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Drug Ads: Has the Picture Changed?

Direct-to-consumer advertising six years after *Perez*

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In *Perez v. Wyeth Laboratories, Inc.*, 161 N.J. 1 (1999), the New Jersey Supreme Court held that a cause of action could exist against a pharmaceutical manufacturer for failure to warn claims based upon direct-to-consumer (DTC) advertising, in addition to failure to warn claims arising from the instructions and warnings given to the prescribing health care professional. On its face, *Perez* appeared to be a bold step towards a new era in pharmaceutical product liability law. Some six years later, however, it is clear that the practical impact of *Perez* is quite limited.

Prior to *Perez*

Prior to *Perez*, pharmaceutical product liability cases in New Jersey and elsewhere were typically governed by the Learned Intermediary Rule, which posits that the prescribing physi-

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cian acts as the intermediary between the drug manufacturer and the consumer. Thus, courts held 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 *Niemiera v. Schnieder*, 114 N.J. 550, 559 (1989) (the Learned Intermediary Rule relieved a DPT vaccine manufacturer of the duty-to-warn patients directly of the vaccine's potential dangers).

In New Jersey, the Learned Intermediary Rule was codified in section 4 of the New Jersey Products Liability Act (PLA), N.J.S. 2A: 58C-4, which states that in prescription drug cases, an adequate warning is one sufficient to warn the prescribing physician. As explained in the Legislative Comments accompanying the PLA, "in the case of prescription drugs, the warning is owed to the physician."

Prior to *Perez*, a few courts recognized two narrow exceptions to the Learned Intermediary Rule. One exception was in the case of mass immunization, where vaccinations were administered by nurses or others without a doctor's involvement. Those cases held that the vaccine manufacturer has a duty to warn consumers directly, because there

was no physician present to evaluate the risks and benefits of the vaccine for individual patients. See *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9th Cir. 1968); *Reyes v. Wyeth Laboratories, Inc.*, 498 F.2d 1264 (5th Cir.), cert. denied, 419 U.S. 1096 (1974). A few other courts discarded the Learned Intermediary Rule in cases where the patient requested the drug as a lifestyle choice, as with oral contraceptives or nicotine patches. See *McDonald v. Ortho Pharmaceuticals Corp.*, 575 N.E.2d 65 (Mass. 1985) (oral contraceptives); *Lukaszewicz v. Ortho Pharmaceuticals Corp.*, 510 F. Supp. 961 (E.D. Wis. 1981) (same); *Edwards v. Bassel Pharmaceuticals*, 933 P.2d 298 (Okla. 1997) (prescription nicotine patches).

A New Path

In 1999, *Perez* appeared as a radical change in New Jersey product liability law, reversing an Appellate Division decision that had dismissed failure to warn claims premised on DTC advertising. See *Perez v. Wyeth Lab.*, 313 N.J. Super. 511 (App.Div. 1998). Arising in the context of personal injury claims involving the contraceptive implant Norplant, *Perez* involved claims for liability based on DTC advertising virtually identical to those rejected months earlier by the Fifth Circuit in *In re Norplant Contraceptive Products Liab.*

Litig., 165 F.3d 374 (5th Cir. 1999). The *Perez* Court held that where a pharmaceutical manufacturer has marketed its prescription drug directly to consumers, the manufacturer has a duty to warn consumers of the drug's potential side effects. *Perez*, 161 N.J. at 30-33. In allowing a cause of action to proceed, the Supreme Court arguably undermined the Learned Intermediary Rule and ignored both the text of the PLA and its legislative history demonstrating that the statute codified the Learned Intermediary Rule without qualification. See *Perez*, 161 N.J. at 33-42 (Pollock, J., dissenting).

Nevertheless, the Supreme Court imposed severe restrictions upon its new cause of action. Compliance with FDA regulations governing advertising, labeling and warning creates a rebuttable presumption that the manufacturer's duty to warn consumers is met. As explained by the Court, "for all practical purposes, absent deliberate concealment or non-disclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive of such claims." *Perez*, 161 N.J. at 25. Rather than imposing a typical "disappearing" statutory presumption of adequacy under N.J.R.E. 301, the *Perez* court established a more stringent "compelling evidence" presumption that a manufacturer has satisfied its duty to warn by complying with FDA regulations. As articulated in *Perez*, this "compelling evidence" presumption applies to all failure to warn claims involving prescription drugs and medical devices, not just DTC advertising claims. *Perez*, 161 N.J. at 24.

