

SYLLABUS

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Sarav Perez, et al. v. Wyeth Laboratories, Inc., et al. (A-16-98)

Argued March 2, 1999 -- Decided August 9, 1999

O'HERN, J., writing for a majority of the Court.

This appeal concerns Norplant, a Food and Drug Administration (FDA)-approved, reversible contraceptive that prevents pregnancy for up to five years.

The Norplant contraceptive employs six thin, flexible, closed capsules that contain a synthetic hormone, levonorgestrel. The capsules are implanted under the skin of a woman's upper arm during an in-office surgical procedure characterized by the manufacturer as minor. A low, continuous dosage of the hormone diffuses through the capsule walls and into the woman's bloodstream. Removal occurs during an in-office procedure, similar to the insertion process.

Because of the procedural posture of this case, the Supreme Court was required to accept plaintiffs' version of the facts as true. According to plaintiffs, Wyeth began a massive advertising campaign for Norplant in 1991, which it directed at women rather than at their doctors. Wyeth advertised on television and in women's magazines, such as Glamour, Mademoiselle, and Cosmopolitan. None of the advertisements warned of any dangers or side effects associated with Norplant, but rather praised its convenience and simplicity. Wyeth also sent a letter to physicians advising that it was about to launch a national advertising program in magazines that the physicians' patients may read.

In 1995, several women began to file lawsuits in various New Jersey counties claiming injuries that resulted from their use of Norplant. Their principal claim was that Wyeth, distributors of Norplant in the United States, failed to warn adequately about the side effects associated with the contraceptive, including weight gain, headaches, dizziness, nausea, diarrhea, acne, vomiting, fatigue, facial hair growth, numbness in the arms and legs, irregular menstruation, hair loss, leg cramps, anxiety and nervousness, vision problems, anemia, mood swings and depression, high blood pressure, and removal complications that resulted in scarring.

Class action certification was denied and all New Jersey cases involving Norplant were consolidated in Middlesex County. Following a case management conference, Perez's counsel sought a determination of whether the "learned intermediary" doctrine applied. The "learned intermediary" doctrine generally relieves a pharmaceutical manufacturer of an independent duty to warn the ultimate user of prescription drugs, so long as it has supplied the physician with information about a drug's dangerous propensities. Five representative plaintiffs, including Perez, were selected to challenge Wyeth's motion for summary judgment concerning the "learned intermediary" doctrine. Subsequently, the trial court dismissed those plaintiffs' complaints, concluding that even when a manufacturer advertises directly to the public, and a woman is influenced by the advertising campaign, a physician nevertheless retains the duty to weigh the benefits and risks associated with a drug before deciding whether the drug is appropriate for the patient. Thus, the trial court held the "learned intermediary" doctrine applicable to plaintiffs' actions.

The trial court was not concerned with the effect that a warning had on the consumer plaintiffs because the Products Liability Act, N.J.S.A. 2A:58C-1 to -11, measures the adequacy of a warning based on the knowledge and characteristics of the health-care provider and not the ultimate consumer. The trial court further found that Perez and the other representative plaintiffs had failed to provide expert testimony to rebut the statutory presumption under the Products Liability Act that the manufacturer's warning is adequate when it has been approved by the FDA. Finally, the trial court determined that Perez failed to establish that her injuries were proximately caused by any failure on the manufacturer's part.

On appeal, Perez and the other representative plaintiffs challenged the trial court's failure to hear expert testimony on the adequacy of the warnings and the decision concerning proximate cause, maintaining that "it [had been] specifically agreed that the production of expert testimony would await the outcome of the decision on the issue of the learned intermediary doctrine." The Appellate Division affirmed the trial court's grant of summary judgment and its determination that the learned intermediary doctrine applied. The Appellate Division further noted that Section 6(d)(2) of the Restatement (Third) of Torts: Products Liability (1997) (Restatement) may require a warning when the physician or health-care provider has a "diminished role as an evaluator or decision maker," in which case the manufacturer would have a duty to warn patients directly. However, the court agreed with the trial court that if the warning was legislatively deemed adequate and has been given to the proper party, then no warning defect existed under the Products Liability Law.

The Supreme Court granted Perez's petition for review.

HELD: The “learned intermediary” doctrine does not apply to the direct marketing of drugs to consumers; prescription drug manufacturers that market their products directly to consumers should be subject to claims by consumers if their advertising fails to provide an adequate warning of the product’s dangerous propensities.

1. The Court has specifically declined to hold as a matter of law and policy that all prescription drugs that are unsafe are unavoidably so; there are circumstances in which the manufacturer should not be relieved of the duty to warn. (pp. 11-14)
2. Direct-to-consumer advertising has become an essential part of pharmaceutical manufacturers’ marketing plans and have been extremely successful. However, given the constraints of modern advertising mediums such as television, pharmaceutical ads often contain warnings of a general nature, which often do not give the consumer a sufficient understanding of the risks inherent in the use of the product. (pp. 14-19)
3. The Restatement has left the issue of a drug manufacturer’s duty to warn the consumer directly of the risks associated with the product use to developing case law. (pp. 19-20)
4. Although the New Jersey Products Liability Act sets forth a physician-based standard for determining the adequacy of the warning due to a physician, it does not legislate the boundaries of the “learned intermediary” doctrine. The Senate Judiciary Committee Statement that accompanied the proposed Act identifies the physician as the party to whom the warning is owed only because, at that point, pharmaceuticals were marketed primarily, if not exclusively to physicians. (pp. 21-23)
5. The “learned intermediary” doctrine is based on four premises: (1) reluctance to undermine the doctor-patient relationship; (2) absence of need for the patient’s informed consent; (3) inability of drug manufacturer to communicate with patients; and (4) complexity of the subject. However, consumer-directed advertising of pharmaceuticals belies each of these premises. (pp. 23-27)
6. New Jersey has long recognized the informed role of the patient in health-care decisions. Thus, a patient must be informed of material risks associated with a drug when the patient would likely attach significance to a risk or cluster of risks in deciding whether to forego the proposed therapy or to submit to it. In the context of “life-style” drugs or elective treatments that may cause significant and incurable side effects, increased consumer protection becomes imperative because such drugs, by definition, are not medically necessary. (pp. 28-30)
7. Had Wyeth simply supplied the physician with the information about Norplant and not advertised directly to patients, then Wyeth would have had no independent duty to warn patients, as opposed to physicians. (pp. 30-31)
8. Prescription drug manufacturers that market their products directly to consumers should be subject to claims by consumers if their advertising fails to provide an adequate warning of the product’s dangerous propensities. In determining whether those warnings are adequate, drug manufacturers should be entitled to the rebuttable presumption that they have satisfied their duty to warn ultimate consumers about the potential harmful side effects of its product if their warnings comply with FDA regulations. (pp. 31-37)
9. In the area of direct marketing of pharmaceuticals, the intervention of the physician does not necessarily break the chain of causation. Rather, neither the manufacturer nor the physician should be relieved of their respective duties to warn. Thus, manufacturers may seek contribution, indemnity or exoneration because of the physician’s deficient role in prescribing a drug. In each case, a jury must resolve the close questions of whether a breach of duty has been a proximate cause of harm and how that harm may be apportioned among culpable defendants. (pp. 37-46)
10. The direct marketing of drugs to consumers generates a corresponding duty requiring manufacturers to warn of defects in the product. It is fair to reinforce the comprehensive FDA regulatory scheme by allowing patients deprived of reliable medical information to establish that the misinformation was a substantial factor contributing to their use of a defective pharmaceutical product. (pp. 46-49)

Judgment of the Appellate Division is **REVERSED** and the matter is **REMANDED** to the Law Division for further proceedings.

JUSTICE POLLOCK has filed a separate dissenting opinion. Justice Pollock believes that the New Jersey Products Liability Law clearly adopts the “learned intermediary” doctrine and that the Court’s holding in this case ignores the Legislature’s clear legislative expression and intent of that Act.

CHIEF JUSTICE PORITZ and JUSTICES HANDLER, STEIN and COLEMAN join in JUSTICE O’HERN’s opinion. JUSTICE POLLOCK has filed a separate dissenting opinion in which JUSTICE GARIBALDI joins.

SUPREME COURT OF NEW JERSEY
A-16 September Term 1998

SARAY PEREZ, CHERYL BAILEY, KIMBERLY
BARTLETT, ANNA CESAREO and SORAYA ARIAS,

Plaintiffs-Appellants,

v.

WYETH LABORATORIES INC., a subsidiary of
American Home Products Corporation;
AMERICAN HOME PRODUCTS CORPORATION;
WYETH-AYERST LABORATORIES DIVISION OF
AMERICAN HOME PRODUCTS CORPORATION;
WYETH-AYERST INTERNATIONAL INC.;
WYETH-AYERST LABORATORIES COMPANY and DOW
CORNING FRANCE, S.A.,

Defendants-Respondents.

Argued March 2, 1999 -- Decided August 9, 1999

On certification to the Superior Court,
Appellate Division, whose opinion is reported
at 313 N.J. Super. 511 (1998).

Richard Galex argued the cause for appellants
(Galex Tortoreti & Tomes, attorneys).

John W. Vardaman, a member of the District of
Columbia bar, argued the cause for respondents
(Porzio, Bromberg & Newman, attorneys; Anita
R. Hotchkiss, Lauren E. Handler, Connie A.
Matteo and Linda Pissott Reig, on the brief).

John F. Brenner submitted a brief on
behalf of amicus curiae, Pharmaceutical
Research and

Manufacturers of America (McCarter & English, attorneys; Mr. Brenner and Jerry P. Sattin, on the brief).

The opinion of the Court was delivered by
O'HERN, J.

Our medical-legal jurisprudence is based on images of health care that no longer exist. At an earlier time, medical advice was received in the doctor's office from a physician who most likely made house calls if needed. The patient usually paid a small sum of money to the doctor. Neighborhood pharmacists compounded prescribed medicines.

Without being pejorative, it is safe to say that the prevailing attitude of law and medicine was that the "doctor knows best." Logan v. Greenwich Hosp. Ass'n, 465 A.2d 294, 299 (Conn. 1983).

