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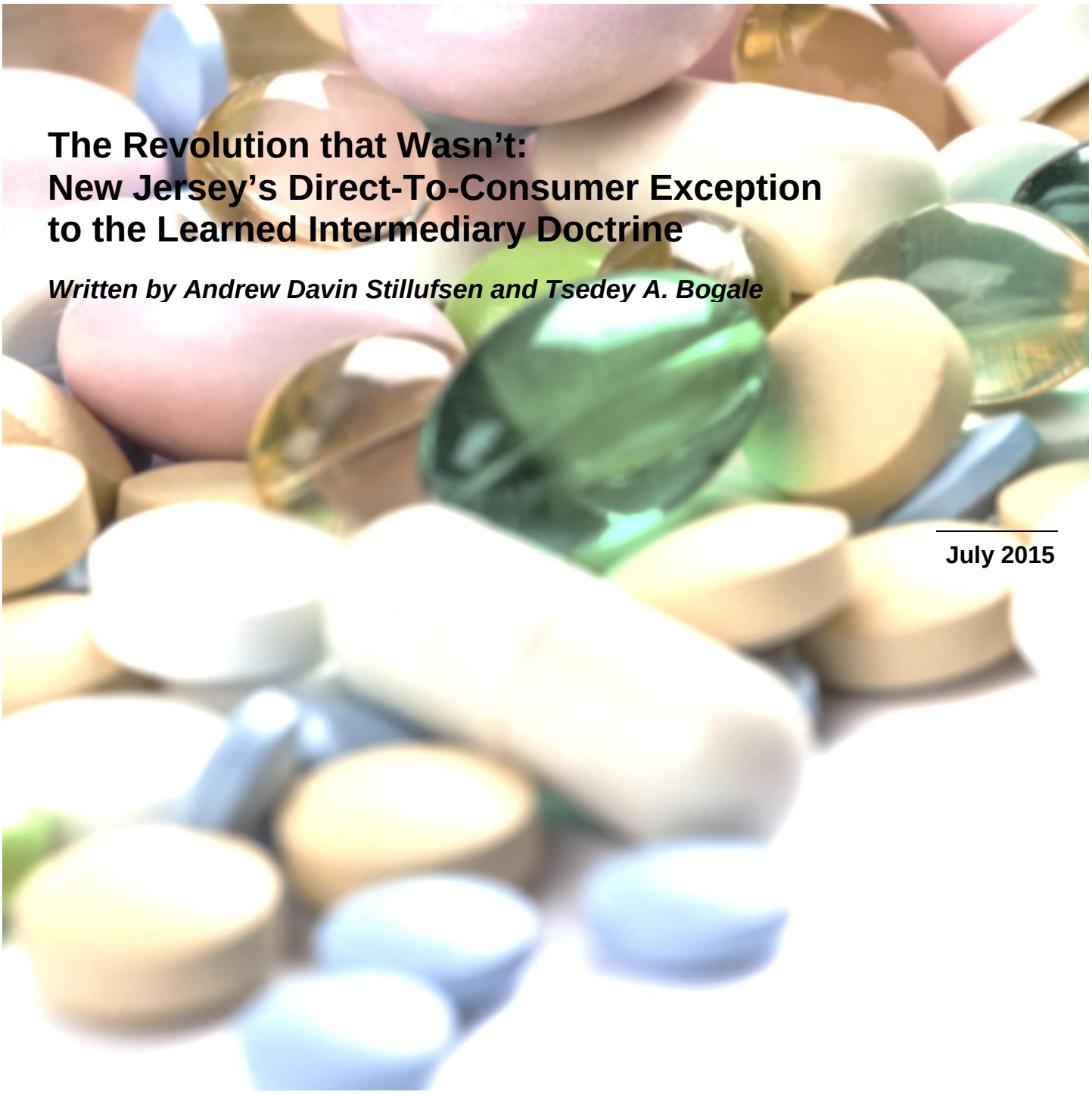

The Revolution that Wasn't: New Jersey's Direct-To-Consumer Exception to the Learned Intermediary Doctrine

