# Direct-to-Consumer Advertising Liability: An Empty Gift to Plaintiffs

*The Hon. William A. Dreier* *

## INTRODUCTION

In the recent case of *Perez v. Wyeth Laboratories, Inc.*,[1] the New Jersey Supreme Court determined that a prescription drug manufacturer might be held liable to consumers based on direct-to-consumer advertising that fails to warn of significant dangers.[2] The court, however, in an opinion authored by Justice O'Hern, imposed stringent limitations on this newly authorized products liability cause of action. In stating the requirements for this new claim, the court also shed light upon the proofs necessary to sustain existing warning defect causes of action under the governing New Jersey statute.[3]

In reaching its conclusion, the majority recognized, but refused to apply, the statutory learned intermediary rule embodied in New Jersey's Products Liability Act (NJPLA).[4] Although the court's new rule may have salutary purposes, Justice Pollock's dissenting opinion observed that the court should have been constrained by the

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* Partner, Norris, McLaughlin & Marcus, P.A.; Presiding Judge, Superior Court of New Jersey, Appellate Division (Retired); B.S., Massachusetts Institute of Technology; J.D., Columbia Law School.

[1] 161 N.J. 1, 734 A.2d 1245 (1999).

[2] *See id.* at 24, 734 A.2d at 1259. The New Jersey Supreme Court's determination of manufacturer liability in *Perez* is directly adverse to the federal courts' treatment of the direct-to-consumer advertising issue concerning the Norplant system. *See generally In re* Norplant Contraceptive Liab. Litig., 165 F.3d 374 (5th Cir. 1999) (upholding application of the learned intermediary doctrine to plaintiff's claims resulting from use of the Norplant contraceptive).

[3] *See* N.J. STAT. ANN. § 2A:58C-4 (West 1999).

[4] *See id.* ("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 . . . a rebuttable presumption shall arise that the warning or instruction is adequate."); *see also* Catherine A. Paytash, Note, *The Learned Intermediary Doctrine and Patient Package Inserts: A Balanced Approach to Preventing Drug-Related Injury*, 51 STAN. L. REV. 1343, 1345-46 (1999) (writing that "the [learned intermediary] rule states that drug manufacturers must adequately warn only the medical community of the risks associated with the use of a prescription drug").

language of the NJPLA.[5] The NJPLA states that the adequacy of a warning in a prescription-drug or medical-device case is to be determined under the learned intermediary rule.[6] The NJPLA further defines an adequate warning in terms of the knowledge of the consuming public, except that "in the case of prescription drugs, [the standard that must be taken into account includes] the characteristics of, and the ordinary knowledge common to, the prescribing physician."[7] Likewise, the New Jersey Senate Judiciary Committee Statement, which the statute requires be consulted in its interpretation, provides unambiguously that in the case of prescription drugs, the required adequate warning is owed only to the physician.[8] When the statute and the committee statement are read together, as the Legislature directed, it is hard to quarrel with the position that Justice Pollock takes in dissent.

The New Jersey Supreme Court also could have reached the same end by different means. The court was not confined to the theories of a defective product claim governed by the NJPLA.[9] The principles of section 9 of the Restatement (Third) of Torts: Products Liability (Restatement (Third)) recognize the possibility of parallel claims alleging both fraud and misrepresentation, and, thus, would permit an action to proceed against the manufacturer on those common-law theories.[10] When faced with a similar legislative preemption concerning cigarette label warnings, the United States Supreme Court in *Cipollone v. Liggett Group, Inc.*[11] determined that claims of fraud or misrepresentation are not encompassed by the preempted warning claim.[12] The *Perez* court could have utilized the same approach. In fact, the majority, in response to the stinging criticism of Justice Pollock's dissent,[13] stated that the principle

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[5] *See Perez*, 161 N.J. at 33-42, 734 A.2d at 1264-69 (Pollock, J., dissenting).

[6] *See* N.J. STAT. ANN. § 2A:58C-4 (West 1999).

[7] *Id.*

[8] *See* N.J. STAT. ANN. § 2A:58C-1(a) (West 1999). The statute states that "[t]he Legislature finds 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." *Id.*

[9] *See generally* N.J. STAT. ANN. § 2A:58C-2 (West 1999).

[10] *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 9 (1997) ("One engaged in the business of selling or otherwise distributing products who, in connection with the sale of a product, makes a fraudulent, negligent, or innocent misrepresentation of material fact concerning the product is subject to liability for harm to persons or property caused by the misrepresentation.").

[11] 505 U.S. 504 (1992).

[12] *See id.* at 530-31.

[13] In the words of Justice Pollock's dissenting opinion, "the majority rejects the

underpinning its holding was that the learned intermediary rule contained in the statute "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."[14] If the genuine focus of the majority's opinion was to prevent fraud or misrepresentation, the court need not have ridden roughshod over the statute in order to achieve its goals. This seemingly plaintiff-friendly approach, however, is blunted by the stringent new rules imposed for a claim of a warning defect based upon direct-to-consumer advertising.

The *Perez* decision does not absolve the manufacturer from giving an adequate warning to the prescribing physician, but merely creates a separate common-law duty to warn the patient who is the target of consumer advertising. Based on the New Jersey Supreme Court's imposition of liability for direct-to-consumer marketing, one might infer that there is now a decidedly pro-plaintiff shift in the law on this subject.[15] In the past, New Jersey has been a bellwether for such changes.