Pharmaceutical manufacturers never advertised their products to patients, but rather directed all sales efforts at physicians. In this comforting setting, the law created an exception to the traditional duty of manufacturers to warn consumers directly of risks associated with the product as long as they warned health-care providers of those risks.

For good or ill, that has all changed. Medical services are in large measure provided by managed care organizations. Medicines are purchased in the pharmacy department of supermarkets and often paid for by third-party providers. Drug manufacturers now directly advertise products to consumers on the radio, television, the Internet, billboards on public transportation, and in magazines.

For example, a recent magazine advertisement for a seasonal allergy medicine in which a person is standing in a pastoral field filled with grass and goldenrod, attests that to "TAKE [THE PRODUCT]" is to "TAKE CLEAR CONTROL." Another recent ad features a former presidential candidate, encouraging the consumer to "take a little courage" to speak with "your physician." The first ad features major side effects, encourages the reader to "talk to your doctor," and lists a brief summary of risks and contraindications on the opposite page. The second ad provides a phone number and the name of the pharmaceutical company, but does not provide the name of the drug.

The question in this case, broadly stated, is whether our law should follow these changes in the marketplace or reflect the images of the past. We believe that when mass marketing of prescription drugs seeks to influence a patient's choice of a drug, a pharmaceutical manufacturer that makes direct claims to consumers for the efficacy of its product should not be unqualifiedly relieved of a duty to provide proper warnings of the dangers or side effects of the product.

I

The Norplant System (Norplant)

This appeal concerns Norplant, a Food and Drug Administration (FDA)-approved, reversible contraceptive that prevents pregnancy for up to five years. The Norplant contraceptive employs six thin, flexible, closed capsules that contain a synthetic hormone,

levonorgestrel.¹ The capsules are implanted under the skin of a woman's upper arm during an in-office surgical procedure characterized by the manufacturer as minor. A low, continuous dosage of the hormone diffuses through the capsule walls and into the bloodstream. Although the capsules are not usually visible under the skin, the outline of the fan-like pattern can be felt under the skin. Removal occurs during an in-office procedure, similar to the insertion process.

We have no doubt of the profound public interest in developing new products for reproductive services. We intend no disparagement of the product when we recite plaintiffs' claims concerning the efficacy of Norplant. The procedural posture that brings this case before us requires that we accept as true plaintiffs' version of the facts. The motion to dismiss was in the nature of a motion for judgment on the pleadings.

According to plaintiffs, Wyeth began a massive advertising campaign for Norplant in 1991, which it directed at women rather than at their doctors. Wyeth advertised on television and in women's magazines such as Glamour, Mademoiselle and Cosmopolitan. According to plaintiffs, none of the advertisements warned of any inherent danger posed by Norplant; rather, all praised its simplicity and

¹ The Norplant System was made available for marketing in the United States by Wyeth-Ayerst Laboratories (Wyeth) in 1990. The "Wyeth" defendants include Wyeth Laboratories, Inc., a subsidiary of American Home Products Corporation; American Home Products Corporation; Wyeth-Ayerst Laboratories Division of American Home Products Corporation; Wyeth-Ayerst International Inc.; and Wyeth-Ayerst Laboratories Company. The complaint against Dow Corning France, S.A., was dismissed for lack of personal jurisdiction in January 1996.

convenience. None warned of side effects including pain and permanent scarring attendant to removal of the implants. Wyeth also sent a letter to physicians advising them that it was about to launch a national advertising program in magazines that the physicians' patients may read.

Plaintiffs cite several studies published in medical journals that have found Norplant removal to be difficult and painful. One study found that thirty-three percent of women had removal difficulty and forty percent experienced pain. Another study found that fifty-two percent of physicians reported complications during removal. Medical journals have catalogued the need for advanced medical technicians in addition to general surgeons for Norplant removal. Plaintiffs assert that none of this information was provided to consumers.

In 1995, plaintiffs began to file lawsuits in several New Jersey counties claiming injuries that resulted from their use of Norplant.

Plaintiffs' principal claim alleged that Wyeth, distributors of Norplant in the United States, failed to warn adequately about side effects associated with the contraceptive. Side effects complained of by plaintiffs included weight gain, headaches, dizziness, nausea, diarrhea, acne, vomiting, fatigue, facial hair growth, numbness in the arms and legs, irregular menstruation, hair loss, leg cramps, anxiety and nervousness, vision problems, anemia, mood swings and depression, high blood pressure, and removal complications that resulted in scarring.

Class action certification was denied. All New Jersey Norplant cases were consolidated in Middlesex County. Eventually,

twenty-five New Jersey Norplant cases involving approximately fifty Norplant users were pending in the Superior Court in Middlesex County.

After a case management conference, plaintiffs' counsel sought a determination of whether the learned intermediary doctrine applied. Pursuant to that conference, five bellwether plaintiffs² were

² Bellwether plaintiffs are not created pursuant to any formal rule. As explained by the Fifth Circuit in In re Chevron, U.S.A., Inc., 109 F.3d 1016, 1019-20 (1997):

The term bellwether is derived from the ancient practice of belling a wether (a male sheep) selected to lead his flock. The ultimate success of the wether selected to wear the bell was determined by whether the flock had confidence that the wether would not lead them astray, and so it is in the mass tort context.

The notion that the trial of some members of a large group of claimants may provide a basis for enhancing prospects of settlement or for resolving common issues or claims is a sound one that has achieved general acceptance by both bench and bar. References to bellwether trials have long been included in the Manual for Complex Litigation. See MANUAL FOR COMPLEX LITIGATION § 33.27-.28 (3d ed. 1995). . . . If a representative group of claimants are tried to verdict, the results of such trials can be beneficial for litigants who desire to settle such claims by providing information on the value of the cases as reflected by the jury verdicts. Common issues or even general liability may also be resolved

. . . .

[B]efore a trial court may utilize results from a bellwether trial for a purpose that extends beyond the individual cases tried, it must, prior to any extrapolation, find that the cases tried are representative of the larger group of cases or claims from which they are selected[,] . . . based on competent, scientific, statistical evidence. . . . so as

selected to challenge defendant's motion for summary judgment concerning the learned intermediary doctrine. See Perez v. Wyeth Labs., Inc., 313 N.J. Super. 646, 650 (Law Div. 1997). The trial court dismissed plaintiffs' complaints, concluding that even when a manufacturer advertises directly to the public, and a woman is influenced by the advertising campaign, "a physician is not simply relegated to the role of prescribing the drug according to the woman's wishes." Id. at 658. Consequently, the court held that the learned intermediary doctrine applied. Ibid. According to the court, the physician retains the duty to weigh the benefits and risks associated with a drug before deciding whether the drug is appropriate for the patient. Ibid. Because N.J.S.A. 2A:58C-4 of the Products Liability Act, N.J.S.A. 2A:58C-1 to -11, measures warning adequacy based on the knowledge and characteristics of the health-care provider, the court was not "concerned with the effect that a warning had on the . . . consumer-plaintiff." Id. at 659. The court found, however, that plaintiffs failed to provide expert testimony to rebut the statutory presumption under N.J.S.A. 2A:58C-4, that the manufacturer's warning is adequate when it has been approved by the FDA, as is the case here. The court found that plaintiffs failed to rebut the presumption by demonstrating that the manufacturer's warnings to the physicians were inadequate or that a warning as to the difficulty of removal would have altered the health-care

to permit a finding that there is a sufficient level of confidence that the results obtained reflect results that would be obtained from trials of the whole

providers' decisions to implant Norplant. Id. at 659-60. Although the trial court listed pain and scarring associated with removal among plaintiffs' complaints, id. at 650-52, when addressing proximate cause the court subsequently stated that "none of the bellwether plaintiffs complained of difficult removals or that they have significant scarring." Id. at 660 n.5. Consequently, the court concluded that plaintiffs had failed to prove failure to warn and proximate cause, and dismissed plaintiffs' complaints. Id. at 660.

Plaintiffs appealed. Plaintiffs challenged the court's failure to hear expert testimony on the adequacy of the warnings and the decision concerning proximate cause because "it was specifically agreed that the production of expert testimony would await the outcome of the decision on the issue of the learned intermediary doctrine." The Appellate Division affirmed the trial court's grant of summary judgment in favor of defendants and its determination that the learned intermediary doctrine applied. 313 N.J. Super. 511 (1998). The court supplemented the trial court's opinion, comparing Section 6d of the Restatement (Third) of Torts: Products Liability (1997) (Restatement) to N.J.S.A. 2A:58C-4, the similar provision of New Jersey's Products Liability Act. Section 6(d) of the Restatement provides:

(d) A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:

(1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance

with the instructions or warnings;
or

(2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

As noted by the Appellate Division, the new Restatement is similar to N.J.S.A. 2A:58C-4, which defines an adequate warning as

one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, . . . in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician.

The court noted that Section 6(d)(2) of the Restatement may require a warning when the physician or health-care provider has a "diminished role as an evaluator or decision maker," in which case the manufacturer would have a duty to warn patients directly. 313 N.J. Super. at 515 (citing Restatement (Third), § 6d comment b).³ Consequently, the court agreed with the trial court that if the warning was "legislatively deemed adequate and has been given to the proper party," no warning defect under N.J.S.A. 2A:58C-4 had been established. Ibid.

³ Although the New Jersey statute refers only to a prescribing "physician," the court assumed that other health-care providers such as dentists, optometrists, podiatrists, nurse practitioners, home health care service firms and physician's assistants, or other professionals licensed to prescribe or administer drugs, would be included. Perez, supra, 313 N.J. Super. at 515-16.

We granted plaintiffs' petition for certification. 156 N.J.
410 (1998).

II

In Feldman v. Lederle Laboratories, Inc., 97 N.J. 429, (1984) (Feldman I), we considered the relationship between principles of products liability law and pharmaceutical products. In Feldman I, we declined to "hold as a matter of law and policy that all prescription drugs that are unsafe are unavoidably so." Id. at 447.

We explained:

Drugs, like any other products, may contain defects that could have been avoided by better manufacturing or design. Whether a drug is unavoidably unsafe should be decided on a case-by-case basis; we perceive no justification for giving all prescription drug manufacturers a blanket immunity from strict liability manufacturing and design defect claims under [Restatement (Second) Torts § 402A] comment k [(1965)].

