

# The Road Less Traveled: West Virginia's Rejection of the Learned Intermediary Doctrine in the Age of Direct-to-Consumer Advertising

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### I. INTRODUCTION

Robert Frost gave us that indelible ideal of two roads diverging in the wood, and urged us to take the road less traveled. Countless schoolchildren and hopeless romantics still read the poem with that tone reserved for sharing life's wisdom as they promote the virtue of taking that road less traveled. The thought is revered, but can the road really remain less traveled if others heed the cacophony of voices promoting this road to the world?

In the world of products liability, few state courts have heeded Frost's advice, instead growing resigned to taking the jurisprudential road that the majority of courts have followed before them. This is especially true in the area of prescription drugs and devices. Nearly every state has applied the learned intermediary doctrine to shield pharmaceutical manufacturers from liability for failure to warn consumers when the manufacturer provided adequate warning to the prescribing physician.<sup>1</sup>

However, every now and then a court comes along and decides to take the road less traveled by questioning the conventional wisdom of this well-accepted legal doctrine. The New Jersey Supreme Court took the road less traveled and rejected the learned intermediary doctrine in cases in which the patient was the subject of direct-to-consumer (DTC) advertising by the pharmaceutical company.<sup>2</sup> Thus, the court restored the general rule, requiring the drug manufacturer to provide adequate warning to the consumer-patient.<sup>3</sup> Practitioners and professors alike sounded an alarm over this departure, and numerous commentators sought to predict whether others would follow New Jersey down this path.<sup>4</sup> Yet, no court followed New Jersey in the eight years after *Perez*. Then, in 2007, the Supreme Court of Appeals of West Virginia picked up where New Jersey left off and declined to adopt the learned intermediary doctrine.<sup>5</sup>

This Note examines whether this rejection of the learned intermediary doctrine is simply another pursuit of Frost's indelible image, or rather, a sign of an impending shift in our medical-legal jurisprudence as the viability of this doctrine is again questioned. In Part II.A, this Note provides a concise background on the development of the learned intermediary doctrine and its exceptions in addition to giving the current state of the law. Part II.B discusses the New Jersey Supreme Court case and the response by commentators and courts in New Jersey and other states. Part III analyzes the West Virginia high court's decision and the court's reasons for declining to adopt the learned intermediary doctrine while looking at the implications for the learned intermediary

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1. *See Vitanza v. Upjohn Co.*, 778 A.2d 829, 836, 838 n.11 (Conn. 2001) (discussing the basis for the learned intermediary doctrine and noting that 44 other jurisdictions had applied the learned intermediary doctrine).

2. *See Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245, 1263 (N.J. 1999) (holding that "direct marketing of drugs to consumers generates a corresponding duty requiring manufacturers to warn [the consumer] of defects in the product").

3. *Id.*

4. *See infra* Part II.B.2.

5. *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 901 (W. Va. 2007).

doctrine and drug manufacturers. Part IV seeks to provide a workable solution for drug manufacturers and consumers alike.

## II. BACKGROUND

### *A. The Long and Storied History of the Development of the Learned Intermediary Doctrine and Its Exceptions*

#### *1. Origins of the Learned Intermediary Doctrine*

The learned intermediary doctrine eliminates the need for a prescription drug manufacturer to warn the ultimate consumer of a drug's risks if the manufacturer has provided adequate warning to the prescribing physician.<sup>6</sup> The doctrine has a long and storied history with deep-rooted common law origins. Courts have traced its origin back to 1925 when a court<sup>7</sup> made the "first intimations that the manufacturer's duty to the ultimate consumer would be limited in the case of prescription drugs."<sup>8</sup> In 1948, a New York Superior Court concluded that the manufacturer of a prescription drug satisfied its duty to warn by providing warnings to the prescribing physician.<sup>9</sup> In 1967, the Eighth Circuit coined the pharmaceutical manufacturers' limited duty to warn as the "learned intermediary" doctrine.<sup>10</sup> The court wrote just one paragraph discussing this learned intermediary doctrine, yet commentators note that the court set a "commanding precedent."<sup>11</sup> Since its inception, the learned intermediary doctrine has been "a crucial defense" for prescription drug manufacturers.<sup>12</sup>

In order to understand how this liability shield works, one must understand the general rules of liability for "failure to warn" in products liability. A product may be defective because of inadequate warnings or instructions.<sup>13</sup> In states that follow section

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6. See *Vitanza*, 778 A.2d at 832. "The learned intermediary doctrine provides, in general terms, that adequate warnings to a prescribing physician obviate the need for a manufacturer of a prescription drug to warn ultimate consumers." *Id.*

7. *Hruska v. Parke, Davis & Co.*, 6 F.2d 536 (8th Cir. 1925).

8. *Karl*, 647 S.E.2d at 906 (tracing the history of the concept behind the learned intermediary doctrine back to *Hruska*).

9. See *id.* (citing *Ogders v. Ortho Pharm. Corp.*, 609 F. Supp. 867, 873 n.12 (E.D. Mich. 1985)) ("The first instance in which a court actually concluded that a manufacturer's duty to warn was satisfied by providing warnings to a prescribing physician is the 1948 case of *Marcus v. Specific Pharms.*, 191 Misc. 285, 77 N.Y.S.2d 508 (N.Y. Sup. Ct. 1948).").

10. See *id.* at 907 n.11 (citing *Sterling Drug Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1966)) (noting how the Eighth Circuit described the physician as a "learned intermediary between the purchaser and the manufacturer," who, if properly warned, was in the best position to keep the consumer from danger).

11. Susan A. Casey, Comment, *Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine*, 19 WM. MITCHELL L. REV. 931, 937 (1993). "From this relatively inauspicious inception, the doctrine of the learned intermediary emerged as an accepted tort principle that has been invoked either directly or indirectly in nearly every case where a plaintiff brought a warning-related action against a prescription drug manufacturer." *Id.*

12. Bernard J. Garbutt III & Melinda E. Hofmann, *Recent Developments in Pharmaceutical Products Liability Law: Failure to Warn, the Learned Intermediary Defense, and Other Issues in the New Millennium*, 58 FOOD & DRUG L.J. 269, 286 (2003).

13. *Vitanza v. Upjohn Co.*, 778 A.2d 829, 835 (Conn. 2001) (citing *Hill v. Searle Labs.*, 884 F.2d 1064, 1067 (8th Cir. 1989)) (holding that "defect" is not limited to matters of error in manufacturing).

402A of the Second Restatement of Torts, a manufacturer is held strictly liable for physical harm resulting from a product that is “in a defective condition unreasonably dangerous to the user.”<sup>14</sup> However, proper warnings may “prevent a product from being unreasonably dangerous.”<sup>15</sup>

Generally, a manufacturer has a duty to warn the ultimate user of any known dangers associated with its products.<sup>16</sup> However, the Second Restatement carved out an important exception to this general rule for manufacturers of prescription products.<sup>17</sup> This exception, commonly referred to as the learned intermediary doctrine, does not require the manufacturer to warn the ultimate consumer directly if it has provided adequate warning to the prescribing physician.<sup>18</sup> The doctrine is based on the principle that prescribing physicians are in the best position to evaluate the patient’s needs to assess the risks and benefits of different treatment options.<sup>19</sup> Another court has explained that the manufacturer is not required to warn the patient because the patient cannot access prescription drugs and medical devices without the intervention of the learned intermediary, i.e., the doctor.<sup>20</sup> Thus, the health care provider is in a better position to warn the patient than the manufacturer.<sup>21</sup>

The Restatement Third of Torts, which governs products liability, retained what the drafters considered “the traditional rule” for duty to warn in the prescription drug and device context by explicitly adopting the learned intermediary doctrine.<sup>22</sup> The comments to this section explain “that only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy.”<sup>23</sup> The health care professional then has a duty to provide the appropriate information to allow the patient to make an informed choice.<sup>24</sup>

## 2. *The Current State of the Learned Intermediary Doctrine*

Courts dispute how many states have adopted the learned intermediary doctrine.<sup>25</sup>

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14. RESTATEMENT (SECOND) OF TORTS § 402A (1965).

15. *Vitanza*, 778 A.2d at 836 (citing RESTATEMENT (SECOND) OF TORTS § 402A cmt. J (1965)).

16. *Id.* (citing *Tomer v. American Home Prod. Corp.*, 368 A.2d 35, 35 (1976)).

17. *See id.* (noting that “[t]he learned intermediary doctrine, which is supported by comment (k) to § 402A of the Restatement (Second) of Torts, is an exception to this general rule”).

18. *Id.* at 836–37 (citing *Vitanza v. Upjohn Co.*, 48 F. Supp. 2d 124, 128 (D. Conn. 1999)).

19. *Id.*

20. *See Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1368 (S.D. Fla. 2007) (finding this rationale for the doctrine justified its extension in the context of medical devices).

21. *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 905–06 n.9 (W. Va. 2007) (citing *McCombs v. Synthes*, 587 S.E.2d 594, 595 (Ga. 2003)). While this Note does not consider the role of the pharmacist under the application of the learned intermediary doctrine, for a discussion of some courts’ imposition of strict liability on pharmacists for failure to warn, see generally James Barney, Note, *Dancing Towards Disaster or the Race to Rationality: The Demise of the Learned Intermediary Standard and the Pharmacists’ Duty to Warn*, 39 GONZ. L. REV. 399, 418 (2004) (advocating that Congress should “curb the erosion of the learned intermediary standard” by preempting state law through the adoption of section 6(d) of the Restatement (Third) of Torts: Product Liability as a “nationwide standard”).