But, despite the apparently pro-plaintiff language of the *Perez* opinion, the New Jersey Supreme Court has announced a rather conservative rule. If, as this Article posits, the net effect of the court's new rule merely substitutes the very stringent Food and Drug Administration (FDA) disclosure requirements for what might have been either a fraud, misrepresentation, or adequate warning to physicians standard under New Jersey law, there will be little real benefit to plaintiffs. This Article will explore the court's reasoning against the background of New Jersey case law, the governing FDA

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Legislature's endorsement of the learned intermediary doctrine as set forth in [the NJPLA]. The majority opinion sustains itself only by ignoring the plain language of an unambiguous statute . . . and by substituting its own policy preferences for that of the Legislature." *Perez*, 161 N.J. at 33, 734 A.2d at 1264 (Pollock, J., dissenting).

[14] *Id.* at 32, 734 A.2d at 1264. The court agreed with the appellate division's finding that the statutory term "physician" is inclusive of all prescribing health-care providers. *See id.* at 9 n.3, 734 A.2d at 1250 n.3.

[15] *See, e.g.*, Noelle Collins, *It Got Under Their Skin*, A.B.A. J., Dec. 1999, at 36 ("*Perez* . . . opens the door for plaintiffs to sue the makers of Norplant because the contraceptive was marketed directly to them, rather than physicians."); Julie Brienza, *N.J. Court Finds Exception to Learned Intermediary Doctrine*, TRIAL, Nov. 1999, at 94 ("In a victory for plaintiffs, the New Jersey Supreme Court has found that manufacturers of the Norplant contraceptive . . . must make warnings of potentially dangerous side effects clear to consumers, not just to doctors."); *Why the Learned Intermediary Doctrine Continues to Apply*, FOR THE DEFENSE, Dec. 1999, at 60 ("As long as this 'central feature that defines the marketing of prescription drugs' exists, the learned intermediary doctrine does not diminish merely because a manufacturer advertises its products directly to the consumer.").

regulations, and the Restatement (Third). The Article also will examine the potential national effect of *Perez* should it become the standard by which other courts determine issues of liability for direct-to-consumer advertising.

## I. ANALYSIS OF *PEREZ V. WYETH LABORATORIES, INC.*[16]

The *Perez* case was a multiplaintiff suit that involved the Norplant contraceptive drug and delivery system, a "reversible contraceptive that prevents pregnancy for up to five years."[17] Wyeth Laboratories markets Norplant in the United States.[18] Plaintiffs alleged that Wyeth failed to warn of possible side effects of Norplant, 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."[19] Most complications, however, resulted from removal of the Norplant system.[20] Plaintiffs further alleged that Wyeth participated in massive marketing attempts to promote Norplant, which included advertisements on television and in women's magazines, such as *Cosmopolitan*, *Glamour*, and *Mademoiselle*.[21] These advertisements did not warn of any dangers associated with Norplant.[22]

The court began the analysis by explaining that regulation of

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[16] The New Jersey Supreme Court decided *Perez* just as a *Seton Hall Law Review* article on the subject was submitted for publication. *See* William A. Dreier, *Manufacturers' Liability for Drug and Medical Devices Under the Restatement (Third) of Torts: Products Liability*, 30 SETON HALL L. REV. 258 (1999). The Article therefore mentioned only briefly the new rules governing direct-to-consumer advertising liability for prescription drugs and medical devices. *See id.* at 262-63. The Article noted the earlier expectation that the comments to section 6(d) of the Restatement (Third), namely, the statement concerning possible development of liability for direct-to-consumer advertising, would have had little, if any, effect in New Jersey. *See id.* The NJPLA and the accompanying Committee Statements required only that an adequate warning be given to the prescribing physician. Under the NJPLA, prescription drug manufacturers should have been shielded from such claims. However, the New Jersey Supreme Court decided to the contrary.

[17] *Perez*, 161 N.J. at 5, 734 A.2d at 1247. The status of the plaintiffs as bellwether parties caused the court to address the issue of direct-to-consumer advertising, notwithstanding the fact that none of the named plaintiffs had seen any of the advertisements.

[18] *See id.* at n.1.

[19] *Id.* at 6, 734 A.2d at 1248.

[20] *See id.*

[21] *See id.*

[22] *See id.*

advertisements concerning prescription drugs is conferred upon the FDA pursuant to the Food, Drug and Cosmetic Act.[23] The FDA regulations govern "advertisements in published journals, magazines, other periodicals, and newspapers, and advertisements broadcast [through] media such as radio, television, and telephone communications systems."[24] If a company fails to comply with the FDA regulations, any drugs that the company distributes, as well as those still in the channels of commerce, will then be deemed "misbranded," with all of the negative ramifications attendant upon this designation.[25] The court also discussed other FDA regulations, including the "brief summary" requirement[26] and the Draft Guidance that "specifically addresses consumer-directed broadcast advertisement such as radio, television and telephone communications."[27] The court noted that, in general, compliance with FDA regulations does not confer a conclusive presumption of adequacy, but "serve[s] as compelling evidence that a manufacturer satisfied its duty to warn the physician about potentially harmful side effects of its product."[28] The court, therefore, determined that compliance with FDA procedures was presumptive proof of an adequate warning.[29]

The court's determination may have departed from the then-prevailing law. Under New Jersey's evidence rules, the establishment of "a [rebuttable] presumption discharges the burden of proving evidence as to a fact."[30] Thus, if evidence is introduced that tends to disprove the presumption, the presumption vanishes, and the litigant is left only with whatever natural inference may be drawn.[31] The holding in *Perez*, however, raises this rebuttable presumption above

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[23] *See Perez*, 161 N.J. at 22, 734 A.2d at 1258 (discussing 21 U.S.C. § 352(n) (1990)).

[24] 21 C.F.R. § 202.1*(l)*(1) (1990).

[25] *See id.* § 202.1(k).