Moreover, even if a prescription drug were unavoidably unsafe, the comment k immunity would not eliminate strict liability for failure to provide a proper warning. As Justice Pollock stated in O'Brien [v. Muskin Corp.], 94 N.J. 169, 183 (1983), "[w]ith those products, the determination of liability may be achieved more appropriately through an evaluation of the adequacy of the warnings." [] Thus, a manufacturer who knows or should know of the danger or side effects of a product is not relieved of its duty to warn. Rather, as the comment expressly states, it is only the unavoidably unsafe product "accompanied by proper * * * warning" that is not defective. (Emphasis added.)

[Ibid. (citations omitted).]

As explained in Niemiera by Niemiera v. Schneider, 114 N.J.
550, 559 (1989):

In New Jersey, as elsewhere, we accept the proposition that a pharmaceutical manufacturer generally discharges its duty to warn the ultimate user of prescription drugs by supplying physicians with information about the drug's dangerous propensities. See, e.g., Bacardi v. Holzman, 182 N.J. Super. 422, 442 A.2d 617 (App. Div. 1981). This concept is known as the "learned intermediary" rule because the physician acts as the intermediary between the manufacturer and the consumer. The phrase appears to have been coined in the case of Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966).

We observed that there were circumstances, such as in Davis v. Wyeth Laboratories, Inc., 399 F.2d 121 (9th Cir. 1968), in which the manufacturer should not be relieved of a duty to warn. Niemiera, supra, 114 N.J. at 559. In Davis, the manufacturer of a polio vaccine was held to have an independent duty to warn the consumer because in mass immunization clinics such as where the plaintiff received a polio vaccine, there was "no physician present to weigh the risks and benefits of the drug therapy for each patient." Ibid. (quoting Reyes v. Wyeth Labs., Inc., 498 F.2d 1264 (5th Cir.), cert. denied, 419 U.S. 1096, 95 S. Ct. 687, 42 L. Ed. 2d 688 (1974); see also Stephens v. G.D. Searle & Co., 602 F. Supp. 379 (E.D. Mich. 1985) (manufacturer of oral contraceptive has duty to warn consumers directly of risks and side effects); Samuels v. American Cyanamid Co., 495 N.Y.S.2d 1006 (N.Y. Sup. Ct. 1985) (pharmaceutical company had duty to warn recipient of "travel" vaccines when company knew vaccines were ordinarily given without meaningful balancing of risks and benefits by informed intermediary).

We were satisfied in Niemiera, supra, that sufficient reasons existed with respect to the DPT vaccine (for diphtheria, pertussis

and tetanus) to conclude that the "'learned intermediary' doctrine should apply." Id. at 560. The question in this appeal is whether sufficient reasons exist to warrant its application under these facts. Norplant appears to be a hybrid prescription medical device exhibiting characteristics both of a medical device implanted in the body and of a drug. For convenience, most of our discussion will use the terminology relevant to prescription drugs, the context in which most such claims may arise.

III

Direct-to-Consumer Advertising

It is paradoxical that so pedestrian a concern as male-pattern baldness should have signaled the beginning of direct-to-consumer marketing of prescription drugs. Upjohn Company became the first drug manufacturer to advertise directly to consumers when it advertised for Rogaine, a hair-loss treatment. Jon D. Hanson & Douglas A. Kysar, Taking Behavioralism Seriously: Some Evidence of Market Manipulation, 112 Harv. L. Rev. 1420, 1456 (1999). The ad targeted male consumers by posing the question, "Can an emerging bald spot . . . damage your ability to get along with others, influence your chance of obtaining a job or date or even interfere with your job performance?" Ibid. (footnotes omitted). A related ad featured an attractive woman asserting suggestively, "I know that a man who can afford Rogaine is a man who can afford me." Ibid. (footnote omitted).

Advertising for Rogaine was the tip of the iceberg. Since drug manufacturers began marketing directly to consumers for products

such as prescription drugs in the 1980s, "almost all pharmaceutical companies have engaged in this direct marketing practice." Ibid. (footnote omitted). Consider the following example:

A hot-air balloon floats lazily across the backdrop of a beautiful, cloudless, sunny sky. Cole Porter sings in the background, "Blue skies smiling at me[.] Nothing but blue skies do I see." A kind voice instructs the viewer to "see your doctor about Claritin (R)" because a "clear answer is out there." This advertisement for Claritin (R), a nondrowsy prescription antihistamine, aired prior to the . . . (FDA's) release of new direct-to-consumer (DTC) broadcast advertising guidelines in August 1997. The viewer often was bewildered because the "clear answer" about what Claritin (R) treated was not in the otherwise well-produced thirty-second television advertisement.

[Kelly N. Reeves, Direct-to-Consumer Broadcast Advertising: Empowering the Consumer or Manipulating a Vulnerable Population?, 53 Food & Drug L.J. 661, 661 (1998) (footnotes omitted).]

These campaigns "bring to 'bear all the slick pressure of which Madison Avenue is capable'." Hanson & Kysar, supra, 112 Harv. L. Rev. at 1456 (footnote omitted).

Pressure on consumers is an integral part of drug manufacturers' marketing strategy. From 1995 to 1996, drug companies increased advertising directed to consumers by ninety percent. Bob Van Voris, Drug Ads Could Spell Legal Trouble[.] Consumer Campaigns May Result in Greater Liability, Nat'l L.J., July 21, 1997, at B1. In 1997, advertising costs of pharmaceutical products surpassed the half-billion dollar mark for the first time, "easily outpacing promotional efforts directed to physicians." Lars Noah, Advertising Prescription Drugs to Consumers: Assessing the Regulatory and

Liability Issues, 32 Ga. L. Rev. 141, 141 (1997) (footnote omitted).

“John F. Kamp, senior vice president of the American Association of Advertising Agencies, said that prescription drug companies spent \$1.3 billion on print and broadcast advertising aimed at consumers last year, up from \$843 million in 1997” Robert Pear, Drug Companies Getting F.D.A. Reprimands for False or Misleading Advertising, N.Y. Times, Mar. 28, 1999, at 28. These efforts are not just an essential part of manufacturers’ marketing plans; they are an extremely successful one. As of December 1998, “because of its testimonials” in print and broadcast media by renowned personalities, sales of a product that treats male impotence had increased to \$788 million, with approximately 7.5 million prescriptions having been written. Jay P. Speivack, Direct Ads May Create Liability Dangers. Consumer Advertising by Drug Manufacturers Has Reopened the Issue of Expanded Liability., Nat’l L.J., Mar. 15, 1999, at B7 n.1.

Without vouching for every decimal point in the discussion, the following is a summary of changes in pharmaceutical marketing.

[Significant technological] advances in [medical] treatment have been accompanied by significant increases in the cost of health care. It is estimated that in 1996, Americans spent more than \$1 trillion on health care products and services. Health care is the single largest business in the United States, representing 14% of the gross domestic product. Health care expenses comprise the largest single area of non-government spending.

Corresponding with the financial burdens attendant to our modern health care system, a fundamental change has taken place in the way Americans pay for their health care [from individually-funded to third-party-funded health care] These fundamental changes

have drastically altered the delivery of health care services.

. . . .

As [pharmaceutical] manufacturers attempt to appropriately position their products in the chain of delivery, new techniques are often employed to supplement traditional marketing efforts which have historically consisted of direct physician education, information provided in medical references, educational seminars, and research grants. . . .

Among the most controversial of the new marketing techniques employed by pharmaceutical manufacturers is direct-to-consumer prescription advertising in a variety of formats and media. Pharmaceutical remedies for varied problems such as allergies, nail fungus, hypertension, hair loss, and depression are placed directly before the consumer in magazines, television, and via the Internet. The utilization of direct consumer marketing raises questions and issues addressing manufacturer liability for failure to adequately warn of risks possibly associated with pharmaceutical use.

. . . .

The American Medical Association (AMA) has long maintained a policy in opposition to product-specific prescription ads aimed at consumers. A 1992 study by the Annals of Internal Medicine reports that a peer review of 109 prescription ads found 92 per cent of the advertisements lacking in some manner.

[Michael C. Allen, Medicine Goes Madison Avenue: An Evaluation of the Effect of Direct-to-Consumer Pharmaceutical Advertising on the Learned Intermediary Doctrine, 20 Campbell L. Rev. 113, 113-116 (1997) (footnotes omitted).]

The difficulties that accompany this [type of advertising] practice are manifest. "The marketing gimmick used by the drug manufacturer often provides the consumer with a diluted variation of the risks associated with the drug product." Even without such manipulation, "[t]elevision spots lasting 30 or 60 seconds are not conducive to 'fair balance' [in presentation of risks]."

Given such constraints, pharmaceutical ads often contain warnings of a general nature. However, "[r]esearch indicates that general warnings (for example, see your doctor) in [direct-to-consumer] advertisements do not give the consumer a sufficient understanding of the risks inherent in product use." Consumers often interpret such warnings as a "general reassurance" that their condition can be treated, rather than as a requirement that "specific vigilance" is needed to protect them from product risks.

[Hanson & Kysar, supra, 112 Harv. L. Rev. at 1456.]

IV

How Has the Law Responded to These Changes?

- A. The new Restatement (Third) of Torts has left the issue to "developing case law."

Parallel to the developments in drug marketing, the American Law Institute was in the process of adopting the Restatement (Third) of Torts: Products Liability (1997). The comment to Section 6 explains that subsection (d)(1) sets forth the traditional rule of the learned intermediary that drug and medical device manufacturers are liable for failing to warn of a drug's risks only when the manufacturer fails to warn the health-care provider of risks attendant to a specific drug. Restatement, supra, § 6(d) comment a. That same comment also notes that subsection (d)(2) reflects decisional law and provides limited exceptions to the traditional rule by requiring manufacturers to warn patients in certain circumstances. Ibid. Because situations may exist when the health-care provider assumes a "much-diminished role as an evaluator or decisionmaker," it is appropriate to impose a duty on the manufacturer to warn the patient directly. Id. at § 6d comment b. Despite the early effort to provide an exception to the doctrine

in the case of direct marketing of pharmaceuticals to consumers, the drafters left the resolution of that issue to "developing case law." Id. at § 6d comment e. One commentator described the Restatement's approach as a "tepid endorsement" of the learned intermediary doctrine. Charles J. Walsh et al., The Learned Intermediary Doctrine: The Correct Prescription for Drug Labeling, 48 Rutgers L. Rev. 821, 869 (1994). Thus, under the new Restatement, "warnings may have to be provided to a health-care provider or even to the patient," depending on the circumstances. William A. Dreier, The Restatement (Third) of Torts: Products Liability and the New Jersey Law -- Not Quite Perfect Together, 50 Rutgers L.J. 2059, 2097 (1998). This is an entirely appropriate resolution. Judge Cardozo, a shaper of both the common law and of the Restatements of law drafted by the American Law Institute, saw each role as complementary:

Cardozo saw the Institute as continuing his own work as a common law judge: to show that new decisions that modernized law had their roots in ancient notions of the purpose of law to accomplish justice through an ongoing reformulation of the governing rules.