22. RESTATEMENT (THIRD) OF TORTS § 6(d)(1) cmt. a (1997).

23. *Id.* § 6(d)(1) cmt. b.

24. *Id.*

25. *See Karl*, 647 S.E.2d at 903–05 (comparing survey findings of three different courts).

Some surveys include those states in which a lower state court has adopted the doctrine or in which a federal court applying state law has concluded that the state high court would adopt the doctrine if given the opportunity.<sup>26</sup> The most inclusive survey concluded that 48 states, the District of Columbia, and Puerto Rico have applied or recognized the learned intermediary doctrine.<sup>27</sup> The Supreme Court of Connecticut relied on similar data and claimed to join the “overwhelming majority” of jurisdictions by adopting the learned intermediary doctrine.<sup>28</sup> On the other hand, the Supreme Court of Appeals of West Virginia, in considering only those states where the highest state court or the state legislature had adopted the doctrine, found that only 22 states had expressly adopted the learned intermediary doctrine.<sup>29</sup> The Supreme Court of Appeals of West Virginia concluded that while a majority of state high courts have adopted the doctrine, it is not “the *overwhelming majority* that has often been suggested by courts and commentators.”<sup>30</sup> While there is no consensus on how many jurisdictions have adopted the learned intermediary doctrine, since only one court<sup>31</sup> has rejected it outright thus far, the doctrine seems to remain the majority view.

### *3. Adapting to New Products and Problems: The Creation of Exceptions to the Learned Intermediary Rule*

One commentator noted that “[a]lmost as soon as the Eighth Circuit Court of Appeals first articulated the learned intermediary doctrine in 1966, courts began limiting its effect by exempting claims arising from specific medical products.”<sup>32</sup> According to the Supreme Court of Appeals of West Virginia, “[m]any jurisdictions have addressed the shortcomings of the learned intermediary doctrine by developing various exceptions,”<sup>33</sup> including exceptions for vaccine inoculations,<sup>34</sup> oral contraceptives,<sup>35</sup> contraceptive devices,<sup>36</sup> over-promoted drugs,<sup>37</sup> and drugs withdrawn from the market.<sup>38</sup> One

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26. *Id.*

27. *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 806–09 (E.D. Tex. 2002). Interestingly, the court noted that Vermont was the only state in which no court seemed to have ever considered the applicability of the learned intermediary doctrine. For a comprehensive analysis of the Norplant litigation, see generally Stacey Leffler Ravetta, Note, *How Many Times Must the Question Be Answered? The Application of the Learned Intermediary Doctrine in the Norplant Contraceptive Products Liability Litigation*, 30 GOLDEN GATE U. L. REV. 331 (2000) (analyzing the federal court’s application of the learned intermediary doctrine in this failure to warn action).

28. *Vitanza v. Upjohn Co.*, 778 A.2d 829, 838 (Conn. 2001) (finding 44 other jurisdictions to have adopted the doctrine and concluding that “[t]he wealth of decisions adopting the doctrine is highly persuasive”).

29. *Karl*, 647 S.E.2d at 903–04 (finding that the highest courts of the following states have expressly adopted the learned intermediary doctrine: Alabama, Alaska, Arkansas, California, Connecticut, Delaware, Florida, Georgia, Illinois, Kansas, Kentucky, Mississippi, Montana, Nebraska, New Jersey, New York, Ohio, Oklahoma, Oregon, Pennsylvania, Tennessee). In addition, North Carolina has adopted the doctrine by statute. *Id.*

30. *Id.* at 905 (emphasis in original).

31. *See id.* at 914 (rejecting the learned intermediary doctrine).

32. *Casey*, *supra* note 11, at 933.

33. *Karl*, 647 S.E.2d at 911.

34. *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 131 (9th Cir. 1968).

35. *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 69–70 (Mass. 1985), *cert. denied*, 474 U.S. 920 (1985).

36. *Hill v. Searle Labs.*, 884 F.2d 1064, 1070–71 (8th Cir. 1989).

commentator concluded that “the central theme, consistent among all of the cases finding an exception to the learned intermediary doctrine, is that the physician-patient relationship is not the same as in typical treatment scenarios.”<sup>39</sup> When this premise, upon which the learned intermediary doctrine is built, is not present, a court may require the drug manufacturer to deliver a warning directly to the consumer.<sup>40</sup> However, one commentator noted that “[t]hese cases illuminate the inconsistencies among courts in finding exceptions to the learned intermediary doctrine and demonstrate their resistance to dislodge this well established doctrine.”<sup>41</sup>

The Third Restatement of Torts,<sup>42</sup> which deals exclusively with products liability, has adopted several common law exceptions that have developed since the traditional rule’s origin. The Restatement requires the manufacturer to provide warnings directly to the consumer 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.<sup>43</sup> The comments to the Restatement note that this provision is applicable when drugs “are dispensed or administered to patients without the personal intervention or evaluation of a health-care provider” such as with mass inoculations distributed in clinics.<sup>44</sup> It may also be appropriate to impose on the manufacturer a duty to warn the patient directly when the “health-care provider has a much-diminished role as an evaluator or decisionmaker.”<sup>45</sup> Comment e also poses the question of whether a DTC advertising exception should be created, stating both sides of the argument, but ultimately “leaves to developing case law” whether this exception should be recognized.<sup>46</sup> However, the drafters had originally taken the position that when prescription drugs were advertised to consumers, “drug manufacturers forfeited their ‘learned intermediary’ immunity.”<sup>47</sup> Yet, the American Law Institute cautioned the drafters about taking this position without support in the case law.<sup>48</sup> One of the drafters, Professor Twerski, believed that the “case law would in quick order vindicate [the drafters’] original position.”<sup>49</sup> As Professor

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37. *Proctor v. Davis*, 682 N.E.2d 1203, 1212–16 (Ill. App. Ct. 1997), *cert. denied*, 689 N.E.2d 1146 (Ill. 1997).

38. *Nichols v. McNeilab, Inc.*, 850 F. Supp. 562, 565 (E.D. Mich. 1993).

39. Jeffrey J. Wiseman, *Annual Survey of South Carolina Law: Tort Law: Another Factor in the “Decisional Calculus”: The Learned Intermediary Doctrine, the Physician-Patient Relationship, and Direct-to-Consumer Marketing*, 52 S.C. L. REV. 993, 1009 (2001).

40. *See, e.g., Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 131 (9th Cir. 1968) (holding that a manufacturer must ensure that warnings about its prescription vaccine reach consumers who are offered the vaccine at mass immunization clinics).

41. Wiseman, *supra* note 39, at 1008.

42. RESTATEMENT (THIRD) OF TORTS (1997).

43. *Id.* § 6(d)(2).

44. *Id.* § 6 cmt. e.

45. *Id.* § 6 cmt. b.

46. *Id.* § 6 cmt. e.

47. Aaron D. Twerski, *Liability for Direct Advertising of Drugs to Consumers: An Idea Whose Time Has Not Come*, 33 HOFSTRA L. REV. 1149, 1150 (2005). Interestingly, Professor Twerski has changed his position and is now against a DTC advertising exception. *Id.* at 1153. He now believes that “it cannot glibly be said, ‘If you can successfully market a drug, you can adequately warn against its side effects.’ The two are very different enterprises.” *Id.* He concluded that “[w]ithout the learned intermediary rule, direct advertising failure-to-warn cases are likely to constitute an expansive and expensive category of liability.” *Id.*

48. *Id.* at 1150.

49. Twerski, *supra* note 47, at 1150.

Twerski commented, “[t]he ink was hardly dry on the final version of the Products Liability Restatement when the New Jersey Supreme Court wrote its bombshell decision in *Perez v. Wyeth Laboratories, Inc.*,” becoming the first court to recognize this DTC advertising exception.<sup>50</sup>

*B. Choosing the Road Less Traveled: Perez and Karl*

*1. The Perez Court’s Adoption of a Direct-to-Consumer Advertising Exception*

In *Perez*, the Supreme Court of New Jersey went further than any other court had ever gone by declaring that “[t]he direct marketing of drugs to consumers generates a corresponding duty requiring manufacturers to warn of defects in the product.”<sup>51</sup> The *Perez* court held that the learned intermediary doctrine rests on four premises: (1) reluctance to undermine the doctor-patient relationship; (2) absence of the need for the patient’s informed consent in the era of “doctor knows best”; (3) inability of drug manufacturers to communicate with patients; and (4) complexity of the subject.<sup>52</sup> The *Perez* court stated that when all of these premises are absent, the learned intermediary doctrine exception “simply drops out of the calculus,” thus requiring pharmaceutical manufacturers to comply with the general duty to warn the ultimate consumer.<sup>53</sup> In *Perez*, the court concluded that all four premises were absent in the DTC advertising of prescription drugs.<sup>54</sup> However, rather than strike down the learned intermediary doctrine entirely because of outdated images of health care,<sup>55</sup> the *Perez* court carved out a new exception, requiring manufacturers who engage in DTC advertising to provide some level of warning to the consumers to whom they advertise.<sup>56</sup>

*2. The Scholarly Response to Perez and the Direct-to-Consumer Advertising Exception*

To some commentators, the *Perez* court’s boldly worded opinion seemed a sign of things to come: widespread acceptance of the DTC advertising exception to the learned intermediary doctrine. Professor Twerski called the opinion “a tour-de-force.”<sup>57</sup> However, other commentators concluded that *Perez* was “an outlier in the abundant case law upholding the learned intermediary doctrine” and was “unlikely to gain general acceptance . . . in the near future.”<sup>58</sup> Others were simply ambivalent about whether courts

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50. *Id.*

51. *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245, 1263 (N.J. 1999).