[26] *See* 21 U.S.C. § 352(n)(3) (1990). The court noted that § 352(n)(3) requires that "all advertising must include a description of 'side effects, contraindications and effectiveness as shall be required in [the] regulations.'" *Perez*, 161 N.J. at 22, 734 A.2d at 1258 (citing 21 U.S.C. § 352 (n)(3) (1990)). The regulations require that the "brief summary" include all risk information in a product's package labeling. *See* 21 C.F.R. § 202 (e)(1), (e)(iii) (1990).

[27] *See* 62 Fed. Reg. 43,172 (Aug. 12, 1997). The Draft Guidance provides that advertisements must contain a "major statement" of the principal risks of the drug. *See id.*

[28] *Perez*, 161 N.J. at 24, 734 A.2d at 1259.

[29] *See id.*

[30] N.J. R. EVID. 301.

[31] *See* Ahn v. Kim, 145 N.J. 423, 439, 678 A.2d 1073, 1081 (1996) (citing Ford Motor Co. v. Township of Edison, 127 N.J. 290, 312, 604 A.2d 580, 591 (1992)).

the disappearing presumption described in New Jersey Rule of Evidence 301, but somewhat below an irrebuttable presumption that would have the effect of a rule of law.[32]

The New Jersey Supreme Court used strong language to describe this newly crafted presumption for direct-to-consumer prescription drug advertising cases. The court stated that "[f]or 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."[33] The court initially discussed the presumption of adequacy contained in the NJPLA for warnings that have received FDA premarketing approval.[34] The court previously had analyzed this issue in *Feldman v. Lederle Laboratories, Inc.*[35] (*Feldman II*), holding "that the presumption in [the NJPLA] was no defense to an inadequate warning claim."[36] Building on this decision, the *Perez* court determined that satisfaction of the FDA regulations was "*compelling evidence* that a manufacturer satisfied its duty to warn the physician."[37] The court then resolved that "the same rebuttable presumption should apply when a manufacturer complies with FDA . . . requirements."[38]

Prior to *Perez*, the common understanding of the statutory presumption of adequacy flowed from *Feldman II* and was to be governed by New Jersey Rule of Evidence 301. The *Perez* court implicitly, without mentioning the New Jersey Rules of Evidence, compared and contrasted the two presumptions with respect to consumer advertising. The statutory presumption of the NJPLA would disappear if New Jersey Rule of Evidence 301 were applied, but in this instance it is to be considered "compelling evidence" under the court's new rule. Evidence of compliance with FDA standards in direct-to-consumer advertisement claims will be "virtually dispositive" of the plaintiff's case.[39]

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[32] In general, an irrebuttable presumption "is one in which proof of basic fact renders the existence of the presumed fact conclusive." BLACK'S LAW DICTIONARY 1186 (6th ed. 1990).

[33] *Perez*, 161 N.J. at 25, 734 A.2d at 1259 (emphasis added).

[34] *See id.* at 24, 734 A.2d at 1259 (discussing N.J. STAT. ANN. § 2A:58C-4 (West 1999)).

[35] 125 N.J. 117, 592 A.2d 1176 (1991). This was the second time the *Feldman* case had reached the New Jersey Supreme Court. *See* Feldman v. Lederle Labs., 97 N.J. 429, 479 A.2d 374 (1984).

[36] William A. Dreier, *The Restatement (Third) of Torts: Products Liability and New Jersey Law—Not Quite Perfect Together*, 50 RUTGERS L. REV. 2059, 2103 (1998).

[37] *Perez*, 161 N.J. at 24, 734 A.2d at 1259 (emphasis added).

[38] *Id.*

[39] *See id.* at 25, 734 A.2d at 1259.

Is the New Jersey Supreme Court also attempting to provide new insight concerning the statutory presumption discussed in *Feldman II*, as well as defining new standards for direct-to-consumer advertising? It appears so. A careful reading of *Perez* shows that its language and that of *Feldman II* can indeed be harmonized, but only by recognizing that the court must have intended that the usual standards of New Jersey Rule of Evidence 301 are, in part, inapplicable to drug warnings, at least insofar as compliance with FDA requirements is concerned. In *Perez*, the court discussed *Feldman II*, in which it had previously stated the effect of the presumption in the NJPLA to be "less clear."[40] The *Feldman II* court applied the plain language of the NJPLA that created the presumption of the adequacy for a warning based upon compliance with the FDA's premarketing approval.[41] This appeared to be in accordance with New Jersey Rule of Evidence 301 principles. At the time of the 1991 *Feldman II* opinion, however, there had been a change in the governing FDA regulation that was effective at the time that the drug was being prescribed.[42] Originally, the FDA did not require a new warning unless there was "unequivocal factual evidence of adverse reaction in man."[43]

By 1991, the FDA required a manufacturer to warn of "possible adverse side effects as soon as reasonably feasible and based upon 'reasonable evidence.'"[44] The *Feldman II* court stated that its decision was driven by the language of the earlier governing regulation.[45] If there had been an FDA determination that no reasonable evidence of possible adverse side effects existed under the new regulatory regime, the *Feldman II* court may have given greater deference to the FDA's action, or lack thereof. Unfortunately, the *Feldman II* court made no definitive pronouncement on the effect of the new federal regulations. Until *Perez*, the effect of the statutory presumption in such cases remained in question. There clearly was no federal preemption; however, there also was little guidance to the bench, bar, or prescription drug industry.

Notwithstanding the usual treatment of a presumption under New Jersey Rule of Evidence 301, the *Perez* court determined that compliance with FDA regulations serves as "compelling evidence that a manufacturer satisfied its duty to warn the physician about

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[40] *See Feldman II*, 125 N.J. at 157, 592 A.2d at 1197.

[41] *See id.*

[42] *See id.*

[43] *Id.*

[44] *Id.* (citing 21 C.F.R. § 201.57(e) (1990)).