[Andrew L. Kaufman, Cardozo 174 (1998).]

- B. The New Jersey Products Liability Act does not legislate the boundaries of the learned intermediary doctrine.

As noted, the New Jersey Products Liability Act provides:

An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the

characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used, or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician. If the warning or instruction given in connection with a drug or device or food or food additive has been approved or prescribed by the federal Food and Drug Administration under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. § 301 et seq., . . . a rebuttable presumption shall arise that the warning or instruction is adequate

[N.J.S.A. 2A:58C-4.]

The Senate Judiciary Committee Statement that accompanied L. 1987, c. 197 recites: "The subsection contains a general definition of an adequate warning and a special definition for warnings that accompany prescription drugs, since, in the case of prescription drugs, the warning is owed to the physician." See N.J.S.A. 2A:58C-1 (providing the Committee Statement) (emphasis added). At oral argument, counsel for Wyeth was candid to acknowledge that he could not "point to a sentence in the statute" that would make the learned intermediary doctrine applicable to the manufacturers' direct marketing of drugs, but rather relied on the Committee Statement.

Although the statute provides a physician-based standard for determining the adequacy of the warning due to a physician, the statute does not legislate the boundaries of the doctrine. For example, the Act does not purport to repeal a holding such as Davis v. Wyeth Labs, supra, which required that manufacturers directly warn patients in mass inoculation cases. Rather, the statute governs the content of an "adequate product warning," when required. As noted, supra at ____ (slip op. at 15), in 1987, direct-to-consumer

marketing of prescription drugs was in its beginning stages. The Committee Statement observes that "the warning is owed to the physician" because drugs were then marketed to the physician. We believe that the part of the provision establishing "a presumption that a warning or instruction is adequate on drug or food products if the warning has been approved or prescribed by the Food and Drug Administration," Committee Statement, supra, will provide the benchmark for this decision.

Our dissenting member suggests that we should await legislative action before deciding that issue. As we explained in Kelly v. Gwinnell,

[t]his Court has decided many significant issues without any prior legislative study. In any event, if the Legislature differs with us on issues of this kind, it has a clear remedy.
. . .

We are satisfied that our decision today is well within the competence of the judiciary. Defining the scope of tort liability has traditionally been accepted as the responsibility of the courts.

[96 N.J. 538, 555-56 (1984) (footnote and internal citations omitted).]

If we decline to resolve the question, we are making the substantive determination that the learned intermediary doctrine applies to the direct marketing of drugs, an issue recently debated but left unanswered by the drafters of the Restatement. Either course, then, requires us to adopt a principle of law. The question is which is the better principle.

- C. Direct advertising of drugs to consumers alters the calculus of the learned intermediary doctrine.

In Reyes, supra, the respected Judge John Minor Wisdom explained the rationale behind the learned intermediary doctrine. His perspective reflects the then-prevalent attitude about doctor-patient relationships:

This special standard for prescription drugs is an understandable exception to the Restatement's general rule that one who markets goods must warn foreseeable ultimate users of dangers inherent in [the] products. . . . Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of [the] patient. [The physician's] task [is to weigh] the benefits of any medication against its potential dangers. The choice [the physician] makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer.

[498 F.2d at 1276 (footnote and citation omitted).]

A more recent review summarized the theoretical bases for the doctrine as based on four considerations.

First, courts do not wish to intrude upon the doctor-patient relationship. From this perspective, warnings that contradict information supplied by the physician will undermine the patient's trust in the physician's judgment. Second, physicians may be in a superior position to convey meaningful information to their patients, as they must do to satisfy their duty to secure informed consent. Third, drug manufacturers lack effective means to communicate directly with patients, making it necessary to rely on physicians to convey the relevant information.

Unlike [over the counter products], pharmacists usually dispense prescription drugs from bulk containers rather than as unit-of-use packages in which the manufacturer may have enclosed labeling. Finally, because of the complexity of risk information about prescription drugs, comprehension problems would complicate any effort by manufacturers to translate physician labeling for lay patients. For this reason, even critics of the rule do not suggest that pharmaceutical companies should provide warnings only to patients and have no tort duty to warn physicians.

[Noah, supra, 32 Ga. L. Rev. at 157-59 (footnotes omitted).]

These premises: (1) reluctance to undermine the doctor patient-relationship; (2) absence in the era of "doctor knows best" of need for the patient's informed consent; (3) inability of drug manufacturer to communicate with patients; and (4) complexity of the subject; are all (with the possible exception of the last) absent in the direct-to-consumer advertising of prescription drugs.

First, with rare and wonderful exceptions, the "'Norman Rockwell' image of the family doctor no longer exists." Id. at 180 n.78 (citing Paul D. Rheingold, The Expanding Liability of the Drug Manufacturer to the Consumer, 40 Food Drug Cosm. L.J. 135, 136 (1985)). Informed consent requires a patient-based decision rather

than the paternalistic approach of the 1970s. See Largey v. Rothman, 110 N.J. 204, 206 (1988) (discussing Canterbury v. Spence, 464 F.2d 772 (D.C. Cir.), cert. denied, 409 U.S. 1064, 93 S. Ct. 560, 34 L. Ed. 2d 518 (1972)). The decision to take a drug is "not exclusively a matter for medical judgment." See Teresa Moran Schwartz, Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule, 46 Food Drug Cosm. L.J. 829, 831 (1991) (citing Margaret Gilhooley, Learned Intermediaries, Prescription Drugs, and Patient Information, 30 St. Louis. U. L.J. 633, 652 (1986)).

Second, because managed care has reduced the time allotted per patient, physicians have considerably less time to inform patients of the risks and benefits of a drug. Sheryl Gay Stolberg, Faulty Warning Labels Add to Risk in Prescription Drugs, N.Y. Times, June 4, 1999, at A27. "In a 1997 survey of 1,000 patients, the F.D.A. found that only one-third had received information from their doctors about the dangerous side effects of drugs they were taking." Ibid.

Third, having spent \$1.3 billion on advertising in 1998, supra at ___ (slip op. at 16-17), drug manufacturers can hardly be said to "lack effective means to communicate directly with patients," Noah, supra, 32 Ga. L. Rev. at 158, when their advertising campaigns can pay off in close to billions in dividends.

Consumer-directed advertising of pharmaceuticals thus belies each of the premises on which the learned intermediary doctrine rests.

First, the fact that manufacturers are advertising their drugs and devices to consumers suggests that consumers are active participants in their health care decisions, invalidating the concept that it is the doctor, not the patient, who decides whether a drug or device should be used. Second, it is illogical that

requiring manufacturers to provide direct warnings to a consumer will undermine the patient-physician relationship, when, by its very nature, consumer-directed advertising encroaches on that relationship by encouraging consumers to ask for advertised products by name. Finally, consumer-directed advertising rebuts the notion that prescription drugs and devices and their potential adverse effects are too complex to be effectively communicated to lay consumers. Because the FDA requires that prescription drug and device advertising carry warnings, the consumer may reasonably presume that the advertiser guarantees the adequacy of its warnings. Thus, the common law duty to warn the ultimate consumer should apply.

[Susan A. Casey, Comment, Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine, 19 Wm. Mitchell L. Rev. 931, 956 (1993) (footnotes omitted).]

When all of its premises are absent, as when direct warnings to consumers are mandatory, the learned intermediary doctrine, "itself an exception to the manufacturer's traditional duty to warn consumers directly of the risk associated with any product, simply drops out of the calculus, leaving the duty of the manufacturer to be determined in accordance with general principles of tort law."

Edwards v. Basel Pharms., 116 F.3d 1341, 1343 (10th Cir. 1997) (discussing question of adequacy of nicotine patch warning under Texas law certified in Edwards v. Basel Pharms., 933 P.2d 298 (Okla. 1997)). We acknowledge that the Fifth Circuit recently held that under Texas law, the learned intermediary doctrine does apply in the context of Norplant. In re Norplant Contraceptive Prod. Liab. Litig. v. American Home Prods. Corp., 165 F.3d 374, 379-80 (1999). Nonetheless, we agree with the Tenth Circuit's approach.

Concerns regarding patients' communication with and access to physicians are magnified in the context of medicines and medical

devices furnished to women for reproductive decisions. In MacDonald v. Ortho Pharmaceutical Corp., 475 N.E.2d 65 (Mass.), cert. denied, 474 U.S. 920, 106 S. Ct. 250, 88 L. Ed. 2d 258 (1985), the plaintiff's use of oral contraceptives allegedly resulted in a stroke. The Massachusetts Supreme Court explained several reasons why contraceptives differ from other prescription drugs and thus "warrant the imposition of a common law duty on the manufacturer to warn users directly of associated risks." Id. at 136-37. For example, after the patient receives the prescription, she consults with the physician to receive a prescription annually, leaving her an infrequent opportunity to "explore her questions and concerns about the medication with the prescribing physician." Id. at 137. Consequently, the limited participation of the physician leads to a real possibility that their communication during the annual checkup is insufficient. Id. at 138. The court also explained that because oral contraceptives are drugs personally selected by the patient, a prescription is often not the result of a physician's skilled balancing of individual benefits and risks but originates, instead, as a product of patient choice. Id. at 137. Thus, "the physician is relegated to a . . . passive role." Ibid.