Creating a new cause of action while simultaneously circumscribing it by establishing a "safe harbor" based upon defendants' compliance with applicable FDA advertising regulations, the *Perez* Court gave with one hand and took away with the other. As discussed further below, the passage of time has confirmed that *Perez* is indeed "an empty gift to plaintiffs" — a pro-defense decision cloaked in pro-plaintiff language. See Honorable William A. Dreier, "Direct-To-Consumer Advertising Liability: An Empty Gift

To Plaintiffs," 30 Seton Hall L. Rev. 806 (2000).

Industry Developments

Consistent with *Perez*, the pharmaceutical industry has likewise made compliance with FDA advertising regulations the focal point of recent efforts to avoid problems raised by DTC advertising. In response to recent industry and political pressure, a major industry trade association, the Pharmaceutical Research & Manufacturers of America (PhRMA) announced in August 2005 the promulgation of specific rules on DTC advertising, effective in January 2006.

Known as the "Guiding Principles," the PhRMA rules seek to ensure that members' DTC communications comply with applicable FDA regulations and also "deliver messages that fundamentally serve to educate patients and consumers and encourage them to seek guidance from their health care professionals." "PhRMA Guiding Principles Direct-To-Consumer Advertisements About Prescription Medicines" at 2 (August 2005) (available through www.PhRMA.org). The Guiding Principles in large part reflect FDA requirements that all DTC information, whether in broadcast or print media: (1) be accurate and not misleading; (2) make claims only when supported by substantial evidence; (3) reflect balance between risks and benefits; and (4) are consistent with FDA-approved labeling.

Beyond compliance with FDA DTC advertising regulations, the Guiding Principles state that "companies should spend an appropriate amount of time to educate health professionals about a new medicine or a new therapeutic indication before commencing the first DTC advertising campaign." *Id.* at 3-4. Rather than recommend a uniform waiting period for all companies and all medicines, Guiding Principle 6 states that companies should take into account "the relative importance of informing patients of the availability of a new medicine, the complexity of the risk-benefit profile of that new medicine, and health care professionals' knowledge of the condition being

treated," and "should continue to educate health care professionals as additional valid information about a new medicine is obtained from all reliable sources." *Id.* at 4.

Although the Guiding Principles are technically voluntary, they arguably supplement existing standards of conduct for prescription drug manufacturers. A manufacturer's adherence to the Guiding Principles, along with applicable FDA advertising regulations, would appear to strengthen the manufacturer's defense against possible claims arising from DTC advertising.

Post-*Perez* Legal Issues

Rather than the harbinger of radical change in pharmaceutical product liability law, *Perez* has had rather limited effect. In the six years following *Perez*, there have been no reported cases in the country following *Perez* and adopting an exception to the Learned Intermediary Rule for failure to warn claims based upon DTC advertising. See, e.g., *In re: Meridia Products Liab. Litig.*, 328 F. Supp.2d 791 (N.D. Ohio 2004); *Vitanza v. The Upjohn Co.*, 257 Conn. 365 (2001); *Wyeth-Ayerst Labs. Co. v. Medrano*, 28 S.W.3d 87 (Tex. App. 2000).

Subsequent case law has arguably limited the scope of available claims even under *Perez*. In *Buckman Co. v. Plaintiffs' Leg. Comm.*, 531 U.S. 341 (2001), the United States Supreme Court held that the plaintiffs' fraud-on-the-FDA claim was pre-empted because such a damages claim would conflict with the federal statutory scheme empowering the FDA to punish and deter fraud against the agency. That statutory scheme permits the FDA to achieve a "somewhat delicate balance of statutory objectives," which could be "skewed" by allowing fraud-on-the-FDA claims under state law." 531 U.S. at 348. Interestingly, the *Buckman* Court did not consider the issue of whether plaintiffs' fraud-on-the-FDA claims were barred by the express pre-emption provision of the 1976 Medical Device Amendments to the Food, Drugs and Cosmetic Act. 531 U.S. at 348, n.2.