[45] *See id.*

potentially harmful side effects of its product."[46] Furthermore, the presumptions discussed in both *Perez* and *Feldman II* must be appraised under the same standard in view of the court's clear language that "the same rebuttable presumption should apply."[47] The conclusion becomes inescapable that the presumptions of adequacy afforded to a manufacturer's compliance with FDA requirements in a usual drug warning case both under *Feldman II* (with modern regulations controlling) and under *Perez* are of greater evidentiary weight than is the customary New Jersey Rule of Evidence 301 presumption. A manufacturer's compliance with FDA regulations, however, is clearly less than an irrebuttable presumption.

Assuming the foregoing as the New Jersey Supreme Court's intention, the enhanced presumption in *Perez* (that the warning was adequate if it complied with FDA regulations) becomes more understandable. The court then underlined the effect of this enhanced presumption when it stated that "[f]or 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."[48] The court reiterated this principle when it concluded the discussion with the statement that compensatory damages will be reserved to "those rare cases where the presumption is overcome."[49] Neither of these comments, however, were confined to direct-to-consumer advertising.

This newly defined duty to consumers is certainly not an absolute liability rule. In fact, this duty is decidedly pro-defendant. The manufacturer's duty is satisfied "by compliance with FDA regulations [that will help] 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.'"[50] This industry-protective effect is reinforced by the court's citation of the definitive article on this issue by Professor Michael D. Green.[51]

Comment e to section 6(d) of the Restatement (Third) left the issue of liability for direct-to-consumer advertising "to developing case

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[46] *Perez*, 161 N.J. at 24, 734 A.2d at 1259.

[47] *Id.*

[48] *Id.* at 25, 734 A.2d at 1259.

[49] *Id.*

[50] *Id.* (quoting *Feldman II*, 125 N.J. at 162, 592 A.2d at 1200) (Garibaldi, J., dissenting).

[51] *See id.* (citing Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461, 466-67 (1997)).

law."[52] The Restatement (Third)'s comment cross-references section 4(b), which governs the effect on liability of compliance with an applicable governmental product safety statute or regulation.[53] The Restatement (Third) posits that such compliance usually is evidential of due care, but has no preclusive effect.[54] Of course, as the comments make clear, the rule is applicable only in the absence of a preemptive statute or regulation.[55] The principle merely establishes "a floor of safety" applicable in most cases.[56]

While the manufacturer's defense of compliance will not be absolute under *Perez*, the defense outlined in the case is formidable. This treatment, however, is not antithetical to the Restatement (Third). Comment e to section 4 recognizes that compliance with safety standards set by particular statutes or regulations may require stronger protection for the manufacturer. Compliance with other standards may be given little or no weight. The factors listed by the comment are (a) whether the standards are of recent promulgation; (b) whether the standards "address the very issue of product design or warning presented in the case before the court"; (c) whether the "the deliberative process that led to the safety standard was full, fair, and thorough and reflected substantial expertise"; and (d) whether "the deliberative process that led to the safety standard with which the defendant's product complies was tainted by the supplying of false information to, or the withholding of information from, the agency that promulgated the standard or certified or approved the product."[57] The *Perez* court applied these principles, and on every point the FDA-required procedures militated for the practically preclusive effect granted by the court.

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[52] *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d) cmt. e (1997).

[53] *See id.* § 4. Section 4 states in part:

> In connection with liability for defective design or inadequate instructions or warnings:
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> . . . .
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> (b) a product's compliance with an applicable product safety standard or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, but such compliance does not preclude as a matter of law a finding of product defect.

*Id.*

[54] *See id.*

[55] *See id.* § 4 cmt. e.

[56] *See id.*

[57] *Id.*

## II. POSTSALE WARNINGS

*Perez* provides that, at least in New Jersey, a manufacturer, by advertising its products directly to the consumer, undertakes a duty to inform potential patients concerning later pharmaceutical developments.[58] Both New Jersey law and the prevailing law in the United States recognize the duty of a seller of a product to warn consumers of dangers involved, even if discoverable after the product has left the manufacturer's hands.[59] The Restatement (Third) rule in this regard is also applicable to the marketing of prescription drugs under section 6. In fact, in comment b to section 10, the Reporters state that, as to "prescription drugs and devices, courts traditionally impose a continuing duty of reasonable care to test and monitor after sale to discover product-related risks."[60] Section 10 also requires that the recipients of the warning must be reasonably identifiable.[61] In reality, however, when a manufacturer has sold millions of units of a product with unrecorded consumer sales, individual contact will be impossible. The Restatement (Third) comments recognize the use of the public media dependent upon the seriousness of the risks involved. Also, if a manufacturer may reasonably assume that the consumers are aware of the risks, the manufacturer need not issue a

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[58] *See* Perez v. Wyeth Labs., Inc., 161 N.J. at 24-25, 734 A.2d at 1259.

[59] *See* Feldman v. Lederle Labs., Inc., 97 N.J. 429, 434, 479 A.2d 374, 376 (1984) (holding that drug manufacturers have a duty to warn customers of dangers of which the manufacturer knew or should have known on the basis of reasonably obtainable or available knowledge). The Restatement (Third) also addresses postsale warnings. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 10 (1997). Section 10 provides:

> (a) One engaged in the business of selling or otherwise distributing products is subject to liability for harm to persons or property caused by the seller's failure to provide a warning after the time of sale or distribution of a product if a reasonable person in the seller's position would provide such a warning.
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> (b) A reasonable person in a seller's position would provide a warning after the time of sale if:
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> > (1) the seller knows or reasonably should know that the product poses a substantial risk of harm to persons or property; and
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> > (2) those to whom a warning might be provided can be identified and can reasonably be assumed to be unaware of the risk of harm; and
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> > (3) a warning can be effectively communicated to and acted on by those to whom a warning might be provided; and
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> > (4) the risk of harm is sufficiently great to justify the burden of providing a warning.