52. *Id.* at 1255 (citing Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141, 157–59 (1997)).

53. *Id.* at 1256 (quoting *Edwards v. Basel Pharms.*, 116 F.3d 1341, 1343 (10th Cir. 1997)).

54. *See id.* (citing *Casey*, *supra* note 11, at 956) (stating that “[c]onsumer-directed advertising of pharmaceuticals thus belies each of the premises on which the learned intermediary doctrine rests”).

55. *See id.* at 1246 (opining that “[o]ur medical-legal jurisprudence is based on images of health care that no longer exist”).

56. *See Perez*, 734 A.2d at 1263 (concluding that “[t]he direct marketing of drugs to consumers generates a corresponding duty requiring manufacturers to warn of defects in the product”).

57. Twerski, *supra* note 47, at 1150.

58. *See, e.g.*, Paul F. Strain & Christina L. Gaarder, *Direct-to-Consumer Advertising and the Learned Intermediary Doctrine: Unsettling a Settled Question*, 30 U. BALT. L. REV. 377, 387 (2001) (predicting that Maryland and other jurisdictions would choose not to follow *Perez*).

would follow *Perez*.<sup>59</sup> Some commentators sought to predict whether *Perez* would lead to the end of DTC advertising or simply an increase in requests for pre-screening of advertisements by the FDA.<sup>60</sup>

After *Perez*, many commentators quickly weighed in on the merits of a DTC advertising exception to the learned intermediary doctrine. Some commentators agreed with *Perez* that there was good cause to create an exception to the learned intermediary doctrine because, in their opinion, mass marketing had destroyed the notion of the physician-patient relationship upon which the doctrine was premised.<sup>61</sup> Those writing in favor of such an exception often argued that drug manufacturers should not be immune from liability for failure to warn when they benefited from increased drug sales by advertising directly to the consumer.<sup>62</sup>

Those who spoke out against the creation of such an exception often argued: (1) the physician-patient relationship remained “fundamentally unchanged,” (2) another exception would have “disastrous effects, both in terms of technological advancements and litigation costs,” and (3) that adequate warnings would be “especially hard to convey to each and every consumer of a particular product.”<sup>63</sup> Some feared that it would decrease the pharmaceutical companies’ incentive to produce and market risky drugs that would be very beneficial to some consumers.<sup>64</sup> One commentator concluded that because there has been “no clear, substantial change” in the physician-patient relationships, courts should recognize that “DTC advertising is simply another factor in the physician’s decisional calculus in the treatment of the patient.”<sup>65</sup>

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59. See, e.g., Garbutt & Hofmann, *supra* note 12, at 286 (“[I]t remains to be seen whether a DTC advertising exception to the learned intermediary doctrine will be recognized. Pharmaceutical companies should nevertheless be aware of the possibility of increased liability.”).

60. Yonni D. Fushman, Note, *Perez v. Wyeth Labs., Inc.: Toward Creating a Direct-To-Consumer Advertisement Exception to the Learned Intermediary Doctrine*, 80 B.U. L. REV. 1161, 1181 (2000) (predicting that drug companies would likely submit their ads for pre-screening but would continue advertising to consumers because of the large amount of revenue generated by such advertising).

61. See, e.g., Amy D. White, Note, *The Mass Marketing of Prescription Drugs and Its Effect on the Learned Intermediary Doctrine*, 25 OKLA. CITY U. L. REV. 745, 770 (2000) (arguing that “the learned intermediary doctrine may have served a valuable purpose in the days before mass marketing, but with the emergence of mass marketing to consumers, this valuable purpose is no longer achieved”).

62. See, e.g., Bradford B. Lear, Note, *The Learned Intermediary Doctrine in the Age of Direct Consumer Advertising*, 65 MO. L. REV. 1101, 1115 (2000). “Without the exception, drug manufacturers can hide behind the learned intermediary doctrine and continue to present information regarding the benefits of their products without being required to inform the consumer of the risks.” *Id.*

63. Jack B. Harrison & Mina J. Jefferson, “*Some Accurate Information is Better than No Information At All*”: *Arguments Against an Exception to the Learned Intermediary Doctrine Based on Direct-to-Consumer Advertising*, 78 OR. L. REV. 605, 620 (1999) (arguing that creating another “exception based on DTC advertising will have disastrous effects, both in terms of technological advancements and litigation costs”). For further arguments against creating a direct-to-consumer advertising exception, see, e.g., Mae Joanne Rosok, Note, *Direct-to-Consumer Advertising of Prescription Drugs: After a Decade of Speculation, Courts Consider Another Exception to the Learned Intermediary Rule*, 24 SEATTLE U. L. REV. 629, 660 (2000) (arguing that “[n]either case law precedent nor policy arguments support” the creation of a direct-to-consumer exception).

64. Fushman, *supra* note 60, at 1182.

65. Wiseman, *supra* note 39, at 1016–17.

### 3. *The Judicial Response to Perez and the Direct-to-Consumer Advertising Exception in New Jersey*

While *Perez* appeared to introduce a revolutionary approach into New Jersey's "failure to warn" jurisprudence, the state's lower courts have narrowly read the *Perez* DTC advertising exception.<sup>66</sup> The *Perez* decision did not explain whether a failure to show actual influence from direct advertising would defeat the applicability of the DTC exception or simply defeat causation.<sup>67</sup> In applying *Perez*, a federal district court held that "it is clear that a plaintiff who has never seen any advertising cannot be harmed by flaws in that advertising."<sup>68</sup>

Judge Dreier, a former New Jersey appellate judge, noted that, "despite the apparently pro-plaintiff language of the *Perez* opinion, the New Jersey Supreme Court has announced a rather conservative rule."<sup>69</sup> Judge Dreier argued that because of the rebuttable presumption that a warning is adequate, which arises when the FDA pre-approves or gives a favorable comment on DTC advertising, absent fraud or concealment by the manufacturer, it is highly unusual for a plaintiff's case to survive summary judgment.<sup>70</sup> Hence, Judge Dreier concludes that "the exuberance of plaintiff attorneys over *Perez* should be short-lived. Read properly, the *Perez* opinion is a victory for the defense."<sup>71</sup>

In a more recent article, Judge Dreier pointed out that no reported New Jersey court decisions since *Perez* have imposed liability for DTC advertising.<sup>72</sup> In fact, there appear to be no reported cases in which a New Jersey court applied the DTC advertising exception to hold a drug manufacturer liable. Thus, *Perez* seems to have had little, if any, impact in New Jersey.

### 4. *Impact of Perez and the Direct-to-Consumer Advertising Exception Outside of New Jersey*

One commentator predicted that *Perez* would be "extremely significant," suggesting that it would lead other states to accept a similar DTC advertising exception.<sup>73</sup> But others, like Judge Dreier, concluded that "it is unlikely that another state resolving this issue will go beyond New Jersey's resolution of [DTC] advertising liability."<sup>74</sup> For the most part, *Perez* seems to have brought about little, if any, change in other jurisdictions.

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66. See, e.g., *Banner v. Hoffmann-La Roche Inc.*, 891 A.2d 1229, 1236 (N.J. Super. Ct. App. Div. 2006) (holding that "the placement of informational brochures in a physician's office" did not qualify for the DTC exception because it "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").

67. *Appleby v. Glaxo Wellcome, Inc.*, No. 04-0062, 2005 WL 3440440, at \*4 (D.N.J. Dec. 13, 2005) (citing *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245, 1260 (N.J. 1999)).

68. *Id.*

69. William A. Dreier, *Direct-to-Consumer Advertising Liability: An Empty Gift to Plaintiffs*, 30 SETON HALL L. REV. 806, 808 (2000) [hereinafter Dreier (2000)].

70. *Id.* at 825.

71. *Id.*

72. William A. Dreier, *Liability for Drug Advertising, Warnings, and Frauds*, 58 RUTGERS L. REV. 615, 646 (2006) [hereinafter Dreier (2006)].