Patient choice is an increasingly important part of our medical-legal jurisprudence. New Jersey has long since abandoned the "professional standard" in favor of the objectively-prudent-patient rule, recognizing the informed role of the patient in health-care decisions. Largey, supra, 110 N.J. at 212. Accordingly, a patient must be informed of material risks, which exist "when a reasonable patient, in what the physician knows or

should know to be the patient's position, would be 'likely to attach significance to the risk or cluster of risks' in deciding whether to forego the proposed therapy or to submit to it." Id. at 211-12 (quoting Canterbury, supra, 464 F.2d at 787). When a patient is the target of direct marketing, one would think, at a minimum, that the law would require that the patient not be misinformed about the product. It is one thing not to inform a patient about the potential side effects of a product; it is another thing to misinform the patient by deliberately withholding potential side effects while marketing the product as an efficacious solution to a serious health problem.

Further, when one considers that many of these "life-style" drugs or elective treatments cause significant side effects without any curative effect, increased consumer protection becomes imperative, because these drugs are, by definition, not medically necessary.

In the development of products liability law, the role of advertising has been a significant factor in defining the duties of sellers.

An early, but important, example is Henningsen v. Bloomfield Motors Inc., [32 N.J. 358 (1960)] the seminal case marking "the date of the fall of the citadel of privity," in which the Court recognized the "advent of large scale advertising by manufacturers" as a basis for reconsidering the long-standing privity rule in warranty cases. The general principle recognized in Henningsen--that a manufacturer's duty runs directly to the consumer when it markets its products directly to the consumer--is as applicable today to prescription drug manufacturers who advertise their products as it was to automobile manufacturers three decades ago in Henningsen.

[Schwartz, supra, 46 Food Drug Cosm. L.J. at 840-41 (footnotes omitted).]

Obviously, the learned intermediary doctrine applies when its predicates are present. "In New Jersey, as elsewhere, we accept the proposition that a pharmaceutical manufacturer generally discharges its duty to warn the ultimate users of prescription drugs by supplying physicians with information about the drug's dangerous propensities." Niemiera, supra, 114 N.J. at 559. Had Wyeth done just that, simply supplied the physician with information about the product, and not advertised directly to the patients, plaintiffs would have no claim against Wyeth based on an independent duty to warn patients. The question is whether the absence of an independent duty to warn patients gives the manufacturer the right to misrepresent to the public the product's safety.

- D. Prescription drug manufacturers that market their products directly to consumers should be subject to claims by consumers if their advertising fails to provide an adequate warning of the product's dangerous propensities.

In reaching the conclusion that the learned intermediary doctrine does not apply to the direct marketing of drugs to consumers, we must necessarily consider that when prescription drugs are marketed and labeled in accordance with FDA specifications, the pharmaceutical manufacturers should not have to confront "state tort liability premised on theories of design defect or warning inadequacy." Note, A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals, 103 Harv. L. Rev. 773, 773 (1990). We draw much of this summary concerning the specifics of FDA pharmaceutical regulation from the brief of amicus curiae, the Pharmaceutical Research and Manufacturers of America. Because such regulations may change from day to day, our commentary concerning the current regulations may soon become moot.

The FDA is authorized to regulate advertisements for prescription drugs pursuant to 21 U.S.C.A. Section 352(n) of the Food, Drug and Cosmetic Act, 21 U.S.C.A. Sections 301-397. Advertisements subject to Section 352(n) include "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems." 21 C.F.R. § 202.1(1)(1). Although the FDA has regulated drug advertising since 1963, those regulations initially addressed only advertising directed at health-care providers. Noah, supra, 32 Ga. L. Rev. at 142-43. Aware of the potential threat to consumers when pharmaceutical companies

first sought to advertise to non-health-care professionals, the FDA, in the early 1980s

initially imposed a [voluntary] moratorium on such advertising so that it could study the issue more carefully; but, in 1985, it lifted the moratorium, content to apply its existing regulations to this new practice. Perhaps spurred by the rapid growth of direct consumer advertising and the inherent shortcomings of rules designed to control advertising to physicians, coupled with the emergence of brand new media such as the Internet for disseminating promotional messages, the Agency has now proposed to modify its approach.

[Id. at 142-43.]

Section 352(n) of the Act contains the "brief summary requirement," which is a misnomer considering that the summary is anything but brief. Accordingly, all advertisements must include a description of "side effects, contraindications, and effectiveness as shall be required in regulations. . . ." 21 U.S.C.A. § 352(n) (3).

The regulations addressing prescription drugs also require that the brief summary provide "all the risk-related information in a product's approved package labeling," which is usually a package insert or product package insert. 62 Fed. Reg. 43,171 (Aug. 12, 1997) (citing 21 C.F.R. § 202.1(e) (1) and (e) (3) (iii)). As noted by amicus curiae, the FDA "[r]egulations are exhaustive, addressing issues as broad as the requirement that ads be fairly balanced (21 C.F.R. § 202.1(e) (6)) and as narrow as how graphs must be labeled (21 C.F.R. § 202.1(e) (7) (iv)) and the type size used to set forth a medicine's established name (21 C.F.R. § 202.1(b) (2))."

In August 1997, the FDA released a Draft Guidance, which specifically addresses consumer-directed broadcast advertisements

such as radio, television and telephone communications. 21 Fed. Reg. 43,172 (Aug. 12, 1997). Broadcast advertisements must contain a "major statement" of the major risks of the drug. Ibid. Instead of presenting a brief summary with the broadcast, which is not as feasible as in the print media, the Guidance proposes an alternative requirement known as the "adequate provision" requirement. Ibid. That provision provides that the manufacturer "may make adequate provision for the dissemination of the approved package labeling in connection with the broadcast presentation (§ 202.1(e)(1))." Ibid. The Guidance explains that four components must be present to meet the "adequate provision" requirement in broadcasts -- a toll-free number that provides information concerning where consumers might find information about package labeling; an alternative mechanism for obtaining package labeling information for consumers who do not have access to technology such as the Internet; a statement directing consumers to pharmacists and/or physicians; and an Internet web-page address. See Guidance for Industry: Consumer-Directed Broadcast Advertisements (visited June 14, 1999) <<http://www.fda.gov/cder/guidance/index.htm>>. Within two years of the release of the Guidance, the FDA "intends to evaluate the effects of the guidance. . . ." 62 Fed. Reg. 43,172. These FDA actions indicate that the agency views direct-to-consumer advertising as a means of providing consumers with improved access to important information about prescription drugs.⁴

⁴ But see Robert Cohen, Regulation on Drugs Unraveling on the Web, Star-Ledger, July 6, 1999, at 1 (noting that although prescription "drug bazaars" on the Internet "are undermining federal drug safety laws, tearing apart the doctor-patient relationship and

breaking state pharmacy and medical regulations," federal officials are uncertain how to "get control of the latest e-commerce phenomenon.").

FDA regulations are pertinent in determining the nature and extent of any duty of care that should be imposed on pharmaceutical manufacturers with respect to direct-to-consumer advertising. Cf. Alloway v. Bradlees, Inc., 157 N.J. 221, 236 (1999) (discussing relevance of federal OSHA standards in determining duty of care to impose on general contractor for injuries incurred by subcontractor's employee on worksite). Presently, any duty to warn physicians about prescription drug dangers is presumptively met by compliance with federal labeling. See N.J.S.A. 2C:58-4. That presumption is not absolute. See, e.g., Feldman v. Lederle Labs., Inc., 125 N.J. 117, 156-7 (1991) (Feldman II) (concluding that under unique circumstances of case, compliance with FDA determination not to require drug warning due to lack of "unequivocal factual evidence of adverse reaction in man," despite evidence of adequacy of product labeling, did not create conclusive presumption that labeling contained adequate warning) cert. denied, 505 U.S. 1219, 112 S. Ct. 3027, 120 L. Ed. 2d 898 (1992). Nevertheless, FDA regulations serve as compelling evidence that a manufacturer satisfied its duty to warn the physician about potentially harmful side effects of its product.

We believe that in the area of direct-to-consumer advertising of pharmaceuticals, the same rebuttable presumption should apply when a manufacturer complies with FDA advertising, labeling and warning requirements. That approach harmonizes the manufacturer's duty to doctors and to the public when it chooses to directly advertise its products, and simultaneously recognizes the public interest in informing patients about new pharmaceutical developments. Moreover, a rebuttable presumption that the duty to consumers is

met by compliance with FDA regulations helps to ensure that manufacturers are not made guarantors against remotely possible, but not scientifically-verifiable, side-effects of prescription drugs, a result that could have a "significant anti-utilitarian effect." See Feldman II, supra, 125 N.J. at 162 (Garibaldi, J., dissenting); see also Michael D. Green, Statutory Compliance and Tort Liability: Examining the Strongest Case, 30 U. Mich. J.L. Ref. 461, 466-67 (1997) (noting that over deterrence in drug advertising context could impede and delay manufacturers from research and development of new and effective drugs, force beneficial drugs from market, lead to shortages in supplies and suppliers of pharmaceuticals, and create unnecessary administrative costs).

We believe that this standard is fair and balanced. For all practical purposes, absent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive of such claims. By definition, the advertising will have been "fairly balanced." This presumptive effect is in accordance with legislative intent that we discern from the punitive damages provision of the Products Liability Act. See L. 1987, c. 142, § 5(c). That provision prohibits, in the case of the sale of pharmaceutical products, an award of punitive damages if there has been compliance with FDA labeling and pre-marketing requirements, impliedly reserving compensatory damages for those rare cases when the presumption is overcome. N.J.S.A. 2A:58C-5(c).

The final issues in this case concern proximate cause, that is, whether misinformation actually affected these patients and, if so, whether the intervention of the physician (without whom the product may not reach the patient) breaks the chain of causation.

Concerning the first issue, defendants argue that we should refrain from deciding whether the learned intermediary doctrine applies because these plaintiffs did not say that they had been influenced by defective advertising of Norplant. We decline to do so for two reasons. First, plaintiffs claim to have been lulled into the view that the only issue for decision at this phase of the case was the application of the learned intermediary doctrine. Moreover, were we to decline to resolve the application of the learned intermediary doctrine, the remainder of the fold would have to relitigate the issue even if their bellwethers were no longer available to lead them.⁵ See supra at ____ (slip op. at 7-8 n.2).