*Id.*

[60] RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 10 cmt. b (1997).

[61] *See id.* § 10.

warning. The risk may be apparent from the product itself, or it may be apparent through publicity. When the product is a prescription drug, however, pharmacists' records are usually available and provide a direct conduit to the consumers.

Lastly, section 10(b)(4) and comment i note that there must be a balancing of the cost of the warning against the extent of the risk.[62] This comment shows clearly that this is an objective balancing to which a negligence rule applies. Nowhere in section 10, its comments, or in the federal statute or regulations is there any indication that a manufacturer may legally balance the adverse public relations effect of giving the warning. In other words, a manufacturer may not balance its good will against potential consumer injuries. Thus, the costs described in the comment are the "expenditures" for public or individual notice and not any lessening of the product's goodwill.

The New Jersey Supreme Court in *Perez* recognized that the failure to disseminate after-acquired knowledge constitutes an exception to the principle that compliance with the FDA disclosure standards is virtually dispositive of any claim regarding inadequate warnings.[63] Also excepted is a situation in which the manufacturer has deceived the FDA. In this case, punitive damages and, of course, compensatory damages, are permitted.[64]

## III. DIRECT-TO-CONSUMER ADVERTISING COMPLIANCE

If the legal community is to assume that the court truly means that compliance with the FDA standards is "virtually dispositive" of a plaintiff's claim, the direct-to-consumer advertising standards must be examined in detail. For example, if compliance constitutes a probable defense, a plaintiff who does not meet his burden on this issue will likely have his case dismissed on a summary judgment motion once the defendant produces evidence of such compliance.

A manufacturer can protect itself by submitting its consumer

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[62] *See id.* § 10(b)(4) cmt. i. This principle is also recognized in title 21, § 201.57(e) of the Code of Federal Regulations. *See* 21 C.F.R. § 201.57(e) (1990).

[63] *See Perez*, 161 N.J. at 25, 734 A.2d at 1259.

[64] *See* N.J. STAT. ANN. § 2A:58C-5(c) (West 1999). The punitive damage protection in title 2A, section 58C-5(c) of the New Jersey Statutes is broader than the adequate warning protection provided in section 58C-4 of the same title. The punitive damage protection extends to a "drug or device or food or food additive which . . . [is] subject to premarket approval or licensure by the [FDA] . . . or is generally recognized as safe and effective . . . ." *Id.* The general warning protection is given only to a "drug or device or food or food additive . . . approved or prescribed by the [FDA]." N.J. STAT. ANN. § 2A:58C-5 (West 1999).

advertising to the FDA for prepublication comment.[65] In fact, as noted earlier, a failure to comply can result in the product being labeled misbranded.[66] Thus, with the exception of claims involving postapproval knowledge regarding new problems that should have been reported and made part of the advertised warnings, a drug manufacturer that complies with FDA requirements may easily be protected from liability.

The FDA standards are minute and definite. Congress requires that manufacturers, packers, and distributors (also called "sponsors") that advertise prescription drugs or biological products disclose in their advertisements certain information about the products' uses and risks, and, in particular, "information in brief summary relating to side effects, contraindications, and effectiveness."[67] In FDA language, this is the "brief summary" requirement, which the court in *Perez* deemed a "misnomer considering that the summary is anything but brief."[68]

Print and broadcast advertising are subject to different regulations.[69] If the advertising is in print, the "brief summary" must be included and must describe all of the risks explained in the product's package labeling.[70] This information usually is found also in the *Physician's Desk Reference* (PDR). If the "brief summary" is stated in consumer-friendly language, it must contain a reference to where the full physician-directed text may be obtained—usually at a local pharmacy, library, or physician's office.[71] Broadcast advertisements merely must disclose a "major statement," such as an audio or visual summary of the product's major risks.[72] In addition, a broadcast advertiser must either present the "brief summary" of the approved or permitted package label or, alternatively, make an adequate provision for dissemination of the labeling in connection with the broadcast presentation.[73] This "adequate provision" requirement can be satisfied in a variety of ways, but the advertisement cannot be false

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[65] 21 C.F.R. § 202.1(j)(4) (1990).

[66] *See id.* § 202.1(k).

[67] *See* 21 U.S.C. § 352(n) (1990).

[68] *Perez*, 161 N.J. at 22, 734 A.2d at 1258.

[69] *See generally* 21 C.F.R. § 202.1 (1990).

[70] *See id.*

[71] *See* Food and Drug Administration, Center for Drug Evaluation and Research, Guidance for Industry (visited Feb. 9, 2000) <http://www.fda.gov/cder/guidance/1804fnl.htm>.

[72] *See* 21 C.F.R. § 202.1(e)(1) (1990).

[73] *See id.*

or misleading in any respect.[74] If the product is a prescription drug, the advertisement must also inform the consumer that the drug is available only by prescription through a prescribing health-care professional who can decide whether the product is appropriate for the particular patient.[75] The advertisement must present a fair balance between information about the product's effectiveness and the product's risks.[76] The advertiser must include a thorough "major statement," which must convey in consumer-friendly language all of the product's most important risk information, including information relevant to the indications for, and limitations on, the product's use.[77]

With respect to the "adequate provision" for dissemination of the package labeling, the sponsor must use an approach that allows most of a potentially diverse audience reasonably convenient access through information on the product's label.[78] The regulations recognize that many people have "only limited access to technologically sophisticated outlets" for this information, such as the Internet, and potential consumers often are uncomfortable with requesting additional product information or even "being personally identified in their search for" this information.[79] The Guidance for Industry and the regulations provide an acceptable approach, which includes offering the consumer a telephone procedure. The telephone procedure involves a toll-free number to obtain the labeling information, where consumers will be given the choice of having the labeling mailed to them or, alternatively, having the labeling read to them over the telephone with the consumer choosing from a selection of prerecorded labeling topics.[80]

When the Internet is offered as a means of access, consumers should be referred in the advertisement to an alternative for those who have restricted access or who are uncomfortable discussing the information or concerned about personal identification.[81] An

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[74] *See id.* § 202.1(e)(3)(i).