73. Fushman, *supra* note 60, at 1181.

74. Dreier (2000), *supra* note 69, at 826.

In fact, no other state has followed New Jersey's lead in carving out a broad DTC advertising exception to the learned intermediary doctrine.<sup>75</sup>

In 2004, a federal district court in Ohio described the *Perez* opinion as "well-reasoned."<sup>76</sup> However, the court declined to accept the plaintiff's invitation to apply *Perez*'s reasoning to their claims.<sup>77</sup> The court stated that it "could not apply *Perez*'s logic even if it desired to do so" because no other state had followed New Jersey's lead in the five years following the *Perez* case.<sup>78</sup> A federal district court in Florida, sitting in diversity, agreed with the reasoning of the Ohio court and found that the Florida Supreme Court was not likely to recognize the exception.<sup>79</sup> In its opinion, the federal district court focused on the fact that no other state had followed *Perez*.<sup>80</sup>

##### 5. *The Effect of Perez on the Viability of the Learned Intermediary Doctrine*

To some, the *Perez* court's boldly worded opinion seemed to suggest the pending demise of the learned intermediary doctrine. *Perez* appears to have led to a marked increase in scholarly dialogue on the merits of the learned intermediary doctrine with students, scholars, and practitioners all weighing in.<sup>81</sup> One commentator asked whether a "Pandora's Box" had been opened that would allow "the learned intermediary doctrine to be swallowed by this trend of judicial exceptions."<sup>82</sup> Meanwhile, the rising use of the Internet led some to suggest, "[i]n the wake of *Perez*, there are indications that other

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75. See *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1376 (S.D. Fla. 2007) (noting that "[i]t is now eight years since *Perez* was decided, and no other state has followed suit"); see also Dreier (2006), *supra* note 72, at 646 ("The action has apparently moved on. In New Jersey and nationally, the focus in the advertising cases involving economic losses has shifted from direct-to-consumer advertising liability and even common-law product liability warning defect claims, to common law fraud and consumer fraud actions."). This Note does not explore these fraud actions in any detail.

76. *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 812 (N.D. Ohio 2004).

77. *Id.*

78. *Id.*

79. *Beale*, 492 F. Supp. 2d at 1376.

80. *Id.*

81. For arguments in support of the learned intermediary doctrine, see, e.g., Laurie K. Marshall, Note, *Keeping the Duty to Warn Patients of the Risks and Side Effects of Mass-Marketed Prescription Drugs Where it Belongs: With Their Physicians*, 26 DAYTON L. REV. 95, 97 (2000) (arguing that "holding a manufacturer who mass-markets prescription drugs liable for this duty to warn the patient directly will ultimately harm, not help, consumers"); Richard C. Ausness, *Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?*, 37 WAKE FOREST L. REV. 97 (2002) (arguing that courts should be cautious in eliminating the learned intermediary doctrine because it will lead to increased liability that will impose costs on society, including decreased availability of drugs and increased prices). For arguments against the learned intermediary doctrine, see Kate Miller, Note, *Hormone Replacement Therapy in the Wake of the Women's Health Initiative Study: An Opportunity to Reexamine the Learned Intermediary Doctrine*, 12 WM. & MARY J. WOMEN & L. 239, 266 (2005) (arguing that expansion of "the oral contraceptives exception to include hormone replacement therapy presents reluctant courts with the most palatable means of chiseling away at the learned intermediary doctrine"); Sheryl Calabro, Note, *Breaking the Shield of the Learned Intermediary Doctrine: Placing the Blame Where it Belongs*, 25 CARDOZO L. REV. 2241, 2306 (2004) (arguing that courts should employ a flexible approach by applying the learned intermediary doctrine only when the physician is still the party who is best able to warn the patient).

82. Timothy McIntire, Note, *Legal and Quality of Patient Care Issues Arising from Direct-to-Consumer Pharmaceutical Sales*, 33 U. MEM. L. REV. 105, 128 (2002).

factors may further erode the learned intermediary defense.”<sup>83</sup> Professor Twerski also believed that *Perez* “would take its place in products liability history as the case that broke the dam” and would bring the learned intermediary doctrine tumbling down.<sup>84</sup> Thus, he was just as surprised as others when “[c]ourts did not sign on to the revolution.”<sup>85</sup>

However, some commentators did not anticipate any kind of judicial revolution against the learned intermediary doctrine. Judge Dreier saw no reason for concern, noting that the *Perez* court had acknowledged the continued applicability of the learned intermediary doctrine in New Jersey, “which it did not consider to be in any way diminished by the new, albeit thin, cause of action based upon consumer advertising.”<sup>86</sup> Most commentators, as well as courts, seemed to believe that the learned intermediary doctrine was still viable because it was an important judicial mechanism to allocate the costs and risks so as to encourage continued production of prescription drugs.<sup>87</sup> Two years after *Perez*, the Connecticut Supreme Court adopted the learned intermediary doctrine despite recognizing that “the health care industry has undergone substantial changes since the learned intermediary doctrine was first announced in *Sterling Drug, Inc. v. Cornish*.”<sup>88</sup> The court acknowledged that courts are able to deal with these changing circumstances by recognizing exceptions to the general rule, but decided it was not necessary to adopt such an exception in this case where there was a traditional doctor-patient relationship.<sup>89</sup> In addition to Connecticut, three other state high courts have adopted the learned intermediary doctrine since *Perez*.<sup>90</sup> As one commentator concluded eight years after *Perez*, “the learned intermediary doctrine [is] as timely as ever.”<sup>91</sup>

While noting that no other courts have followed *Perez*, some commentators still suggest that “as DTC advertising becomes more prolific, *Perez* may foreshadow a transformation away from the traditional application of the ‘learned intermediary

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83. Garbutt & Hofmann, *supra* note 12, at 276. For a discussion of the difficulties in applying the learned intermediary doctrine in an internet prescribing context, see generally Chester Chuang, Note, *Is There a Doctor in the House? Using Failure-to-Warn Liability to Enhance the Safety of Online Prescribing*, 75 N.Y.U. L. REV. 1452, 1476–88 (2000) (concluding that manufacturers would likely be required to warn the consumer directly and suggesting ways that manufacturers could use technology to satisfy this duty to warn).

84. Twerski, *supra* note 47, at 1150–51.

85. *Id.*

86. Dreier (2006), *supra* note 72, at 617.

87. See Wiseman, *supra* note 39, at 1002.

The courts have recognized this value by creating a protective device that balances the need to hold a manufacturer liable if that manufacturer fails to meet a duty of care with the general policy of creating a system that will not discourage the production of an overall useful product, even though, because of the drug’s unique nature, the product will almost assuredly cause injury to someone.

*Id.*

88. *Vitanza v. Upjohn Co.*, 778 A.2d 829, 846 (Conn. 2001).

89. *Id.* at 846–47.

90. See *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 908–09 (W. Va. 2007) (citing *McCombs v. Synthes*, 587 S.E.2d 594 (Ga. 2003)); *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758 (Ky. 2004); *Freeman v. Hoffman-La Roche, Inc.* 618 N.W.2d 827 (Neb. 2000)).

91. Jennifer Girod, Note, *The Learned Intermediary Doctrine: An Efficient Protection for Patients, Past and Present*, 40 IND. L. REV. 397, 398 (2007) (arguing that while doctor-patient relationships have changed since the learned intermediary doctrine was first adopted, the primary justification for the doctrine, the disparity between physician and patient knowledge, still exists today).

doctrine.”<sup>92</sup> While *Perez* sparked much discussion in courts throughout the country, the learned intermediary doctrine remained largely unaffected.<sup>93</sup> This changed in June 2007 when the Supreme Court of Appeals of West Virginia picked up where *Perez* left off. Instead of simply adopting a narrow exception to the learned intermediary doctrine as the *Perez* court did, the *Karl* court used the *Perez* court’s reasoning to refuse to adopt the learned intermediary doctrine altogether.<sup>94</sup>

#### 6. *The Karl Court’s Rejection of the Learned Intermediary Doctrine*

The Supreme Court of Appeals of West Virginia took the road less traveled by declining to adopt the learned intermediary doctrine in *State ex rel. Johnson & Johnson Corp. v. Karl*.<sup>95</sup> In *Karl*, the estate of a woman who died after using Propulsid,<sup>96</sup> a drug used to treat heartburn, filed a products liability action in the Circuit Court of Marshall County, West Virginia against the manufacturer for failure to provide adequate warnings.<sup>97</sup> The manufacturer filed a motion for summary judgment asserting that it had no duty to warn the consumer under the learned intermediary doctrine since it had provided adequate warning to the physician.<sup>98</sup> However, the court found that there were disputed factual questions and denied the motion.<sup>99</sup> The manufacturer again asserted the learned intermediary doctrine in a motion in limine to exclude any evidence or argument by the Estate that the manufacturer had a duty to provide warnings to the decedent.<sup>100</sup> The circuit court found that the Supreme Court of Appeals of West Virginia had not yet recognized the learned intermediary doctrine and denied the manufacturer’s motion.<sup>101</sup> The manufacturer then filed a petition with the Supreme Court of Appeals for a writ of prohibition to have the court prohibit enforcement of the circuit court’s order.<sup>102</sup> Thus, this case came to the Supreme Court of Appeals before trial on the narrow legal question of whether the circuit court had been correct in refusing to apply the learned intermediary doctrine.

Confronted with this legal question of first impression, the *Karl* court picked up where the *Perez* court left off. “After thorough consideration of the learned intermediary

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92. Audiey C. Kao & Erica Ozanne Linden, *Direct-to-Consumer Advertising and the Internet: Informational Privacy, Product Liability and Organizational Responsibility*, 46 ST. LOUIS U. L.J. 157, 171 (2002).