Notwithstanding the absence of an

express statutory pre-emption provision, the pervasive regulation of consumer drug advertising in 21 C.F.R. § 202.1 arguably should result in a finding post-*Buckman* of federal pre-emption on the grounds that the field of consumer prescription drug advertising has been pervasively occupied by the FDA. The Sixth Circuit has so held in a case involving a Michigan drug product liability statute that immunizes drug manufacturers from liability if the drug was FDA approved, and the drug and its labeling complied with the FDA's approval when it left the manufacturer's control that included a "fraud on the FDA" exception to the statutory immunity very similar to the "fraud on the FDA" exception referenced in *Perez*. *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004) (*Buckman* pre-empted fraud-on-the-FDA claim asserted based on statutory exception to drug manufacturer immunity from liability for FDA-approved drugs).

Plaintiffs seeking to avoid *Buckman*-pre-empted claims of fraud-on-the-FDA have asserted state-based fraud or consumer fraud claims. See *Woods v. Glatech, Inc.*, 218 F. Supp.2d 802 (W.D. Va. 2002) (state causes of action permitted where defendant is alleged to have not complied with FDA regulations, rather than having defrauded the FDA); *Dawson v. Ciba-Geigy Corp. USA*, 145 F. Supp.2d 565 (D.N.J. 2001) (statutory consumer fraud and state tort claims are "not necessarily preempted" by the Food, Drug, and Cosmetics Act and are not the same as "fraud on the FDA" claims pre-empted under *Buckman*). While a discussion of federal pre-emption is beyond the scope of this article, the application of federal pre-emption to tort claims against pharmaceutical and medical device manufacturers continues to develop, and may

well impact this strategy in future cases. See *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004) (defective design and failure to warn claims pursuant to Pennsylvania law regarding heart pump held completely pre-empted by FDA Pre-Market Approval under 21 U.S.C. § 360e(c)).

In a noteworthy November 8 decision, the United States District Court for the District of Delaware dismissed for failure to state a claim a putative national class action asserting consumer fraud claims based on allegedly misleading advertising materials for the prescription drug Nexium. The court held that the advertising materials were consistent with the FDA-approved labeling and therefore not actionable under the Delaware Consumer Fraud Act, 6 Del. C. § 2511 et seq., and that even if actionable, they complied with the FDA-approved labeling, which therefore pre-empted claims under any state consumer fraud act. *Pa. Employee Benefit Trust Fund v. Zeneca, Inc.*, 2005 U.S. Dist. LEXIS 27444, No. 05-075-SLR (D. Del. Nov. 8, 2005).

Against this evolving landscape — both in the area of DTC advertising, or a more traditional failure to warn theory based upon product labeling — the pharmaceutical manufacturer is presented with a seemingly unworkable quandary. The FDA regulates all drug labeling, and violations of the labeling standards set forth in 21 C.F.R. § 202.1 causes the drug to be considered "misbranded." 21 C.F.R. § 202.1(k). Further, the FDA requires that notice regarding prescription drugs be given verbatim, as approved; failure to do so subjects the manufacturer to both civil and criminal penalties. See 21 U.S.C. §§ 331(o), 333, 334; 21 C.F.R. § 314.105. Is it appropriate to require that a manufacturer comply with the possible application of 50

state warning standards, imposed after the fact on an ad hoc basis by juries in individual cases which may be inconsistent with FDA-approved labeling?

Beyond these regulatory issues, DTC advertising failure to warn claims raise troublesome issues of proximate cause. While *Perez* left open the possibility of a claim where the manufacturer's advertising failed to warn the consumer, and the physician was unaware that the patient had a special need for warnings, the Court did not exempt plaintiffs from showing that the proposed additional warnings would have been accepted by the FDA and approved for inclusion by the manufacturer. Rather, *Perez* made it clear that plaintiffs must show a definite causal nexus between the withheld or omitted warnings and the plaintiffs' alleged injury. *Perez*, 161 N.J. at 25-30. The problems inherent in such proofs — claims asserting what the FDA might have done with certain data — would threaten to turn such cases into a FDA approval process, a function for which the courts are not well suited.

Notwithstanding developments in case law following *Perez*, it is not clear how far the New Jersey Supreme Court will go in precluding common law fraud and/or consumer fraud claims involving claims of fraud on the public or allowing claims premised on DTC advertising. What is clear is that pharmaceutical manufacturers can take strong steps to protect themselves by having their DTC advertisements (whether for broadcast or print) approved by the FDA under applicable regulations, and can exercise additional prudence by following PhRMA's Guiding Principles. In that regard, *Perez* seems to have done as much or more for pharmaceutical defendants as plaintiffs. ■