[75] *See* Food and Drug Administration, Center for Drug Evaluation and Research, Guidance for Industry (visited Feb. 9, 2000) <http://www.fda.gov/cder/guidance/1804fnl.htm>.

[76] *See* 21 C.F.R. § 202.1(e)(5)(ii) (1990).

[77] *See id.* § 202.1(e)(3)(i).

[78] *See* Food and Drug Administration, Center for Drug Evaluation and Research, Guidance for Industry (visited Feb. 9, 2000) <http://www.fda.gov/cder/guidance/1804fnl.htm>.

[79] *See id.*

[80] *See id.*

[81] *See id.*

acceptable mechanism is to provide printed "advertisements appearing concurrently in publications that reach" an audience similar to that exposed to the broadcasts.[82] The broadcasts could then reference at least one of these advertisements. The print advertisement also "should supply a toll-free telephone number and an address for further consumer access" for the full package labeling.[83]

The mechanism chosen for providing this back-up access must provide considerable information, at least in the form of the required "brief summary," which is also included in the advertising text itself. The advertisement should contain an Internet web page address for access to the package labeling and should disclose that pharmacists and health-care providers may supply "additional product information to the consumer."[84] Another alternative for providing private access to package information would be to ensure that sufficient numbers of brochures containing the package labeling are available in an assortment of publicly accessible locations, such as grocery stores, pharmacies, doctors' offices, and public libraries.[85] Consumers should not be forced to travel beyond their normal range of activities. This alternative is logistically feasible only when the targets of the broadcast-advertising campaign are relatively limited.

An advertiser may also choose telephone advertisements that make a product claim that communicates the product name and a representation or suggestion relating to the product. In these circumstances, the advertisements are subject to the same disclosure requirements, but these requirements are less stringent than are the requirements for television or radio broadcasts.[86] The consumer, by participating in the telephone call, has "indicated his willingness to discuss the topic or receive [the additional information]."[87] Thus, fewer sources of the information need be disclosed to constitute an adequate provision. Mailing in a timely manner, having the label read to the consumer over the telephone with selections from pre-recorded topics, or disclosing that health-care providers are an additional source of the information would be deemed adequate.[88]

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[82] *Id.*

[83] *Id.*

[84] Food and Drug Administration, Center for Drug Evaluation and Research, Guidance for Industry (visited Feb. 9, 2000) <http://www.fda.gov/cder/guidance/1804fnl.htm>.

[85] *See id.*

[86] *See id.*

[87] *Id.*

[88] *See id.*

If the "advertisement is presented in a foreign language," the advertisements, as well as any brochures, websites, toll-free telephone numbers, recorded messages, and operators should all present information "in the language of the broadcast."[89] The Guidance for Industry recognizes that the current regulations require dissemination of product labeling in English.[90] The FDA, however, encourages sponsors to provide "consumers with nonpromotional consumer-friendly product information in the language of the broadcast [advertisement]."[91] The FDA also has encouraged sponsors who use the adequate provision mechanisms to collect relative data on consumer use to make known "research relating to the overall effects" of direct-to-consumer promotions on the public health.[92]

The standards of the various federal regulations fit well with the conclusions of the court in *Perez* if the court's avoidance of the New Jersey Legislature's learned intermediary language is accepted. Title 2A, section 58C-4 of the New Jersey Statutes requires the manufacturer, seller, or sponsor to give an adequate warning. The statute provides that the warning is adequate if it 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.[93]

Contrast this approach with section 6 of the Restatement (Third), which similarly imposes liability on a prescription drug or medical device manufacturer that gives inadequate instructions or warnings.[94] Section 6 also requires reasonable instructions and warnings to be given to a patient if a 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.[95] The Reporters of the Restatement (Third) state the arguments for and against liability imposed against manufacturers for

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[89] *Id.*

[90] *See* Food and Drug Administration, Center for Drug Evaluation and Research, Guidance for Industry (visited Feb. 9, 2000) <http://www.fda.gov/cder/guidance/1804fnl.htm>.

[91] *Id.*

[92] *Id.*

[93] N.J. STAT. ANN § 2A:58C-4 (West 1999).

[94] *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(b)(3) (1997).

[95] *See id.* § 6(d)(2).

direct-to-consumer advertising.[96]

The New Jersey Supreme Court, through its holding in *Perez*, has chosen to join what had previously been a limited rule established only within Massachusetts,[97] Oklahoma (as interpreted by the Tenth Circuit Court of Appeals),[98] and Michigan (as interpreted by the United States District Court for the Eastern District of Michigan).[99] New Jersey federal courts, however, had previously rejected this rule when interpreting New Jersey state law.[100] Given the Reporters' comments, however, liability clearly is not beyond the intent of the Restatement (Third).

The federal regulation sets forth a detailed requirement and contains precise definitions of terms used both in the regulation and in the Guidance to Industry.[101] For example, ingredient information must be stated without intervening material.[102] The regulations

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[96] *See id.* § 6(d)(2) cmt. e.

[97] *See* McDonald v. Ortho Pharm. Corp., 475 N.E.2d 65, 68 (Mass. 1985) ("The narrow issue . . . is whether . . . a manufacturer of birth control pills owes a direct duty to the consumer to warn her of the dangers inherent in the use of the pill. We concluded that such a duty exists under the law of this Commonwealth.").