93. See, e.g., *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1376–77 (S.D. Fla. 2007); *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 812 (N.D. Ohio 2004); *Vitanza v. Upjohn Co.*, 778 A.2d 829, 846–47 (Conn. 2001).

94. *Karl*, 647 S.E.2d at 914.

95. See *id.* (holding that “[w]e decline to adopt the learned intermediary exception to this general rule”).

96. The drug, which had been used by over 30 million people, was withdrawn from the market in early 2000 after having been linked to approximately 80 deaths. Sheryl Gay Stolberg, *Heartburn Drug Linked to Deaths to Be Withdrawn*, N.Y. TIMES, Mar. 24, 2000, at A15, available at <http://query.nytimes.com/gst/fullpage.html?res=9507EFDC153DF937A15750C0A9669C8B63>. For a detailed account of the problems that resulted from Propulsid, see Gardiner Harris & Eric Koli, *Lucrative Drug, Danger Signals and the F.D.A.*, N.Y. TIMES, June 10, 2005, at A1, available at <http://www.nytimes.com/2005/06/10/business/10drug.html>.

97. *Karl*, 647 S.E.2d at 901.

98. *Id.*

99. *Id.*

100. *Id.*

101. *Id.* at 914.

102. *Karl*, 647 S.E.2d at 901.

doctrine in light of the current state of the prescription drug industry and physician/patient relationships,” the Supreme Court of Appeals of West Virginia declined to adopt this doctrine.<sup>103</sup> The *Karl* court cited *Perez* with approval<sup>104</sup> and concluded that the justifications for the learned intermediary doctrine were “outdated and unpersuasive.”<sup>105</sup> The *Karl* court also expressed concern over consumers’ increased exposure to harm that it believed had resulted from the large increase in DTC advertising.<sup>106</sup> While these concerns led the *Perez* court to create an exception to the learned intermediary doctrine, these same concerns led to a wholesale rejection of the doctrine by the *Karl* court just eight years after *Perez*.<sup>107</sup>

The *Karl* court concluded that it could “ascertain no benefit in adopting a doctrine that would require the simultaneous adoption of numerous exceptions in order to be justly utilized.”<sup>108</sup> The *Karl* court concluded that if drug manufacturers are able to provide adequate warnings under the exceptions to the learned intermediary doctrine, then they should “experience no substantial impediment to providing adequate warnings to consumers in general.”<sup>109</sup> And with that the learned intermediary doctrine met its demise at the hands of a state high court for the first time. It was not long before practitioners began to ask whether *Karl* was a “harbinger[] of things to come.”<sup>110</sup> Commentators have already begun to weigh in on whether courts should continue to follow the learned intermediary doctrine.<sup>111</sup> While the learned intermediary doctrine is still generally accepted, the Supreme Court of Appeals of West Virginia has awoken dormant fears about the continued viability of the doctrine in this age of DTC advertising.

### III. ANALYSIS

While the outcome of the *Karl* decision was striking, the road the Supreme Court of Appeals of West Virginia took to get there is even more striking. Despite the strong support for the learned intermediary doctrine, the *Karl* court did not hesitate in building upon *Perez* to reject the learned intermediary doctrine outright. As a result, the *Karl* decision has sparked an assault upon the learned intermediary doctrine. As this Part seeks to demonstrate, this bold decision will likely have far-reaching consequences for drug manufacturers and consumers alike.

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103. *Id.*

104. *Id.* at 910.

105. *Id.* at 906.

106. *Id.* at 909.

107. *Karl*, 647 S.E.2d at 914.

108. *Id.*

109. *Id.*

110. Nancy Sher Cohen & Rene L. Siemens, *Learned Intermediary Doctrine: West Virginia Supreme Court Recently Rejected Doctrine in Its Entirety; Will Others Follow Suit?*, 29 NAT'L L.J. 50, Aug. 13, 2007, S1.

111. See generally Richard B. Goetz & Karen R. Growdon, *A Defense of the Learned Intermediary Doctrine*, 63 FOOD & DRUG L.J. 421, 438 (2008) (arguing that the learned intermediary doctrine is still useful for patients and manufacturers); Jerica L. Peters, *State v. Karl: An Unreasonable Rejection of the Learned Intermediary Doctrine*, 48 JURIMETRICS J. 285 (2008) (concluding that “[t]he West Virginia Supreme Court’s decision in *Karl* was flawed” and urging states to retain the learned intermediary doctrine).

*A. Analyzing Karl Through a Post-Perez Lens*

Many courts that have directly considered whether their state high court would adopt the DTC advertising exception have concluded that the state high court would not likely adopt it. These determinations were largely based on the fact that no other state had adopted the exception. In fact, few courts have questioned the validity of the oft-used statement that the learned intermediary doctrine is a well-settled principle of law. Thus, it is striking that the Supreme Court of Appeals of West Virginia took the road less traveled by refusing to adopt the learned intermediary doctrine after concluding that acceptance of the learned intermediary doctrine was not as widespread as reported by earlier cases. The *Karl* court stated that their “own research has yielded a markedly different result” with only 22 states having adopted the learned intermediary doctrine.<sup>112</sup> Thus, the *Karl* court cleared the hurdle that so many courts had used as a complete barrier to rejection of the learned intermediary doctrine itself: that the doctrine was such a well established common law tradition that there was not adequate support to reject it.

In *Karl*, the defendant sought to shield itself behind a long line of federal district cases, in which both federal district courts in West Virginia, sitting in diversity, had predicted that the Supreme Court of Appeals of West Virginia would adopt the doctrine.<sup>113</sup> Yet, the *Karl* court concluded that it was not bound by this speculation by the federal courts.<sup>114</sup> The court seemed to suggest that the federal district courts had promulgated a great misperception: that the learned intermediary doctrine was the overwhelming majority rule. In refusing to listen to its federal brethren, the *Karl* court seemed to suggest that this supposedly overwhelming majority rests upon an unstable foundation that could quickly come tumbling down in state courts around the country.

Once the court determined that it was not bound by the general level of acceptance of the learned intermediary doctrine, it launched into an extensive policy discussion considered “revolutionary” even by *Perez* standards. The court used the existence of the many exceptions to the learned intermediary doctrine as evidence that the doctrine itself has become outdated and useless.<sup>115</sup> The court stated that it could “ascertain no benefit in adopting a doctrine that would require the simultaneous adoption of numerous exceptions in order to be justly utilized.”<sup>116</sup> Thus, the *Karl* court seemed to implicitly recognize that the exceptions to the general rule had swallowed the learned intermediary doctrine as some commentators predicted would happen after *Perez*.

Yet, in the end, it seemed to be a question of which party should be responsible for bearing the risks in the development and marketing of prescription drugs. In his brief to the court, the treating physician in this case argued that the *Karl* court should refuse to adopt the learned intermediary doctrine because the doctrine “reduces the sources of recovery for injured patients, promotes the unfair allocation of liability upon local physicians while allowing the pharmaceutical companies that reap the direct beneficial gain to remain immune from their potential negligence, and simply does not properly

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112. *Karl*, 647 S.E.2d at 903–04.

113. *Id.* at 913 n.18.

114. *Id.*

115. *Id.* at 913.

116. *Id.*

reflect the modern marketplace.”<sup>117</sup> The court seemed to rely on this argument in declining to adopt the learned intermediary doctrine, concluding that:

[B]ecause it is the prescription drug manufacturers who benefit financially from the sales of prescription drugs and possess the knowledge regarding potential harms, and the ultimate consumers who bear the significant health risks of using those drugs, it is not unreasonable that prescription drug manufacturers should provide appropriate warnings to the ultimate users of their products.<sup>118</sup>

Thus, freed from the federal court decisions and the supposedly overwhelming majority, the *Karl* court ultimately made a policy decision that the pharmaceutical manufacturer—rather than the treating physician or the individual patient—should assume the risks inherent in the use of prescription drugs.

One justice went even further in a concurring opinion by arguing that it would be “unfair” to adopt the learned intermediary doctrine because “a small-town West Virginia doctor would become solely responsible for the injury to Patient Doe while an out-of-state multi-million dollar drug manufacturer is off the hook.”<sup>119</sup> This striking statement suggests that the most pertinent policy interest for one member of the slim *Karl* majority was the protection of in-state interests, such as rural doctors and consumers. It is unclear whether this will water down the effect of the majority’s opinion and lead other courts to write off *Karl* as a biased opinion existing at the extreme fringes of the products liability spectrum.

### *B. Potential Implications of Karl*

In light of the revolutionary approach of the *Karl* court, it is uncertain whether other courts will distinguish or even ignore the opinion as they did with *Perez*. Less than two weeks after the *Karl* opinion was released, a West Virginia trial court attempted to adapt to the new failure-to-warn calculus that *Karl* had created.<sup>120</sup> This court was able to avoid having to carefully consider the implications of *Karl* because the issue in the case was not whether there was a duty to warn, but whether the warning was adequate.<sup>121</sup> While ultimately inconsequential in the decision, the West Virginia court’s inclusion of this “very recent decision”<sup>122</sup> shows how quickly plaintiffs’ attorneys incorporated *Karl* into their briefs and trial strategies.

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117. Daniel W. Wilson, M.D.’s Response to Rule to Show Cause in Opposition to Petitioners Johnson & Johnson Corp. and Janssen Pharm., Inc.’s Application for the Writ of Prohibition at \*17–18, *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899 (W. Va. 2007) (No. 33211), 2006 WL 3915377.