We believe it best to resolve the threshold issue of whether the learned intermediary doctrine applies in the case of direct-to-consumer marketing of pharmaceutical goods and to remand the matter for further proceedings. The issue on remand will be whether, on a summary judgment motion, there is sufficient evidence for a reasonable jury to determine in the cases of the bellwether plaintiffs, or any remaining plaintiffs, that the absence of information or presence of misinformation in Norplant advertising was in violation of FDA requirements and whether such violations,

⁵ Several of the bellwether plaintiffs submitted supplemental affidavits concerning exposure to advertising of Norplant.

if any, were a substantial factor in bringing about the harm suffered.

The more difficult question is whether the role of the physician breaks the chain of causation. Although the physician writes the prescription, the physician's role in deciding which prescription drug is selected has been altered. With the arrival of direct-to-consumer advertising, patients now enter physicians' offices with "preconceived expectations about treatment because of information obtained from DTC [direct-to-consumer] advertisements."

Tamar V. Terzian, Direct-to-Consumer Prescription Drug Advertising, 25 Am. J.L. & Med. 149, 157 (1999). Consequently,

[p]hysicians may relent to patient pressure, even if it is not in the best interest of the patient. In fact, physicians state that they are increasingly asked and pressured by their patients to prescribe drugs that the patient has seen advertised. For example, the diet drug combinations known as fen-phen was prescribed despite little hard scientific evidence of its potential side-effects. Physicians are under attack for prescribing the pills too often and too readily to inappropriate patients. Physicians argue that it is not their fault; rather, they claim pushy patients, prodded by DTC advertisements, pressed, wheedled, begged and berated them for quick treatments. This scenario comes at a time when physicians cannot afford to lose patients, because their income is already strained by managed care cost cutting. Physicians complain that it is impossible to compete with pharmaceutical companies' massive advertising budgets, and resign themselves to the fact that if consumers make enough noise, they will eventually relent to patient pressure.

[Id. at 157-58 (footnotes omitted).]

We disagree that these "ads change the physician into 'simply a functionary, filling out prescriptions[,]' " but we must examine

whether the changed relationship affects the finding of proximate cause. See Van Voris, supra, Nat'l L.J., at B1 (quoting Michael Traynor, adviser to the Restatement project).

We have described proximate cause as an expression as much of policy as it is an expression of the effect of sequential events.

A proximate cause need not be the sole cause of harm. It suffices if it is a substantial contributing factor to the harm suffered.

"Proximate or legal causation is that combination of 'logic, common sense, justice, policy and precedent' that fixes a point in a chain of events, some foreseeable and some unforeseeable, beyond which the law will bar recovery." People Express Airlines, Inc. v. Consolidated Rail Corp., 100 N.J. 246, 264, 495 A.2d 107 (1985) (quoting Caputzal v. Lindsay Co., 48 N.J. 69, 77-78, 222 A.2d 513 (1966); see also Kuzmich v. Ivy Hill Park Apartments, Inc., 147 N.J. 510, 540-41, 688 A.2d 1018 (1997) (Stein, J., dissenting) (same); Contey v. New Jersey Bell Tel. Co., 136 N.J. 582, 587, 643 A.2d 1005 (1994) ("We have . . . defined the limits of proximate cause as an instrument of fairness and policy.") (internal quotation omitted); Brown v. United States Stove Co., 98 N.J. 155, 173, 484 A.2d 1234 (1984) ("The assessment as to whether conduct can be considered sufficiently causally connected to accidental harm so as to justify the imposition of liability also implicates concerns for overall fairness and sound public policy."); Rappaport v. Nichols, 31 N.J. 188, 205, 156 A.2d 1 (1959) ("We are fully mindful that policy considerations and the balancing of the conflicting interests are the truly vital factors in the molding and application of the common law principles of negligence and proximate causation.").

Ordinarily, issues of proximate cause are considered to be jury questions. See Martin v. Bengue, Inc., 25 N.J. 359, 374 136 A.2d 626 (1957). However, in unique cases our courts have rejected the imposition of liability as a matter of law for highly extraordinary consequences. . . .

[Garrison v. Township of Middletown, 154 N.J. 282, 307-38 (1998) (Stein, J., concurring).]

As a matter of policy then, we could hold that even if deceptive advertising were a substantial contributing factor influencing a patient's choice of a medicine, the intervening role of the physician should insulate the manufacturer who has engaged in deceptive trade practices. In other contexts, we have not insulated manufacturers when another might have given better warning. Freund v. Cellofilm Properties, Inc., 87 N.J. 229, 245 (1981); see also Campos v. Firestone Tire & Rubber Co., 98 N.J. 198, 208 (1984), citing Bexiga v. Havir Mfg. Corp., 60 N.J. 402, 410 (1972) (holding that manufacturer may be responsible for failing to include safety precautions on its machine despite its expectation that someone would install these safety devices, because public interest required that duty of assuring such installation should not be left to others); and Davis supra, 399 F.2d at 131 (holding that prescription drug manufacturer may have duty to see that warnings of drug's risks, distributed to medical profession, in fact reached drug's ultimate consumers).

Furthermore, a manufacturer who fails to warn the medical community of a particular risk may nonetheless be relieved of liability under the learned intermediary doctrine if the prescribing physician either did not read the warning at all, and thus did not rely on any information from the manufacturer in prescribing the product, or if the physician was aware of the risk from other sources and considered the risk in prescribing the product. Under these circumstances, the learned intermediary's conduct is deemed to be the superseding or intervening cause that breaks the chain of liability between the manufacturer and the user.

[Richard J. Heafey & Don M. Kennedy, Products Liability: Winning Strategies and Techniques § 10.03 (1999) (footnotes omitted).]

The superseding cause rationale

is appealing because it is based on the familiar tort concept that a tortfeasor is liable only for the injuries that he or she proximately causes. Despite its appeal, one problem with using the causation rationale is the inherent difficulty of establishing causation in failure-to-warn cases as compared with other product liability claims. In a typical defective design case, a plaintiff points to the existence of a viable alternative design and asserts that the manufacturer's failure to use that design proximately caused the plaintiff's injury. Failure-to-warn claims, however, entail a different sort of showing. A plaintiff suing under a failure-to-warn theory must presumably establish that she would have heeded an adequate warning if one were given.

Due to the individualized nature of the inquiry into what warning would have caused the plaintiff to alter her behavior, Professors Henderson and Twerski suggest that predicting how additional information would have affected any given individual may be well nigh impossible.

[Lloyd C. Chatfield II, Medical Implant Litigation and Failure to Warn: A New Extension for the Learned Intermediary Rule, 82 Ky. L.J. 575, 582-83 (1993-94) (footnotes omitted).]

On balance, we believe that the patient's interest in reliable information predominates over a policy interest that would insulate manufacturers. "Products liability law is based on concepts of fairness, feasibility, practicality and functional responsibility. We have always stressed the public's interest in motivating individuals and commercial entities to invest in safety to protect workers." Zaza v. Marquess and Nell, Inc., 144 N.J. 34, 64 (1996). Within bounds, that policy extends to consumers of pharmaceuticals.

Obviously, the physician is almost always the essential link between the patient and the pharmaceutical. Most ads for drugs caution the patient to consult with a physician. Because of that essential link, under the learned intermediary rule drug manufacturers were found not liable even if they did not provide an adequate warning to those physicians who eventually prescribed a drug, to inform them of the risk.⁶

⁶ The sale of pharmaceuticals is changing even faster than the manufacturers themselves might have anticipated. Doctors in "cyberspace" write prescriptions for patients whom they have never seen. Sometimes the "learned intermediary" owns the pharmacy. Sheryl Gay Stolberg, Internet Prescriptions Boom in the 'Wild West' of the Web, N.Y. Times, June 27, 1999, at A1.

Courts have differed in their application of the learned intermediary doctrine in cases in which the defendant claimed that the prescribing physician knew of the risk that the manufacturer did not warn about. Some courts have applied a presumption that the physician would not have prescribed the product if an adequate warning had been given. The defendant may then rebut the presumption with evidence that the physician's decision would not have been affected by such a warning. Other courts have refused to create such a presumption, and have required the plaintiff to prove that an adequate warning would actually have changed the physician's decision. The courts have also differed in the quantum of proof a defendant must establish to show that the physician would have prescribed the drug even if the manufacturer had warned of the risk.

[Heafey & Kennedy, supra, at § 10.03 (footnotes omitted).]

However, we must consider as well a case in which a diabetic patient might have been influenced by advertising to request a drug from a physician without being warned by the manufacturer or the physician of the special dangers posed to a diabetic taking the drug. If an overburdened physician does not inquire whether the patient is a diabetic, the question remains whether the manufacturer should be relieved entirely of responsibility. In the case of direct marketing of drugs, we believe that neither the physician nor the manufacturer should be entirely relieved of their respective duties to warn. Pharmaceutical manufacturers may seek contribution, indemnity or exoneration because of the physician's deficient role in prescribing that drug. In each case, a jury must resolve the close questions of whether a breach of duty has been a proximate cause of harm, Cowan v. Doering, 111 N.J. 451 (1988), and how that causative harm, if found, may be apportioned among culpable defendants. In our experience, jurors are extremely skilled at sorting out the justly and legally responsible parties. See Estate of Chin v. St. Barnabas Med'l Ctr., ___ N.J. ___ (1999) (explaining how jury assessed evidence to determine relative fault of physician and attending nurses when medical device manufacturer was relieved of liability). As our dissenting member observes, it is still the physician in whom the patient reposes the greatest trust for health-care decisions. Post at ___ (slip op. at 8). We are certain that today's ruling will not alter the existing fair balance of trust and responsibility for patient health care as between physician and pharmaceutical manufacturer.

To sum up, the dramatic shift in pharmaceutical marketing to consumers is based in large part on significant changes in the health-care system from fee-for-service to managed care. Managed care companies negotiate directly with pharmaceutical companies and then inform prescribers which medications are covered by the respective plans. Because managed care has made it more difficult for pharmaceutical companies to communicate with prescribers, the manufacturers have developed a different strategy, marketing to consumers.

Pharmaceutical companies have a right to communicate with the public. These companies hope to increase their market share by making their product well known to both patients and physicians. Pharmaceutical executives, aware of the high levels of spending on DTC efforts, are trying to determine how to best spend their funds to obtain the highest return on their investment. Since the FDA Guidance was released, pharmaceutical companies have taken consumer advertising crash courses. Pharmaceutical companies are already seeing results in strong sales growth, due to DTC advertising.