[98] *See* Edwards v. Basel Pharms., 116 F.3d 1341, 1342 (10th Cir. 1997) (interpreting Oklahoma law regarding the duty to warn of dangers associated with nicotine patches). The Tenth Circuit certified the duty to warn issue to the Oklahoma Supreme Court. *See* Edwards v. Basel Pharms., 933 P.2d 298, 299 (Okla. 1997) ("Compliance with FDA warning requirements does not necessarily satisfy the manufacturer's common law duty to warn the consumer.").

[99] *See* Odgers v. Ortho Pharm. Corp., 609 F. Supp. 867, 878-79 (E.D. Mich. 1985); Stephens v. G.D. Searle & Co., 602 F. Supp. 379, 381 (E.D. Mich. 1985) (applying Michigan law, but limiting its holding to oral contraceptives only).

[100] *See* Spychala v. G.D. Searle & Co., 705 F. Supp. 1024, 1032 (D.N.J. 1988) (applying the learned intermediary rule with respect to contraceptives). In *Spychala*, Judge Barry specifically wrote:

> Although a woman may be actively involved in the decision to use contraceptives, those contraceptives are administered only by prescription and upon the advice of a physician . . . . There is no reason apparent to me to differentiate between contraceptives and other prescription drugs to which the learned intermediary rule applies.

*Id.* (footnotes omitted).

[101] *See* 21 C.F.R. § 202.1 (1990).

[102] *See id.* § 202.1(a)(1). For example, the listing of ingredients in an advertisement must be in the same order as on the label of the product, and quantity information must similarly correspond. *See id.* § 202.1(a)(2). The advertisement may not imply ostensible proprietary names for the drug or any ingredient implying a unique effectiveness or composition when the ingredient is a common substance. *See id.* § 202.1(a)(3). In addition, inactive ingredients cannot be listed to imply a value "greater than their true functional role"; a drug or ingredient cannot be called by a proprietary name similar in spelling or pronunciation with an established name of a different drug or ingredient. *Id.* § 202.1(a)(4)-(5).

further treat in detail exactly how proprietary names may be used.[103] If there is an established name for a drug, its printing is minutely regulated.[104] Descriptions of drugs with multiple active ingredients are also regulated.[105] Importantly, the regulation requires a true statement of information in the "brief summary" listing the side-effects, contraindications, and effectiveness of the drugs. Separate provisions are made for reminder advertisements, advertisements of bulk-sale drugs, and advertisements of prescription-compounding drugs.

Title 21, § 202.1(e)(3) of the Code of Federal Regulations clearly states:

> The requirement of a true statement of information relating to side-effects, contraindications and effectiveness applies to the entire advertisement. Untrue or misleading information in any part of the advertisement will not be corrected by the inclusion in another distinct part of the advertisement of the brief statement containing true information relating to side-effects, contraindications and effectiveness of the drug.[106]

The regulation is also applicable to the "theme of the advertiser."[107] If part of either the advertisement or its theme is misleading by reason of an omission of an appropriate qualification of pertinent information, that part or theme must include an appropriate qualification.[108] Information may be concise if it is supplemented by a permanent reference on each page to the presence of the location of the complete discussion.[109] Furthermore, any claim of effectiveness must include specific indications for use of the drug or particular purposes claimed in the advertisement.[110] For example, if the drug is an antibacterial agent, the advertisement must name a type or types of infections and microorganisms for which the drug is clinically effective, as required, approved, or permitted in the drug-package labeling. The same is true as to side effects and contraindications, except that the particulars may be limited to those pertinent to the indications for which the drug is recommended or suggested in the advertisement.

The "brief summary" requirement is governed by the same

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[103] *See id.* § 202.1(b).
[104] *See id.*
[105] *See id.* § 202.1(c).
[106] *Id.* § 202.1(e)(3)(i).
[107] 21 C.F.R. § 202.1(e)(3)(i) (1990).
[108] *See id.*
[109] *See id.*
[110] *See id.* § 202.1(e)(3)(ii).

permitted-labeling standard as new drug applications, and claims of increased or new effectiveness are also as sharply scrutinized. All require that each be a "true statement." The definition of a "true statement" in the "brief summary" and elsewhere appears in the negative in the text of title 21, § 202.1(e)(5) of the Code of Federal Regulations, which states that an advertisement does not "present a 'true statement' of information in [its] brief summary relating to side effects, contraindications, or effectiveness" if it is false or misleading with respect to these properties, or if it fails to present a fair balance between information relating to these properties.[111] Claims of effectiveness, safety, side effects, and contraindications must be of comparable depth and detail.[112] The statement must reveal both facts material in light of its representations and consequences that may result from the use of the drug recommended or suggested in the advertisement.[113] There are twenty paragraphs of examples, samples of which are an unfair balance of information, representations, or suggestions not approved or permitted for use in the labeling concerning effectiveness, misleading drug comparisons, or comparisons based on outmoded favorable data, conclusions from nonclinical studies when no such clinical significance has been demonstrated, the use of statistics to arrive from pooling data from insignificant or dissimilar studies, and the use of headlines and pictorial or other graphic matter in a way that is misleading.[114] A provision of this subsection may be waived with respect to a specified advertisement only via a written communication from the FDA on petition of a party adversely affected by enforcement of the provision.[115] The party still must show that the advertisement is not false, lacking in fair balance, or otherwise misleading or violative of the statute.[116] These standards themselves are defined in additional sections that limit the FDA's discretion.[117]

Any new product information that comes to the attention of the FDA or the manufacturer, and which is not generally known to prescribing health-care providers, must also be subject to a new publicity program and shall be put in all advertisements if the FDA

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[111] *Id.* § 202.1(e)(5).
[112] *See id.* § 202.1(e)(5)(ii).
[113] *See* 21 C.F.R. § 202.1(e)(5)(iii) (1990).
[114] *See id.* § 202.1(e)(6)(i)-(xx).
[115] *See id.*
[116] *See id.*
[117] *See id.* § 202.1(e)(7)(i)-(xiii).