118. *Karl*, 647 S.E.2d at 913.

119. *Id.* at 917 (Maynard, J., concurring). Interestingly, Justice Maynard was the subject of controversy when he “disqualified himself . . . from further participation in a case involving a powerful coal executive after photographs of the two men meeting in Monte Carlo in 2006 were filed in court.” Adam Liptak, *West Virginia Judge Steps Out of Case Involving a Travel Companion*, N.Y. TIMES, Jan. 19, 2008, at A15, available at <http://www.nytimes.com/2008/01/19/us/19judge.html>. The U.S. Supreme Court recently agreed to review this closely watched case. See Adam Liptak, *Supreme Court Takes on Campaign Finance Case*, N.Y. TIMES, Nov. 15, 2008, A10, available at <http://www.nytimes.com/2008/11/15/washington/15scotus.html>.

120. *Price v. Cook*, No. 99-C-12-R, 2007 WL 2154766, at \*6 (W. Va. Cir. Ct. July 9, 2007).

121. *Id.*

122. *Id.*

*1. The Assault on the Learned Intermediary Doctrine*

This quick response by plaintiffs' lawyers is not limited to West Virginia. Plaintiffs' lawyers have already begun to urge courts in other jurisdictions to follow the *Karl* court's reasoning and reject the learned intermediary doctrine.<sup>123</sup> Counsel for the plaintiff in *Kantner v. Merck*<sup>124</sup> urged an Indiana trial court to refuse to allow the defendant to use the learned intermediary doctrine as a shield from liability for failure to warn in a drug liability case.<sup>125</sup> The attorneys cited *Karl*, which they described as a "remarkable" decision, to point out that "a growing trend is emerging that rejects the learned intermediary doctrine altogether."<sup>126</sup> They asserted that since the Indiana Supreme Court has not directly addressed the learned intermediary exception, it could "follow the learned West Virginia Supreme Court's lead in rejecting such an outdated doctrine."<sup>127</sup>

In a similar lawsuit in Wyoming, plaintiff's counsel argued that "there is substantial reason to believe that the Wyoming Supreme Court, like its sister court in West Virginia, will reject the doctrine outright."<sup>128</sup> The plaintiff in this case relied on the *Karl* court's survey of states having adopted the learned intermediary doctrine, emphasizing that Wyoming is not one of the 22 states where the state high court or state legislature had adopted the doctrine.<sup>129</sup> The plaintiff urged the federal district court, sitting in diversity, to certify the question of whether the learned intermediary doctrine applies in Wyoming.<sup>130</sup> The plaintiff noted that in Wyoming, as in West Virginia, the federal district court had predicted that the state high court would adopt the doctrine if faced with the question, but "[a]s *Karl* illustrates, their predictions were wrong" in West Virginia.<sup>131</sup> While the outcome in Wyoming is unclear, the plaintiff's reliance on *Karl* in *Van Dyke* illustrates how the Supreme Court of Appeals of West Virginia has renewed the discussion over the viability of a doctrine that, until recently, courts had considered well-settled.<sup>132</sup>

Plaintiff's counsel<sup>133</sup> in another drug liability case sought to cast doubt on Georgia's

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123. See Brief of Plaintiff's Opposition to Merck's Repetitive Motion to Dismiss Plaintiff's First Amended Complaint at 12, *Kantner v. Merck & Co., Inc.*, No. 49D06-0411-PL-002185 (Ind. Super. Ct. Aug. 27, 2007), 2007 WL 3092703 (arguing the emergence of a legal trend that rejects the learned intermediary doctrine).

124. *Kantner v. Merck & Co., Inc.*, No. 49D06-0411-PL-002185 (Ind. Super. Ct. Amended Complaint filed Apr. 27, 2007). Plaintiff alleged that Merck concealed information about adverse health effects of Vioxx from consumers and healthcare professionals and is seeking the "difference between the purchase price of Vioxx and the price of much safer, cheaper and equally effective alternatives." Amended Complaint at 13, *Kantner v. Merck & Co., Inc.*, No. 49D06-0411-PL-002185 (Ind. Super. Ct. Apr. 27, 2007).

125. See Brief of Plaintiff's Opposition to Merck's Repetitive Motion to Dismiss Plaintiff's First Amended Complaint at 12, *Kantner v. Merck & Co., Inc.*, No. 49D06-0411-PL-002185 (Ind. Super. Ct. Aug. 27, 2007) (arguing against the learned intermediary doctrine in failure to warn cases).

126. *Id.*

127. *Id.*

128. Plaintiff's Motion to Certify Questions of State Law to Wyoming Supreme Court at \*17, *Van Dyke v. Glaxo Smithkline*, No. 2:05-cv-00153-ABJ (D. Wyo. Aug. 20, 2007).

129. *Id.* at \*13.

130. *Id.*

131. *Id.*

132. *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 812 (N.D. Ohio 2004).

133. Interestingly, the plaintiffs in *Van Dyke* and *Porter* were represented by the same counsel: Andy Vickery of Vickery, Waldner & Mallia, LLP in Houston, Texas. For more information about Vickery's practice, see generally Vickery, Waldner & Mallia, LLP, Andy Vickery Trial Lawyer, <http://justiceseekers.com/>

“deference to the doctrine” by citing *Karl* and *Perez*.<sup>134</sup> Unlike Wyoming, in Georgia, the state supreme court has already adopted the learned intermediary doctrine.<sup>135</sup> Therefore, plaintiff’s counsel asserted that the court was bound to follow the doctrine, unless it was willing to certify an inquiry to the Georgia Supreme Court “asking whether, in light of the current circumstances described in *Karl* the court would still adhere to it.”<sup>136</sup> Counsel for the defendant countered that “[t]he learned intermediary doctrine is well settled in Georgia law.”<sup>137</sup> Defendant’s counsel also asserted that the plaintiff’s reliance on *Karl* was “misplaced” and that the plaintiff had “mischaracterized” *Perez*.<sup>138</sup>

Plaintiff’s counsel correctly recognized that the Georgia courts are unlikely to overturn their “clear deference” to the learned intermediary doctrine even in light of the recent erosion of the doctrine in New Jersey and West Virginia.<sup>139</sup> Plaintiff’s counsel could not make the same argument they made in the Wyoming case because the Georgia Supreme Court had applied the learned intermediary doctrine as late as 2003, while no Wyoming state court had yet weighed in.<sup>140</sup> This suggests that plaintiffs’ lawyers will seek to bring lawsuits in states where the highest state court has not yet weighed in on the applicability of the learned intermediary doctrine. This was the tactic employed in *Kantner v. Merck & Co., Inc.*, a case in which the plaintiff sought to capitalize on the high state court’s failure to directly address the topic.<sup>141</sup> Thus, in the 28 states in which the state high courts have not expressly adopted or rejected the learned intermediary doctrine, *Karl* may provide plaintiffs’ lawyers with a venue to litigate whether this liability shield still makes sense in light of the changes in medical care and drug promotion that were emphasized by the *Perez* and *Karl* courts.

## 2. Another Court Weighs in on the Learned Intermediary Doctrine

A federal district court recently weighed in on the learned intermediary doctrine in

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index.cfm/aol/1/MenuItemID/158.htm (last visited Oct. 7, 2008) (detailing Vickery’s professional biography and experience in bringing drug liability suits).

134. Plaintiff’s Response to Defendant Eli Lilly and Company’s Motion for Summary Judgment on Each of Plaintiff’s Claims at \*\*13, *Porter v. Eli Lilly & Co.*, 2008 U.S. Dist. LEXIS 14273 (N.D. Ga. Feb. 25, 2008) (No. 1:06-cv-01297-JOF), 2007 U.S. Dist. Ct. Motions LEXIS 7795.

135. *McCombs v. Synthes*, 587 S.E.2d 594, 595 (Ga. 2003).

136. Plaintiff’s Response to Defendant Eli Lilly and Company’s Motion for Summary Judgment on Each of Plaintiff’s Claims at \*\*13–14, *Porter v. Eli Lilly & Co.*, 2008 U.S. Dist. LEXIS 14273 (N.D. Ga. 2008) (No. 1:06-cv-01297-JOF), 2007 U.S. Dist. Ct. Motions LEXIS 7795.

137. Defendant Eli Lilly & Company’s Reply Memorandum in Support of its Motion for Summary Judgment at \*\*11 n.5, *Porter v. Eli Lilly & Co.*, 2008 U.S. Dist. LEXIS 14273 (N.D. Ga. Feb. 25, 2008) (No. 1:06-cv-01297-JOF), 2007 U.S. Dist. Ct. Motions LEXIS 7796 (citing *Presto v. Sandoz Pharms. Corp.*, 497 S.E.2d 70, 73 (Ga. Ct. App. 1997)).

138. *Id.*

139. In its opinion, the court cited *Karl* but did not seriously consider the challenge to Georgia’s adherence to the learned intermediary doctrine. *Porter v. Eli Lilly & Co.*, No. 1:06-cv-01297-JOF, 2008 U.S. Dist. LEXIS 14273, at \*12–23 (N.D. Ga. Feb. 25, 2008).