Written by Andrew Davin Stillufsen and Tsedey A. Bogale

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The learned intermediary doctrine – in which a manufacturer's duty to warn runs to the physician, not to the patient – is one of the most potent weapons in the arsenal for a pharmaceutical or medical device manufacturer faced with product liability litigation. Thus it was indeed "revolutionary" [1] when the New Jersey Supreme Court found that there was a direct-to-consumer (DTC) advertising exception to the doctrine in *Perez v. Wyeth Lab., Inc.,* 734 A.2d 1245 (N.J. 1999). This "bombshell decision" [2] held that, where a pharmaceutical manufacturer directly markets to consumers, the learned intermediary doctrine is not available. However, since the *Perez* decision was issued in 1999, no court applying New Jersey law has actually imposed liability for DTC advertising, and the overwhelming majority of jurisdictions – with West Virginia being the one notable exception – still fully embrace the learned intermediary doctrine. Accordingly, it is fair to say that the DTC exception is the revolution that wasn't, though practitioners should nonetheless still take steps to make sure this remains the case.

Perez, the Learned Intermediary Doctrine, and the DTC Exception

Before we examine *Perez* and the DTC exception, a brief discussion of the learned intermediary doctrine is warranted. Under well-settled precedent, the learned intermediary doctrine limits a pharmaceutical or medical device manufacturer's duty to adequately warn of risks to only the prescribing physician, and not to the patient. *Niemiera v. Schnieder*, 555 A.2d 1112, 1117 (N.J. 1989). Courts have applied the doctrine for decades,[3] under four generally accepted premises:

- Reluctance to undermine the doctor-patient relationship
- Physicians are in a superior position to convey meaningful information to their patients

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[1] Fushman, Yonni, *Perez v. Wyeth Labs, Inc.: Toward Creating a Direct-to-Consumer Advertisement Exception to the Learned Intermediary Doctrine*. 80 B.U.L.Rev. 1161 (2000).

[2] Twerski, Aaron, *Liability for Direct Advertising of Drugs to Consumers: An Idea Whose Time Has Not Come*, 33 Hofstra L. Rev. 1149 (2005).

[3] *See, e.g., Marcus v. Specific Pharm., Inc.*, 77 N.Y.S.2d 508, 509-10 (N.Y. Sup. Ct. 1948) (prescription drug manufacturer fulfills its duty to warn when it provides an adequate warning to the prescribing physician); *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966) (adopting "learned intermediary" phrase).

- Manufacturers lack effective means to communicate directly with patients
- Complexity of risk information

Perez, 734 A.2d at 1255. This logic has proven to be persuasive, as courts in 47 states, including New Jersey, have adopted the learned intermediary doctrine in some form in prescription product liability litigation.[4]

In the *Perez* case, which involved the Norplant contraceptive, the court confronted the question of whether the learned intermediary doctrine should apply when the prescription medical product manufacturer markets its products directly to consumers. Given the exponential growth of DTC advertising for pharmaceuticals, the prospect of the elimination of the learned intermediary doctrine was likely very alarming to both manufacturers and the defense bar.

While the decision did assuage some of those fears by reaffirming the availability of the learned intermediary doctrine, the court stated in the opening line of its opinion – with a heavy dose of foreshadowing - that "[o]ur medical-legal jurisprudence is based on images of health care that no longer exist." *Id*. at 1246. The court noted that the dramatic increase in spending on DTC advertising had undermined the premises of the learned intermediary doctrine:

- Informed consent requires patients to have a more active role in medical decisions
- The modern system of managed care has decreased the amount of time physicians speak to patients
- The increasing amount of money spent on advertising meant that manufacturers could effectively communicate with patients

Id. at 1255-56. Therefore, the court held that the "direct marketing of drugs to consumers generates a corresponding duty requiring manufacturers to warn [consumers] of defects in the product." *Id*. at 1263. However, consistent with the New Jersey Product Liability Act, the same "rebuttable presumption [of adequacy of

