeding, and threatened or habitual abortion; in 1960 to treat endometritis; and in 1972 as adjuvantive therapy and palliative treatment of endometrial cancer. In the meantime, it withdrew the drug’s approval for amenorrhea and uterine bleeding and, in 1972, for endometritis and threatened or habitual abortion.

2 562 So. 2d 680 (Fla. 1990).


5 Id. at 450-51.

6 103 So. 2d 603, 609 (Fla. 1958).


8 The jury also found that Upjohn did not negligently market Depo-Provera and the judge granted Upjohn’s motion for a directed verdict on strict liability for marketing an experimental drug. Neither issue was appealed.


10 Id. at 341.

11 Id.

12 Id. at 340.


14 562 So. 2d 680, 683.

15 536 So. 2d 337.

16 562 So. 2d 680, 681-82 (quoting Felix v. Hoffmann-LaRoche, Inc., 540 So. 2d 102, 105 (Fla. 1989)).

17 562 So. 2d 680, 683.

18 Id. at 683 n.3.

19 Id. at 683.

20 Id. at 684.

21 Id. at 684.

22 Id. at 683 n.4, referring to Schwally & Assenza, *Contraceptive Use: Efficacy Study Utilizing Medrogestone Acetate Administered at an Intramuscular Injection Once Every Ninety Days*, 24 FERTILITY & STERILITY 381 (1973).

23 562 So. 2d 680, 683 n.4.

24 Id. at 684 (emphasis in original).


26 562 So. 2d 680, 683.

27 Respondent’s Motion for Rehearing at 9, Upjohn, 562 So. 2d 680.

28 Id. at 8.

29 Interview with Michael Ericksen of West Palm Beach, Fla. (Jun. 3, 1991).

30 549 So. 2d 102, 104 (Fla. 1989).

31 Respondent’s Motion for Rehearing at 6, Upjohn, 562 So. 2d 680.