140. *See State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 904 (W. Va. 2007) (citing *McCombs v. Synthes*, 277 Ga. 252, 253, 587 S.E.2d 594, 595 (2003)) (discussing how the Georgia Supreme Court had applied learned intermediary doctrine in a medical device context while stating that it would apply with equal force to the prescription drug context).

141. *See* Brief of Plaintiff’s Opposition to Merck’s Repetitive Motion to Dismiss Plaintiff’s First Amended Complaint at 12, *Kantner v. Merck & Co., Inc.*, No. 49D06-0411-PL-002185 (Ind. Sup. Ct. Aug. 27, 2007).

the wake of *Karl*. In *Rimbert v. Eli Lilly & Co.*,<sup>142</sup> the District of New Mexico federal court refused to grant the drug manufacturer's motion for summary judgment on a failure to warn claim because the court believed that the New Mexico Supreme Court would not adopt the learned intermediary doctrine.<sup>143</sup>

The New Mexico Supreme Court had never directly addressed the applicability of the learned intermediary doctrine under New Mexico failure-to-warn jurisprudence.<sup>144</sup> However, there were three state appellate court decisions that seemed to have adopted the learned intermediary doctrine.<sup>145</sup> These decisions by the New Mexico Court of Appeals suggested that a drug manufacturer could insulate the company from liability if it provided an adequate warning to the physician.<sup>146</sup> Interestingly, none of these cases used the term "learned intermediary doctrine."<sup>147</sup>

In *Rimbert*, the federal district court did not certify the question of whether the New Mexico Supreme Court would adopt the learned intermediary doctrine because the Supreme Court's certification rules barred it from considering the issue in this particular situation.<sup>148</sup> As a result, the federal district court set out to predict whether the New Mexico Supreme Court would adopt the learned intermediary doctrine if faced with this issue.<sup>149</sup> The *Rimbert* court concluded that the New Mexico Supreme Court would not follow the cases from the 1970s and 1980s where the New Mexico Court of Appeals had adopted the learned intermediary doctrine.<sup>150</sup> Instead, the *Rimbert* court predicted that the Supreme Court would decline to adopt the learned intermediary doctrine because "it is fundamentally inconsistent with New Mexico's strict-liability jurisprudence."<sup>151</sup>

The *Rimbert* court relied on *Karl* to conclude that the New Mexico Supreme Court would not adopt the learned intermediary doctrine. The court expressly stated that it believed the Supreme Court would be persuaded by the *Karl* court's analysis.<sup>152</sup> The court thought that the New Mexico Supreme Court would agree with the West Virginia Supreme Court that the justifications for the learned intermediary doctrine are "'largely outdated and unpersuasive."<sup>153</sup> The *Rimbert* court addressed each of these justifications in turn, finding that: (1) Because manufacturers have adequately drafted warnings for physicians, they should be able to draft sufficient warnings for consumers;<sup>154</sup> (2) patients' reliance on their physician's judgment in selecting prescription drugs does not

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142. *Rimbert v. Eli Lilly & Co.*, No. 06-0874JB/LFG, 2008 WL 4330626 (D.N.M. Aug. 22, 2008).

143. *Id.* at \*1.

144. *Id.* at \*38-39.

145. *Id.* These appellate decisions were: *Serna v. Roche Labs.*, 684 P.2d 1187 (N.M. Ct. App. 1984); *Perfetti v. McGhan Med.*, 662 P.2d 646 (N.M. Ct. App. 1983); *Hines v. St. Joseph's Hosp.*, 527 P.2d 1075 (N.M. Ct. App. 1974).

146. *See, e.g., Serna*, 684 P.2d at 1189 (stating that "[w]here the product is a prescription drug, the manufacturer's duty to warn is fulfilled if it warns the physician, not the patient" (citing *Perfetti*, 662 P.2d at 646)).

147. *Rimbert*, 2008 WL 4330626, at \*39.

148. *Id.* at \*38-39.

149. *Id.* at \*39.

150. *Id.*

151. *Id.*

152. *Rimbert*, 2008 WL 4330626, at \*42.

153. *Id.* (quoting *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 906 (W. Va. 2007)).

154. *Id.* at \*43.

mandate adoption of the learned intermediary doctrine;<sup>155</sup> (3) “refusal to adopt the learned-intermediary doctrine does not impact adversely the exercise of [the physician’s] professional judgment”;<sup>156</sup> (4) the drug manufacturer is in the best position to provide warnings to consumers;<sup>157</sup> and (5) the Supreme Court would not believe that direct warnings from drug manufacturers would interfere with the physician-patient relationship.<sup>158</sup>

Ultimately, the *Rimbert* court concluded that “the Supreme Court of New Mexico, given the opportunity in 2008, would not adopt the learned-intermediary doctrine, because of the erosion of the justifications for adoption of the doctrine, given the changing dynamics between doctors and patients, patients’ self-diagnosis, and DTC advertising by drug manufacturers.”<sup>159</sup> The import of *Rimbert* is unclear since the federal district court was simply predicting whether the New Mexico Supreme Court would adopt the learned intermediary doctrine. It is not readily apparent that the *Rimbert* court was correct in ignoring those decisions of the New Mexico Court of Appeals in which the court had purported to adopt the learned intermediary doctrine. Thus, we will have to wait and see if the decision is a sign of things to come or simply an isolated instance. Of course, this is more of a following than *Perez* ever garnered (or at least until *Karl* was decided).<sup>160</sup> At a minimum, it confirms that plaintiffs’ lawyers will continue to rely on *Karl* to challenge the learned intermediary doctrine in those states, like New Mexico, where the high state court has never expressly adopted the doctrine.

### 3. Will the Learned Intermediary Doctrine Survive This Assault?

While many plaintiffs’ attorneys are clamoring to use *Karl* to advance their efforts to dislodge the learned intermediary doctrine in other states, it is unlikely that these states will follow *Karl*. In analyzing the judicial response to *Perez* (or lack thereof) it seems as though states are hesitant to go against the status quo in drug liability cases.<sup>161</sup> After *Perez*, courts emphasized how well established the learned intermediary doctrine was.<sup>162</sup> Ultimately, this general adherence to the learned intermediary doctrine and the absence of decisions of other courts following *Perez* provided the courts a basis for their ultimate rejection of the *Perez* DTC advertising exception.<sup>163</sup>

While *Perez* involved a narrow exception to the learned intermediary doctrine when the consumer had been the target of DTC advertising, *Karl* involved a wholesale rejection of the doctrine. If courts were hesitant to adopt *Perez*’s narrow *exception* to the general rule, they are even more wary to consider *Karl*’s outright *rejection* of the general rule. In analogizing the judicial response to *Perez* to the broad rejection of the learned intermediary doctrine, it appears all but certain that courts will again decide not to upset the status quo and hold onto the learned intermediary doctrine.

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155. *Id.*

156. *Id.* at \*44.

157. *Rimbert*, 2008 WL 4330626, at \*44.

158. *Id.* at \*46.

159. *Id.*

160. See text accompanying notes 92–93.

161. See discussion *supra* Part II.B.4.

162. See *supra* notes 87–91 and accompanying text.

163. See *supra* notes 76–80 and accompanying text.

*C. West Virginia Has Taken Us All for a Ride*

While the Supreme Court of Appeals of West Virginia took the road less traveled by rejecting the learned intermediary doctrine, arguably, the court has taken all of us along. Courts are unlikely to dislodge the liability shield that the learned intermediary doctrine provides to drug manufacturers. Even though *Karl* may have little impact on the “failure to warn” jurisprudence of other states, it is likely to have real implications on the interactions between drug manufacturers and consumers. Because of *Karl*, drug manufacturers will be required to provide adequate warnings to West Virginia consumers or else potentially be liable for their failure to warn these consumers. The only other option that *Karl* leaves drug manufacturers is to not sell prescription drugs in West Virginia. However, this does not seem like a realistic option, nor is it likely that drug companies would decide not to provide direct warnings to the consumer in hopes of simply winning the “liability lottery.” While the costs of providing adequate warnings to patients for all prescription drugs is likely high, the costs of not providing warnings is likely greater. Furthermore, drug companies will likely pass these costs off to consumers. Thus, consumers will ultimately bear the costs of these patient-centered warnings.

Once drug companies have spent money developing adequate warnings for their prescription drugs in West Virginia, they are unlikely to only share these warnings with West Virginia consumers. In fact, to avoid having to use different labeling, packaging, and advertising in West Virginia and in other states, and to better apportion the costs of developing these warnings, drug companies are likely to use these same warnings in other states. Thus, in practice, *Karl* will lead manufacturers to provide warnings to consumers in other states, not because they are required to provide such warning and want to avoid liability, but because West Virginia has required such warning in order for them to avoid liability to West Virginia consumers.