[Terzian, supra, 25 Am. J.L. & Med. at 160-61.]

The direct marketing of drugs to consumers generates a corresponding duty requiring manufacturers to warn of defects in the product. The FDA has established a comprehensive regulatory scheme for direct-to-consumer marketing of pharmaceutical products.

Given the presumptive defense that is afforded to pharmaceutical manufacturers that comply with FDA requirements, we believe that it is fair to reinforce the regulatory scheme by allowing, in the case of direct-to-consumer marketing of drugs, patients deprived

of reliable medical information to establish that the misinformation was a substantial factor contributing to their use of a defective pharmaceutical product.

Before concluding, we acknowledge that the procedural posture of this case casts defendant's product in an unfair light. Because the case arises on a motion for summary judgment, we are obliged to view the issues in the light most favorable to the claimants. We have no doubt that substantial proofs will be marshaled to show that Norplant is a safe and efficacious product and that Wyeth's advertising, if any, was fairly balanced. An agreed statement of facts submitted to the trial court suggested as much. And Norplant probably does not afford the best context in which to address the general question whether direct-to-consumer marketers of pharmaceutical products are unqualifiedly relieved of a duty to warn consumers of the dangerous propensities of a product. After all, in the case of Norplant, the role of the physician can never be insubstantial because only a physician may implant the device. Just as it is difficult to legislate a rule for every foreseeable circumstance, so too it is difficult to create a special rule of law for a hybrid product such as Norplant.

We are called upon, however, to resolve a question of law that will apply equally as well to an unprincipled marketer of pharmaceutical products as to a principled marketer. To place the issue in context, consider if prescription diet drugs were heavily advertised without warning of a known potential for heart damage.

Health hazards associated with prescription diet treatments in the 1990s . . . provide a modern example of the continuing threat posed by the premature approval of drugs. This threat is exacerbated by unprecedented access to information for an increasing number of patients. With access to more and more information about new drugs, consumers not only become empowered to direct their own treatment, but often become demanding as well, pressuring physicians to prescribe drugs that are expensive and sometimes ineffective at best, and harmful or even deadly at worst.

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That is the normative situation for which we must decide if a pharmaceutical manufacturer is free to engage in deceptive advertising to consumers. We believe that the answer in such a case should be no. Any question of fairness in imposing on the direct

marketer of a product such as Norplant a duty to warn the targeted consumers will be resolved in the proximate cause analysis.

Finally, we return briefly to the main theme of the dissent, post at ___ (slip op. at 6), that our decision is inconsistent with legislative mandate. We are certain that legislative codification of the learned intermediary doctrine -- which generally relieves a pharmaceutical manufacturer of an independent duty to warn the ultimate user of prescription drugs, as long as it has supplied the physician with information about a drug's dangerous propensities -- does not confer on pharmaceutical manufacturers a license to mislead or deceive consumers when those manufacturers elect to exercise their right to advertise their product directly to such consumers.

The judgment of the Appellate Division is reversed and the matter is remanded to the Law Division for further proceedings.

CHIEF JUSTICE PORITZ and JUSTICES HANDLER, STEIN and COLEMAN join in JUSTICE O'HERN's opinion. JUSTICE POLLOCK has filed a separate dissenting opinion in which JUSTICE GARIBALDI joins.

SARAY PEREZ, CHERYL BAILEY, KIMBERLY
BARTLETT, ANNA CESAREO and SORAYA
ARIAS,

Plaintiffs-Appellants,

v.

WYETH LABORATORIES INC., A subsidiary
of American Home Products
Corporation; AMERICAN HOME PRODUCTS
CORPORATION; WYETH-AYERST
LABORATORIES DIVISION OF AMERICAN
HOME PRODUCTS CORPORATION;
WYETH-AYERST INTERNATIONAL INC.;
WYETH-AYERST LABORATORIES COMPANY
and DOW CORNING FRANCE, S.A.,

Defendants-Respondents.

POLLOCK, J., dissenting

With disarming understatement, the majority opinion raises profound questions about the purpose of judicial opinions, the role of courts, and the separation of powers. In raising those questions, the majority rejects the Legislature's endorsement of the learned intermediary doctrine as set forth in N.J.S.A. 2A:58C-4. The majority opinion sustains itself only by ignoring the plain language of an unambiguous statute, the New Jersey Products Liability Act,

N.J.S.A. 2A:58C-1 to -7 (NJPLA), and by substituting its own policy preference for that of the Legislature. Contrary to the majority opinion, the point of this dissent is not that the Court should await legislative action. Ante at ____ (slip op. at 22). Rather, the point is that the Legislature has already acted. Believing that the Court is bound by the NJPLA, I respectfully dissent.

The Law Division held that the duty of defendants Wyeth Laboratories Inc., American Home Products Corporation, Wyeth-Ayerst Laboratories Division of American Home Products Corporation, Wyeth-Ayerst International Inc., and Wyeth-Ayerst Laboratories Company ("defendants" or "Wyeth") extended not to plaintiffs, but to their physicians or other health-care professionals. 313 N.J. Super. 646, 658 (1997). The Appellate Division affirmed. 313 N.J. Super. 511, 516 (1998). The Law Division further held that defendants adequately warned the bellwether plaintiffs' physicians or other health-care professionals of the risks associated with Norplant. 313 N.J. Super., supra, at 658. The Appellate Division likewise affirmed that holding. 313 N.J. Super., supra, at 518. The majority reverses the judgment of the Appellate Division. I would affirm.

To place the issue in perspective, a brief summary of relevant principles of products liability law may be helpful. At common law, a manufacturer is strictly liable for a defective product. Feldman v. Lederle Lab., Inc., 97 N.J. 429, 441-42 (1984) (Feldman I). The manufacturer, however, is not liable if the product is "unavoidably unsafe" and is "accompanied by proper warning." Id. at 447. In general, the manufacturer must communicate this warning directly

to the consumer. Niemiera v. Schneider, 114 N.J. 550, 559 (1989).

With prescription drugs, however, the "manufacturer generally discharges its duty to warn the ultimate user . . . by supplying physicians with information about the drug's dangerous propensities." Ibid. This rule, known as the learned intermediary doctrine, reflects the common law's awareness of the unique role that physicians serve in warning their patients of the risks associated with prescription drugs. See Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966). New Jersey courts consistently have recognized the vitality of the learned intermediary doctrine. See, e.g., Bacardi v. Holzman, 182 N.J. Super. 422 (App. Div. 1981); Torisello v. Whitehall Lab., 165 N.J. Super. 311, 322-23 (App. Div.) ("[W]hile it is the customer who is entitled to the warning in respect of non-prescription drugs, only the prescribing physician need be warned as to the risks involved in a prescription drug."), certif. denied, 81 N.J. 50 (1979). In 1987, the Legislature codified the learned intermediary doctrine in the NJPLA. L. 1987, c. 197, § 4 (effective July 22, 1987). Thus, although the learned intermediary doctrine remains a common-law rule in most states, it is now a statutory rule in New Jersey.

Before the enactment of the NJPLA, this Court had issued numerous products liability opinions based primarily on the common law. In those opinions, we emphasized the rights of injured persons and consumers in a mass-marketing economy. New Jersey manufacturers, including pharmaceutical companies, thought we had gone too far. The Legislature agreed and enacted the NJPLA. As the passed bill memorandum to Governor Kean explained:

The New Jersey manufacturers that have lobbied heavily for the enactment of this bill argue that in certain areas the New Jersey Supreme Court has gone beyond the laws of other states. These groups state that this bill will "bring New Jersey back into the mainstream" of product liability law. New Jersey manufacturers argue that because certain areas of New Jersey product liability law provide more protection for the consumer than other states, injured consumers from out-of-state are likely to bring a lawsuit against the New Jersey manufacturers in New Jersey. Thus, to the extent this bill conforms the New Jersey product liability law to the law of the majority of states, New Jersey will no longer be a "favorable forum" to out-of-state injured parties.

[Passed Bill Memorandum to Governor Thomas H. Kean on S-2805, at 3 (July 10, 1987).]

Of special interest to the pharmaceutical companies and the Legislature was the learned intermediary doctrine.

Analysis of the status of the learned intermediary doctrine thus depends on the intent of the Legislature. Merin v. Maglaki, 126 N.J. 430, 435 (1992). When a statute is clear, a court need not look beyond the statutory language to discover the legislative intent. State v. Kittrell, 145 N.J. 112, 123 (1996). The language of the NJPLA is clear.

The NJPLA states that a manufacturer has a duty to include an "adequate warning or instruction" with a product. Otherwise, the product may be considered defective. According to the statute, an "adequate warning" is

one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used, or in the case of

prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician.

[N.J.S.A. 2A:58C-4 (emphasis added).]

The majority finds ambiguity in the NJPLA, stating that "[a]lthough the statute provides a physician-based standard for determining the adequacy of the warning due to a physician, the statute does not legislate the boundaries of the doctrine." Ante at ___ (slip op. at 22). According to the Senate Committee statement accompanying the NJPLA, however, a drug manufacturer's duty to warn is owed to the physician, not the consumer:

[A] manufacturer or seller is not liable in a warning-defect case if an adequate warning is given when the product has left the control of the manufacturer or seller The subsection contains a general definition of an adequate warning and a special definition for warnings that accompany prescription drugs, since, in the case of prescription drugs, the warning is owed to the physician.

[Senate Judiciary Committee, Statement to Senate Bill No. 2805 (L. 1987, c. 197), N.J.S.A. 2A:58C-1a (emphasis added).]

The NJPLA provides that "committee statements that may be adopted or included in the legislative history of this act shall be consulted in the interpretation and construction of this act." N.J.S.A. 2A:58C-1a; Roberts v. Rich Foods Inc., 139 N.J. 365, 374 (1995). Through that extraordinary mandate, the Legislature sought to preclude judicial circumvention of the plain meaning of the statute.