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[4] Discussed below, West Virginia has outright rejected the doctrine in prescription drug litigation. *See State ex rel. Johnson & Johnson v. Karl*, 647 S.E.2d 899, 914 (W. Va. 2007). The highest courts in Vermont and New Mexico have not accepted or rejected the learned intermediary doctrine. *See Drake v. Allergan, Inc.*, No. 2:13-cv-234, 2014 WL 5587029, at *5 (D. Vt. Oct. 31, 2014) (noting that Vermont has neither adopted nor rejected the learned intermediary doctrine); *Rimbert v. Eli Lilly & Co.*, 577 F. Supp. 2d 1174, 1214–1224 (D.N.M. 2008) (predicting that the Supreme Court of New Mexico would not adopt the learned intermediary doctrine). The availability of the learned intermediary doctrine in Arizona has recently been called into question by an appellate court's holding that the doctrine conflicts with the state's comparative fault statute. *See Watts v. Medicis Pharm. Corp.*, 342 P.3d 847, 854-55 (Ariz. Ct. App. 2015).

the warnings given to consumers] should apply [to the DTC advertising] when a manufacturer complies with FDA advertising, labeling and warning requirements." *Id*. at 1259.

The Revolution That Wasn't

In the wake of the court's attempt in *Perez* to blow a hole in the learned intermediary doctrine with the DTC exception, notable commentators - including one of authors of the Third Restatement of Torts: Products Liability – expected that "the learned intermediary doctrine would [not] survive in the face of the onslaught of massive advertising of drugs in the media...."[5] Instead, the exact opposite occurred. Not only has no New Jersey court – or court applying New Jersey law – actually held a manufacturer liable for DTC advertising, but other jurisdictions have also declined to follow the rationale in *Perez*.

While the creation of the DTC exception indeed seemed "revolutionary" at first glance, the handful of New Jersey courts that have actually looked at this issue have strictly applied the DTC exception, and have required the plaintiff to show that she not only saw DTC advertising, but that it also influenced her decision to take the medication or undergo the procedure. First, a New Jersey appellate court rejected a plaintiff's argument that the learned intermediary doctrine was not applicable because informational brochures in the physician's office constituted DTC advertising. *Banner v. Hoffman-LaRoche, Inc.*, 891 A.2d 1229, 1236 (N.J. App. Div. 2006), *cert. denied* 921 A.2d 447 (N.J. 2007). In *Banner*, which involved the Accutane medication, the court noted that plaintiff "read[s] *Perez* too broadly," and held that, under FDA rules, "the placement of informational brochures in a physician's office cannot fairly be equated with a course of mass advertising or be deemed direct-to-consumer advertising so as to remove the predicates of the learned intermediary doctrine." *Id*. Furthermore, even in the absence of FDA rules, which considered these brochures to be labeling and not advertising, the brochures merely "memorialized the information supplied to the patient by the prescribing physician." *Id*. at 1237. Accordingly, the court concluded that the learned intermediary doctrine still applied because plaintiff failed to show that the manufacturer had even engaged in DTC advertising.

In the second decision, a New Jersey federal court held that the learned intermediary doctrine applied to a case where the plaintiff could not demonstrate that she was influenced or affected by the manufacturer's DTC advertising. *Appleby v. Glaxo Welcome, Inc.*, No. 04-0062, 2005 WL 3440440 (D.N.J. Dec. 13, 2005). In *Appleby*, which involved a drug indicated to treat irritable bowel syndrome, the plaintiff testified that she had never heard of the drug before her doctor prescribed it. Furthermore, during the time that she ingested the medication, plaintiff testified that she had not been exposed to any advertising or direct-to-consumer marketing. Accordingly, the court held that the DTC exception did not apply, because even if a manufacturer engages in DTC advertising,

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[5] Twerski, Aaron, *Liability for Direct Advertising of Drugs to Consumers: An Idea Whose Time Has Not Come*, 33 Hofstra L. Rev. 1149 (2005).

"it is clear that a plaintiff who has never seen any advertising cannot be harmed by flaws in that advertising." *Id*. at *4 n.5 (emphasis added).