West Virginia is not usually viewed as a leader in driving the common law. In fact, some groups have noted how removed the state’s jurisprudence is from the mainstream common law approach.<sup>164</sup> Others question the very integrity of the state judicial system.<sup>165</sup> Yet, in taking the road less traveled by requiring drug manufacturers to provide warnings to West Virginia consumers, West Virginia has essentially required drug manufacturers to provide warnings to all consumers. Furthermore, West Virginia courts will be left to their own devices to determine what warnings are adequate, thus establishing a kind of national standard.<sup>166</sup> Consumers, physicians, drug manufacturers,

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164. AM. TORT REFORM FOUND., JUDICIAL HELLHOLES 2007, at 11–14 (2007), available at <http://www.atra.org/reports/hellholes/report.pdf>. The American Tort Reform Foundation named West Virginia a “judicial hellhole” for “adopting theories of liability that are out of the mainstream.” *Id.* at 11. The group labeled *Karl* as “[a]nother [b]ad [d]ecision from the [s]tate’s [h]igh [c]ourt.” *Id.* at 12.

165. See generally AM. TORT REFORM FOUND., JUDICIAL HELLHOLES 2006, at 11–13 (2006), available at <http://www.atra.org/reports/hellholes/2006/hellholes2006.pdf>. In 2006, the American Tort Reform Foundation named West Virginia its number one “judicial hellhole.” *Id.*; see also Motion of Washington Legal Foundation for Leave to File Brief as Amicus Curiae in Support of Petitioner, Daniel Measurement Services, Inc. v. Eagle Research Corp., 128 S. Ct. 655 (2007) (No. 07-384), 2007 WL 3129912 (arguing that the absence of any kind of right to appeal trial court decisions and the Supreme Court of Appeals of West Virginia’s prejudicial bias towards in-state plaintiffs make it difficult for out-of-state corporations sued in West Virginia to get equal justice).

166. One could argue that such extraterritorial regulation is in violation of the Dormant Commerce Clause, but a discussion of such an issue is beyond the scope of this Note.

and legislators in other states should ask themselves whether they are content to let the West Virginia courts establish the standards that govern prescription drug warnings.

#### IV. RECOMMENDATION

West Virginia is the only state that holds drug manufacturers liable for failing to provide warnings directly to the consumer. Every other state continues to shield drug manufacturers from liability under the learned intermediary doctrine.<sup>167</sup> Thus, the only place where manufacturers have any incentive to create adequate warnings directed to the consumer is West Virginia. So long as it is the only state where drug manufacturers have a duty to warn consumers directly, then West Virginia will be able to determine the answer to important questions, including what constitutes an adequate warning, the form of the warning, and in what situations warnings are necessary under the West Virginia duty to warn.

While the answers the West Virginia courts provide to these questions have no effect on the liability of drug manufacturers in failure to warn cases in other states, they inevitably have an impact on the quality of warnings that drug manufacturers will provide to consumers across the country. The answers could have important consequences for the physician-patient relationship, treatment decisions, and the ability to recognize and avoid side effects and other adverse risks of prescription drugs. These are questions that will have an inevitable impact on the quality of health care delivery in the United States. Thus, these questions should not be left to the West Virginia courts to resolve on behalf of the rest of the states.

West Virginia's extraterritorial regulation of prescription drug warnings is a national problem that calls for a national solution. While products liability law has generally been left to the states, the problem *Karl* has created is one that Congress alone can remedy. *Perez* correctly recognized that delivery of health care and prescription drugs has seen many changes since the creation of the learned intermediary doctrine. However, the doctrine remains a justifiable compromise between the risks and costs associated with the production and distribution of risky but beneficial prescription drugs. While the application of the learned intermediary doctrine to individual cases sometimes seems unfair, to not adhere to the doctrine would hinder the production of innovative prescription drugs, which would be a tragedy for society as a whole.

The learned intermediary doctrine, with its long and storied history, is a national tradition. With the exception of *Karl*, every state court that has considered the issue has adopted the learned intermediary doctrine.<sup>168</sup> Even though the *Karl* court failed to recognize it, the learned intermediary doctrine remains the overwhelming majority view. No other state court has even entertained serious notions of rejecting the doctrine. Thus, Congress should expressly preempt *Karl* by enacting a bill to adopt the learned intermediary doctrine as a national standard so as to exempt drug manufacturers from having to warn consumers in West Virginia, or any other state, when the manufacturer

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167. Of course, some of these states have adopted specific exceptions to the learned intermediary doctrine. See *supra* Part II.A.3 (discussing the various exceptions that have been developed to the learned intermediary doctrine); see also *supra* Part II.B.1 (discussing New Jersey's adoption of a DTC advertising exception in *Perez*).

168. See *supra* Part II.A.2 (discussing the number of states that have adopted the learned intermediary rule).

provides the physician with an adequate warning.

In adopting the learned intermediary doctrine as a national standard, Congress should expressly allow states to adopt, if they so desire, exceptions to the learned intermediary doctrine. Courts have developed a host of exceptions in response to the absence or ineffectiveness of the physician-patient relationship, such as in the case of mass immunizations.<sup>169</sup> The development of such exceptions should continue to be left up to state courts and legislatures. Of course, that also means allowing states to follow *Perez*, if they so desire, by creating a DTC advertising exception. While no court outside of New Jersey has followed *Perez*,<sup>170</sup> Congress should ensure that states have the ability to adopt a DTC advertising exception in the future. If pharmaceutical manufacturers continue to rely on DTC advertising, then some states may determine that a DTC advertising exception is needed. Thus, Congress should expressly allow states to create such an exception.

Congress, of course, must be vigilant to ensure that such exceptions do not swallow the rule as some commentators feared would occur after *Perez*.<sup>171</sup> Those exceptions that are simply a means of abolishing the learned intermediary doctrine should be prohibited. In addition, Congress should require that state-created exceptions can only be effective when there is some deviation from the typical physician-patient relationship.<sup>172</sup> Such provisions will ensure that states like West Virginia are not able to make an end-run around the statute by adopting a broad exception to effectively abolish the learned intermediary doctrine.

Finally, Congress should provide that states may opt out of the learned intermediary regime if either the state high court or state legislature expressly rejects the learned intermediary doctrine. However, under this provision, the states would be expressly preempted by the federal legislation until the majority of states decide to opt out. Thus, such state action would be effective only after at least 25 states had opted out of the learned intermediary regime. This opt-out provision would prevent states like West Virginia from setting the national standard while still ensuring that states have the ability to set their own products liability policy.

In setting out to create a national standard, Congress will be forced to decide whether the judicial compromise between drug manufacturers, physicians, and consumers still makes sense. *Karl* challenged the status quo and should spark a national discussion about the learned intermediary doctrine and the assumptions that it is based upon. State high courts that have not yet directly addressed the learned intermediary doctrine are already being asked to weigh in on what was previously a well-settled issue.<sup>173</sup> One state legislature has already begun considering legislation that would effectively abolish the learned intermediary doctrine.<sup>174</sup> In the years to come, the country will see whether the

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169. See *supra* Part II.A.3 (discussing the various exceptions to the learned intermediary doctrine that have been recognized by the courts).

170. See discussion *supra* Part II.B.4.

171. See *supra* note 82 and accompanying text.

172. See *supra* notes 38–40 (discussing exceptions to the learned intermediary doctrine that are triggered when the typical physician-patient relationship is absent).

173. See *supra* Part III.B.1 (discussing cases in several states where the court has been asked to consider the applicability of the learned intermediary doctrine under state law).

174. A.B. 2690, 2007–08 Gen. Assem., Reg. Sess. (Cal. 2008), available at <http://www.leginfo.ca.gov/pub/>

states, as a whole, continue to view the doctrine as a justifiable defense for drug manufacturers, or whether they too choose to take the road less traveled and reject the learned intermediary doctrine.

#### V. CONCLUSION

When viewed in the context of the long and storied history of the learned intermediary doctrine, *Karl* seems quite a departure from the common law approach. The *Karl* court went further than those courts that have created narrow exceptions to the doctrine to justify the continued existence of the doctrine in the wake of DTC advertising. Some commentators thought that these new exceptions, most notably the DTC advertising exception created in *Perez*, would eventually swallow the general rule. However, these predictions have yet to be borne out. Every court that has considered the learned intermediary doctrine since *Perez* has sanctioned its continued existence within the state, except for West Virginia.

West Virginia has now provided more fodder to plaintiffs' counsel as they seek to further erode the learned intermediary doctrine. However, just as no states have followed *Perez* in the eight years since the New Jersey Supreme Court penned its ground-breaking opinion, other states will not likely follow *Karl* by rejecting the learned intermediary doctrine. For the time being, the learned intermediary doctrine remains the majority rule.<sup>175</sup> Because of the general adherence to the learned intermediary doctrine, drug manufacturers do not have a duty to warn prescription drug users in other states. Yet, by imposing such a duty upon drug manufacturers in West Virginia, *Karl* has effectively mandated that they provide warnings to all consumers. This extraterritorial regulation by West Virginia will effectively allow the West Virginia courts to create a national standard for prescription drug warnings.

The determination of such a standard should not be left up to the West Virginia courts. Congress should act to make the learned intermediary doctrine what the majority of courts have already determined it to be—a national standard. This is the only way to ensure that West Virginia does not bring us all along on its journey down the road less traveled.

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07-08/bill/asm/ab\_2651-2700/ab\_2690\_bill\_20080222\_introduced.pdf. For further discussion about this legislation, see Drug & Device Blog, <http://druganddevicelaw.blogspot.com> (Mar. 6, 2008, 03:48 EST).

175. See *supra* Part II.A.2 (discussing the number of states that have adopted the learned intermediary rule).