Today's decision demonstrates that the Legislature's efforts were unavailing. The majority has mischaracterized both the statute and the rationale for the learned intermediary doctrine. Contrary

to the majority opinion, the statute directs that the warning is owed to the physician not "because drugs were then marketed to the physician," ante at ___ (slip op. at 22), but because the physician is in the best position to make an individualized evaluation of the risks of drugs and warn the patient of those risks. The patient, moreover, cannot obtain the drugs without a prescription written by a physician.

Underlying the majority opinion is the assumption that the Legislature in 1987 could not have anticipated the mass-marketing of prescription drugs. That assumption, however, has no basis in the record. In fact, the drug companies and the Legislature, like the Federal Food and Drug Administration (FDA), were aware of such marketing. See Direct-to-Consumer Advertising of Prescription Drugs, 50 Fed. Reg. 36,677 (1985) (commenting that "the public discussion on direct-to-consumer advertising of prescription drugs has provided interested individuals and organizations ample opportunity to consider and express opinions on the issue"). As the majority opinion states: "Aware of the potential threat to consumers when pharmaceutical companies first sought to advertise to non-health-care professionals, the FDA, in the early 1980s 'initially imposed a [voluntary] moratorium on such advertising so that it could study the issue more carefully; but in 1985, it lifted the moratorium, content to apply its existing regulations to this new practice.'" Ante at ___ (slip op. at 32-33) (quoting Lars Noah, Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues, 32 Ga. L. Rev. 141, 142-43 (1997)).

The majority's imposition of expanded duties on drug manufacturers contravenes the legislative history of the NJPLA. That history demonstrates that the statute was intended to strengthen the protections afforded manufacturers:

It is important to recognize that this bill not only conforms New Jersey product liability law to the law of the majority of states but, in some instances, changes New Jersey law in favor of the manufacturer in a way that is not currently recognized by the law of the majority of states. Thus, the effect of the enactment of this bill would be to shift the status of the law of New Jersey on certain issues from its current position of being more favorable to the injured consumer than the majority of states to being more favorable to the manufacturer than the majority of states.

[Passed Bill Memorandum to Governor Thomas H. Kean on S-2805, supra, at 3.]

Judges, although they may disagree with a legislative policy, are bound to respect it. In adapting the common law to society's needs, this Court may not have favored manufacturers, including pharmaceutical companies, as enthusiastically as has the Legislature. The issue, however, is not whether the Court shares the Legislature's enthusiasm or even whether the majority would prefer to amend the common-law learned intermediary doctrine. Because of the enactment of the NJPLA, the issue is whether the majority should respect the learned intermediary doctrine as declared by the Legislature.

As the majority recognizes, the modern law of product liability began with Justice Francis's opinion in Henningsen v. Bloomfield Motors Inc., 32 N.J. 358 (1960), ante at ___ (slip op. at 30); see Prosser & Keeton on Torts § 97 (5th ed. 1984) (describing Henningsen

as "the most rapid and altogether spectacular overturn of an established rule in the entire history of the law of torts"). Given the prominence of that opinion, written by Justice Francis while serving on this Court with Chief Justice Joseph Weintraub, Justice Francis's eulogy at the proceedings before this Court in memory of Chief Justice Weintraub is worth recalling. Justice Francis eloquently described the distinction that the late Chief Justice drew between respecting the will of the Legislature and adapting the common law to the needs of the time. Speaking of Chief Justice Weintraub, Justice Francis stated:

Throughout his years on the Court, he remained acutely aware of the line of demarcation between the judicial and legislative branches of government, and of the duty of the judicial branch to refrain from encroaching on the area of operation of the legislative branch. So if a statutory rule or doctrine were in question before the Court, even if it appeared to be inadequate to serve the needs of the times, he would declare that the remedy was in the hands of the Legislature, and the Courts should not interfere.

[72 N.J. XIX, XXVIII-XXIX (1977)].

That demarcation remains valid today.

Given the statutory basis for the learned intermediary doctrine in New Jersey, recourse to the Restatement (Third) of Torts: Products Liability § 6 (1998) ("Restatement") is gratuitous. Furthermore, the Restatement generally endorses the traditional rule that a drug manufacturer's duty to warn is owed to the health-care provider, not the consumer. Id. § 6(d)(1). The Restatement suggests, however, that it may be appropriate to impose a duty to warn the patient directly "when the manufacturer knows or has reason to know

that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings."

Id. § 6(d)(2). Here, the Restatement does not apply for two reasons.

First, as prestigious as any Restatement may be, it cannot supersede a governing statute. Second, the surgical implantation of Norplant requires the significant involvement of a health-care provider who must make an individualized evaluation of the risk to the patient.

Such involvement stands in contrast to the "diminished role as an evaluator or decision maker" that is a predicate for liability under the Restatement. See id. § 6(d) comment a. That involvement also distinguishes the implantation of Norplant from the administration of mass inoculations, see ante at ___ (slip op. at 13-14), which proceed without an individualized evaluation of the risks to the patient.

Contrary to the majority opinion, the question is not "whether the absence of an independent duty to warn patients gives the manufacturer the right to misrepresent to the public the product's safety." Ante at _ (slip op. at 31). No defendant claims such a license. Neither does the FDA, which regulates prescription drug advertising, allow it. For example, FDA regulations require that print and broadcast advertisements promoting prescription drugs be "balanced." 21 C.F.R. § 202.1(e)(6). Additionally, the FDA has issued a Draft Guidance that requires prescription drug broadcast advertisements to include a thorough "major statement" in "consumer-friendly" language about a drug's major risks. 62 Fed. Reg. 43,171; see also Guidance for Industry: Consumer-Directed

Broadcast Advertisements (visited July 14, 1999)

<<http://www.fda.gov/cder/guidance/index.htm>>.

On the facts, moreover, Norplant is a poor vehicle to import so momentous a change. Unlike other drugs that concern the majority, the record reveals that Norplant cannot be purchased in a supermarket, see ante at ___ (slip. op. at 3), is not promoted by health maintenance organizations, see ante at ___ (slip. op. at 26), approved by compliant physicians to placate overbearing patients, see ante at ___ (slip op. at 29), or implanted over the Internet, ante at ___ (slip op. at 3, 44 n.6). Through the incorporation of presumed facts, the majority has created a phantom record to support the creation of its exception to the learned intermediary doctrine. That exercise has led the majority to wander from the confines of the present case.

Norplant is not an over-the-counter drug; it can be obtained only with a doctor's prescription. To insert Norplant, a physician or other health-care professional anesthetizes an area in a patient's upper arm, makes a one-eighth-inch incision, and implants six capsules just below the patient's skin. Similar surgery is required to remove the capsules.

The use of Norplant thus requires the significant involvement of the prescribing physician. Even Norman Rockwell, see ante at _ (slip op. at 25), would recognize the procedure as one performed in accordance with the traditional physician-patient relationship.

Presumably, Wyeth's mass-marketing campaign has increased the demand for Norplant and led many women to request it by name. In some contexts, the extent to which pharmaceutical companies seek

to influence consumers, like the extent to which they seek to influence physicians, may be disturbing. Here, however, the mass-marketing campaign apparently was ineffectual; none of the bellwether plaintiffs saw any advertising about Norplant. The invasiveness of the Norplant procedure, moreover, would give any patient pause and a physician cause to evaluate the risks. As the Law Division stated, "a physician is not simply relegated to the role of prescribing the drug according to the woman's wishes." 313 N.J. Super. 646, 648 (Law Div. 1997).

Earlier this year, the Fifth Circuit Court of Appeals held, in a case involving Norplant, that "as long as a physician-patient relationship exists, the learned intermediary doctrine applies." In re Norplant Contraceptive Prods. Liab. Litig., 165 F.3d 374, 379 (5th Cir. 1999). The court rejected the creation of an exception to the learned intermediary doctrine for mass-marketed drugs. Specifically, the court stated that "Norplant is nevertheless a prescription drug . . . [and] physicians play a significant role in prescribing Norplant and in educating their patients about the benefits and disadvantages to using it." Ibid.

The majority identifies four premises underlying the learned intermediary doctrine that it asserts are inapplicable when a manufacturer advertises the drug directly to consumers: "(1) reluctance to undermine the doctor-patient relationship; (2) absence in the era of 'doctor knows best' of need for the patient's informed consent; (3) inability of drug manufacturer to communicate with patients; and (4) complexity of the subject." Ante at ___ (slip op. at 25). Contrary to the majority, ante at ___ (slip op. at 25-27),

those four considerations remain relevant to the implantation of Norplant.

First, the Norplant System must be implanted surgically. Implicit in the performance of a surgical procedure is respect for the physician-patient relationship. "[T]he physician is in the best position to take into account the propensities of the drug and the susceptibilities of the patient, and to give a highly individualized warning to the ultimate user based on the physician's specialized knowledge." Spychala v. G.D. Searle & Co., 705 F. Supp. 1024, 1031-32 (D.N.J. 1988). Second, the physician is the only person who can communicate with the patient to obtain the patient's informed consent to the procedure. Third, a pharmaceutical company, such as Wyeth, cannot provide an adequate warning to each individual consumer about the potential side-effects and risks associated with the device. Each patient has individualized risks associated with surgical procedures. Lastly, the Norplant implant, far more than other birth control devices, is a complex contraceptive system that requires detailed instructions and warnings.

To soften the impact of its opinion, the majority creates a rebuttable presumption that a warning is adequate if it complies with FDA regulations. Ante at ___ (slip op. at 36). Regrettably, the Court has not granted the parties the opportunity to address the creation, nature, or sufficiency of such a presumption. To the extent that such a presumption is essential to the majority's rationale, the parties should have been given that opportunity. See Office of Employee Relations v. Communication Workers, 154 N.J. 98, 108 (1998); see also Canesi v. Wilson, 158 N.J. 490, 539-41 (1999)

(Pollock, J., dissenting). Similarly, the parties should have been accorded the opportunity to address the issue of proximate cause, see ante at ___ (slip op. at 37)), as well as that of contribution and indemnity from physicians, see ante at ___ (slip op. at 45). In a judicial proceeding, the test of a hypothesis through the adversary process serves as a safeguard when addressing issues of broad public concern, such as those introduced by the majority.

To conclude, when enacting the NJPLA, the Legislature chose to confine the expansion of product liability law. The majority's preference for a different policy does not justify ignoring the one chosen by the Legislature.

Justice Garibaldi joins in this dissent.