In the third case, which involved a medical device, the same federal court explained that, under *Perez*, "[t]he key issue in determining whether the learned intermediary doctrine applies is whether a drug or device is directly marketed to consumers." *Seavey v. Globus Med. Inc.*, No. 11-2240, 2014 WL 1876957, at *8 (D.N.J. Mar. 11, 2014). Since the device was only marketed to physicians, and "not [marketed] directly to the ultimate recipients," the court held that the DTC exception could not apply. *Id*.

Following this line of cases, the fourth and most recent New Jersey state court case involving a human tissue product also rejected the DTC exception. The court held that, where "plaintiffs concede that [the manufacturer] advertised and marketed [the product] only to doctors and healthcare providers…the *Perez* exception to the learned intermediary doctrine is inapplicable here." *Simineri, et al. v. LifeCell Corp.*, No. L-5972-11, Mem. Decision at n. 3 (N.J. Super. Ct. May 8, 2015).[6] Other than in these four cases, we have located no other New Jersey state or federal court decision that has attempted to determine whether the DTC exception applied under *Perez*. Thus, the impact of *Perez* and the creation of the DTC exception can hardly be called "revolutionary." [7]

Courts outside of New Jersey have been no more charitable in applying *Perez* and the DTC exception to the learned intermediary doctrine. In *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795 (E.D. Tex. 2002), the MDL court held in a choice of law ruling that New Jersey law and *Perez* applied to plaintiffs who had a birth control device implanted in New Jersey. However, the court noted that plaintiffs' "argument [that the DTC exception should apply] is critically weakened by the absence on the record that any of the plaintiffs actually saw, let alone relied on any marketing materials issued to them by Defendants." *Id*. at 797 (internal citation and quotations omitted). While the court did not specifically reach the issue of whether the DTC exception applied, given the absence of any DTC advertising or reliance, it seems highly unlikely that it could.

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[6] In an issue of first impression in New Jersey, Judge Mayer held that the learned intermediary doctrine applied to human tissue products. The court rejected plaintiffs' arguments that this would be an "unwarranted expansion of New Jersey's learned intermediary doctrine" and, applying "the well-established rationales underlying the learned intermediary doctrine," found that, "where a medical product is available only through the intervention of a licensed physician, a duty to warn is owed to the physician and not the patient." *Id*. at 15, 9.

[7] *See also N.J. Citizen Action v. Schering-Plough Corp.*, 367 N.J. Super. 8, 15-16 (N.J. App. Div. 2003) (rejecting a "fraud-on-the-market" theory of reliance under the New Jersey Consumer Fraud Act in a case alleging fraudulent DTC advertising of prescription drugs).

Similarly, the MDL court in *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791 (N.D. Ohio 2004) declined to apply the DTC exception to New Jersey cases where plaintiffs could not show that a manufacturer who actually engaged in DTC advertising violated the FDA's regulations. *Id*. at 812 n.19. Under *Perez*, even if a manufacturer engaged in DTC advertising, compliance in the advertising with FDA rules and regulations

> creates a rebuttable presumption that the manufacturer fulfilled its duty to adequately warn consumers (not physicians, because the learned intermediary doctrine does not apply in New Jersey when the manufacturer advertises directly to consumers). Plaintiffs have provided no reason to believe that defendants violated the FDA's rules and regulations. Therefore, even applying *Perez* gets the Plaintiffs nowhere.

Id.

Two trends are apparent from these decisions. First, for the DTC exception to apply, a manufacturer must have actually engaged in DTC advertising for the drug or device at issue - no DTC advertising, no DTC exception. Second, and more importantly, the plaintiff can only satisfy her burden by showing that she not only saw the advertising and that it contained inadequate risk information, but that she also was influenced or affected by it when deciding to use to product. Thus far, no plaintiff has been able to satisfy this burden.