Commissioner so directs.[118] If an adequate program is not being followed, preapproval will be required of any such publicity.[119] These actions are in addition to the Commissioner's rights to notify the public of the problem, suspend any new drug application, decertify any antibiotic, or recommend any regulatory action.[120]

Importantly, there is a safe-harbor provision if the sponsor has sought FDA comment before running the advertisement and has complied with the FDA's suggestions.[121] A failure to seek such comment leaves a sponsor to proceed at its peril.

Thus, the general guidelines of the Guidance to Industry can provide the casual observer with an overview of direct-to-consumer advertising. Any particular advertisement that will be challenged in court, however, must first be examined to see if the FDA provided any preliminary favorable comment or must be assessed anew against the specific standards of title 21, § 202.1 of the Code of Federal Regulations. It is this scrutiny that apparently moved the *Perez* court to find that the presumption of adequacy applies when the manufacturer has complied with the FDA's advertising and labeling requirements, and to comment that in only the "rare case" will this presumption be overcome.[122]

## CONCLUSION

The *Perez* court had four basic options for establishing standards for direct-to-consumer advertising. First, the court could have adopted the New Jersey statutory language as it existed and determined that an adequate warning, as defined in title 2A, section 58C-4 of the New Jersey Statutes, need be given solely to the prescribing health-care provider. Second, the court could have decided that the statute governed disclosure to a prescribing health-care provider and limited a products liability cause of action. Under this result, parallel fraud and misrepresentation claims would be available through common-law standards for a consumer who had relied upon deceptive advertising. Third, the court could have avoided the statutory language, as the court did, but applied existing common-law or statutory principles for failure to warn claims. Fourth, the court could have taken the course that it took, avoiding the New Jersey statutory language and engrafting the FDA standards

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[118] *See id.* § 202.1(j)(1).

[119] *See* 21 C.F.R. § 202.1(j)(1) (1990).

[120] *See id.*

[121] *See id.* § 202.1(j)(4).

[122] *See Perez*, 161 N.J. at 25, 734 A.2d at 1259.

as the basis of a new cause of action. Having chosen the fourth course, the court, through the attendant enhanced presumption of adequacy for compliance with the federal standards, has given with one hand and taken back with the other. The New Jersey Supreme Court's "compelling evidence," "virtually dispositive," and "rare case" language indicates that seldom, if ever, will the inquiry proceed beyond an analysis of compliance with the federal standards. This effectively stifles any claim when there has been favorable FDA comment and de facto clearance of the challenged advertisement. Even when such comment is lacking, the FDA regulations will provide the standard of review for the courts.[123]

In effect, the ambiguous language of *Feldman II* has now been explained, even as to an ordinary failure to warn claim involving a prescription drug. Those who took delight in the court's rejection of the preemption argument in *Feldman II* now find themselves faced with this superpresumption of adequacy, subject to extremely difficult, if any, rebuttal. Any fraud upon the FDA, of course, still is a basis for an award of punitive damages, and "concealment or nondisclosure of after-acquired knowledge of harmful effects" may still avoid the bar now imposed by compliance with FDA standards.[124] Absent such fraud or concealment, however, it would be highly unusual if a plaintiff's case is able to survive a motion for summary judgment when there had been premarket approval or favorable FDA comment concerning direct-to-consumer advertising. For these reasons, the exuberance of plaintiff attorneys over *Perez* should be short-lived. Read properly, the *Perez* opinion is a victory for the defense.

If the New Jersey Supreme Court intended otherwise, its next opinion on this topic is eagerly awaited.[125] If history is any indication,

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[123] *See generally* 21 C.F.R. § 202.1 (1990).

[124] *Perez*, 161 N.J. at 25, 734 A.2d at 1259.

[125] The New Jersey Superior Court, Appellate Division, rendered an opinion in *R.F. v. Abbott Laboratories* that was withdrawn at the request of the New Jersey Supreme Court, which will hear the case this year. *See* R.F. v. Abbott Labs., 158 N.J. 72, 726 A.2d 936 (1999) (granting certification). In *R.F.*, the plaintiff claims that the defendant's HIV test was defective because it carried inadequate warnings. *See Federal Preemption*, 17 No. 1 PROD. LIAB. L. & STRATEGY 7, July 1998, *available in* WESTLAW. The defendant claims that because its warnings were approved by the FDA, the plaintiff's case should be preempted. *See id.* The appellate division "agreed with Abbott that the claim was preempted . . . . 'and that the pretrial motions to dismiss should have been granted on preemption grounds because it was undisputed that the FDA specifically reviewed Abbott's package insert and approved it only after it incorporated the changes the FDA had directed.'" *Abbott HIV Defense Verdict Affirmed on Preemption by New Jersey Appellate Division*, 3 No. 10 MEALEY'S LITIG. REP.: DRUGS & MED. DEVICES 14, May 22, 1998, *available in* WESTLAW (quoting the withdrawn

however, it is unlikely that another state resolving this issue will go beyond New Jersey's resolution of direct-to-consumer advertising liability.

Lastly, one must consider whether this decision is a forerunner of similar treatment to be afforded claims in other closely regulated industries when there is no actual preemption by statute or regulation. The New Jersey Supreme Court's reasoning, coupled with the standards of comment e to section 4(b) of the Restatement (Third), may forecast the court's reluctance to reassess conduct or products that have already passed stringent administrative review.

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appellate division opinion).