Mixed Results for the DTC Exception Outside of New Jersey

The highest courts in the two jurisdictions outside of New Jersey that have been urged to follow *Perez* and adopt the DTC exception have reached opposite results. In 2012, the Texas Supreme Court adopted the learned intermediary doctrine and rejected the DTC advertising exception. *Centocor Inc. v. Hamilton*, 372 S.W.3d 140 (Tex. 2012). In rejecting the DTC advertising exception, the court pointed to the role of the prescribing physician and explained that even "patients who seek prescription drugs based solely on DTC advertising will obtain them only when the prescribing physician has evaluated the potential risks and benefits for the particular patient." *Id*. at 163.

A divided West Virginia Supreme Court reached the opposite conclusion in 2007. In *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 901-02 (W. Va. 2007), a plurality of the court explicitly rejected the learned intermediary doctrine altogether, regardless of whether there was DTC advertising or not. Relying heavily on *Perez*, the decision noted that significant changes in the prescription drug industry since the doctrine's origin has led to an increased role of the patient in the prescription process. Specifically, the increase of manufacturers' DTC advertising and its impact on the physician/patient relationship, and the development of the Internet as a method of dispensing and obtaining prescription drug information, had fundamentally changed the

physician-patient relationship, and thus the rationalizations for the learned intermediary doctrine were, according to the court, "largely outdated and unpersuasive." *Id*. at 906.

However, the impact of the *Karl* decision has thus far been limited. Most recently, two West Virginia federal courts have narrowed its scope and held that *Karl* only applied to cases with "drug manufacturers that engage in DTC advertising." *See Tyree v. Boston Scientific Corp.*, 56 F. Supp.3d 826, 830 (S.D. W.Va. 2014); *see also O'Bryan v. Synthes, Inc.*, No. 5:13-cv-25981, 2015 WL 1220973, at *6-7 (S.D. W.Va. Mar. 17, 2015). Both decisions reasoned that the learned intermediary doctrine still applied to medical device cases – which can only be obtained and implanted through a physician – where the manufacturer never engaged in DTC advertising. *Tyree*, 56 F. Supp.3d at 832-33; *O'Bryan*, 2015 WL 1220973, at *6-7.

Looking Forward

For practitioners, even though the learned intermediary doctrine is robust in New Jersey, it is still imperative to prevent any avenue by which a plaintiff could invoke the DTC exception. Thus, at a plaintiff's deposition, it is important to confirm that she never personally saw any type of advertising, or, if she did, the specifics of what was seen; as demonstrated above in the *Banner* case, this distinction could make the difference between a court applying the learned intermediary doctrine or the DTC exception. Similarly, if an advertisement was seen, the timing is critical, as is whether the plaintiff was actually influenced or affected by it.

For pharmaceutical and device manufacturers, risk mitigation is still warranted, even though the current trend is against adoption of the DTC exception. Given the level of current DTC advertising, and the likelihood of advertising on social media, it is possible that a court will be sympathetic to an argument that the patient – to whom all the advertising is directed – should have some role in the risk analysis. One way to minimize this possibility is to continue to vigilantly review all DTC advertisements for risk disclosure; this is especially true with social media. Furthermore, the role of the physician in the prescribing decision should be re-emphasized. While this is currently the norm, repeated and emphasized references to the physician's role is one way to help mitigate the risk of a court adopting the DTC exception.

Conclusion

While at first seen as a "bombshell," in practice, the "revolutionary" decision announced in *Perez* to create the DTC exception has been much less so in its application. New Jersey courts, and courts applying New Jersey law, have strictly interpreted *Perez*. For plaintiffs, this means that not only must they show that the manufacturer engaged in DTC advertising, and that they actually saw the advertising, but they also must show that the advertising influenced or affected their decision to undergo the recommended treatment. In addition, even if these requirements are met, a manufacturer is still entitled to a rebuttable presumption of adequacy of its warnings if the advertising complies with FDA regulations, and the plaintiff still must show that the relied-upon advertising contained inadequate risk information. Furthermore, the overwhelming majority of states continue to

apply the learned intermediary doctrine, and have rejected arguments that the DTC exception undermines the learned intermediary doctrine. With vigilant monitoring of DTC advertising, and repeated references to the physician's role, this should continue to be the case into the future.

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