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## Learned Intermediary Doctrine in the Age of Direct Consumer Advertising, The

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Lear: Lear: Learned Intermediary Doctrine in the Age of Direct Consumer Advertising

# The Learned Intermediary Doctrine in the Age of Direct Consumer Advertising

*Doe v. Alpha Therapeutic Corp.*<sup>1</sup>

## I. INTRODUCTION

Traditionally drug manufacturers have been excused from the general duty to warn consumers about the risks associated with their products by the learned intermediary doctrine.<sup>2</sup> Though the doctrine has a sound grounding in public policy, drug companies have recently employed marketing strategies that undermine the usefulness of the learned intermediary rule. In *Doe v. Alpha Therapeutic Corp.*, the Missouri Court of Appeals for the Eastern District of Missouri recently addressed whether the learned intermediary doctrine can be used as a defense when a drug company markets a product directly to consumers. This Note discusses the learned intermediary defense and its applicability to drug companies that engage in direct-to-consumer advertising.

## II. FACTS AND HOLDING

*Doe v. Alpha Therapeutic Corp.* was a consolidated lawsuit brought by hemophiliac patients against a pharmaceutical company.<sup>3</sup> As part of their treatment, the plaintiffs were regularly prescribed Factor VIII concentrate manufactured by Alpha Therapeutic Corporation (“Alpha Therapeutic”).<sup>4</sup> At various times, the plaintiffs were diagnosed as HIV-positive and later contracted AIDS.<sup>5</sup> The evidence demonstrated that in a newsletter sent to Factor VIII concentrate users in the summer of 1983, Alpha Therapeutic reported that it had “stepped up efforts to protect hemophilia patients from AIDS.”<sup>6</sup> The newsletter also noted that scientists had uncovered evidence that suggested AIDS was not necessarily associated with blood or blood products, even though by the summer of 1983, in the words of the court, “it was clear that AIDS was transmitted through blood and that hemophiliacs were being exposed to the disease through contaminated blood products used to treat their condition.”<sup>7</sup>

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1. 3 S.W.3d 404 (Mo. Ct. App. 1999).

2. For an explanation of the learned intermediary doctrine, see *infra* Part III.A.

3. *Alpha Therapeutic*, 3 S.W.3d at 406-07.

4. *Id.* at 408. Hemophilia is a genetic disease characterized by a deficiency in Factor VIII, a protein that aids blood in clotting. Because hemophiliacs do not have Factor VIII, their blood cannot clot and therefore they are unable to control hemorrhaging. Factor VIII concentrate is manufactured by drawing blood from donors, extracting the Factor VIII protein and concentrating it. *Id.* at 407.

5. *Id.* at 408.

6. *Id.* at 409.

7. *Id.*

On December 1, 1997, a consolidated jury trial was held in which the plaintiffs alleged, in pertinent part, that Alpha Therapeutic failed to adequately warn the plaintiffs about the risk of contracting AIDS through the use of Factor VIII concentrate.<sup>8</sup> Alpha Therapeutic denied the existence of a duty to warn, alleging that the plaintiffs' doctors were learned intermediaries who were knowledgeable of Factor VIII and its risks, and therefore, Alpha Therapeutic could rely on the doctors to warn their patients.<sup>9</sup>

At trial, the court admitted evidence as to the extent of information regarding HIV and AIDS received by the plaintiffs from their respective doctors.<sup>10</sup> The plaintiffs' doctors never specifically warned them that the Factor VIII concentrate they were taking could cause AIDS.<sup>11</sup> However, there was some evidence that at least one of the plaintiffs' doctors had printed material in his office that contained warnings that AIDS was likely transmitted through blood and blood products, such as Factor VIII concentrate.<sup>12</sup> Evidence also suggested that even though the medical profession did not, at the time, have a clear understanding of AIDS, at least one of the plaintiffs' doctors was aware of studies that indicated the risks associated with Factor VIII concentrate and had knowledge of a trend among doctors of removing their patients from the treatment.<sup>13</sup>

Alpha Therapeutic presented evidence that at the time of the plaintiffs' infection with AIDS, the National Hemophilia Foundation recommended that doctors continue to use the existing treatment methods (including Factor VIII concentrate) because the cause of AIDS was still unclear.<sup>14</sup> There was also evidence suggesting that the general consensus of the medical profession, at the time, was that AIDS was transmitted through blood and blood products.<sup>15</sup> Moreover, as early as 1981, Alpha Therapeutic had begun researching methods for heat-treating Factor VIII concentrate to rid it of viruses.<sup>16</sup>

By the summer of 1983, "it was clear that AIDS was transmitted through blood and that hemophiliacs were being exposed to the disease through contaminated blood products used to treat their condition."<sup>17</sup> This view was widely accepted when Alpha Therapeutic sent its Summer 1983 newsletter to the patients using its products. The newsletter reported that Alpha Therapeutic had increased its efforts to protect hemophilia patients from AIDS, but noted that

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8. *Id.* at 410.

9. *Id.* at 411.

10. *Id.* at 415-18.

11. *Id.*

12. *Id.* at 415-16.

13. *Id.* at 416.

14. *Id.* at 417.

15. *Id.* at 416.

16. *Id.* at 417.

17. *Id.* at 409.

there was evidence that AIDS was not necessarily related to blood or blood products.<sup>18</sup>

At the close of evidence, the trial court submitted an instruction to the jury on the learned intermediary doctrine.<sup>19</sup> The jury returned a verdict in favor of Alpha Therapeutic.<sup>20</sup> On appeal, the plaintiffs alleged, in pertinent part, that the trial court erred in submitting an instruction on the learned intermediary doctrine to the jury because such an instruction was not supported by Missouri law or the facts at issue in the case.<sup>21</sup> The Missouri Court of Appeals for the Eastern District of Missouri upheld the trial court's decision. The court found that there was sufficient evidence to support the instruction on the learned intermediary doctrine because the treating physicians were aware of the risk of contracting AIDS associated with the use of Factor VIII concentrate, and that Alpha Therapeutic's failure to warn was not the proximate cause of the plaintiffs' injuries.<sup>22</sup>

### III. LEGAL BACKGROUND

#### *A. History of the Learned Intermediary Doctrine*

In 1966, the term "learned intermediary" was coined by the Eighth Circuit Court of Appeals in *Sterling Drug, Inc. v. Cornish*.<sup>23</sup> In *Sterling Drug*, the court found that a drug manufacturer has a duty to warn at least a patient's doctor of the risks associated with the use of its product.<sup>24</sup> The court reasoned that because the patient's doctor could act as a learned intermediary, a warning by the pharmaceutical company to the doctor had a good chance of preventing harm to the plaintiff.<sup>25</sup> In *Sterling Drug*, the drug manufacturer advocated placing the

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18. *Id.*

19. *Id.* at 418. The text of the instruction read:

On the claim of plaintiff Jim [John, James and Carol] based on failure to use ordinary care to adequately warn of the risk of harm from AIDS, your finding must be for defendant if you believe Jim's treating physician, Dr. Andrew Weiss [Dr. John Bouhassin], was aware of the information that should have been provided to plaintiff concerning the risk of contracting HIV from the use of factor concentrate.

*Id.*

20. *Id.*

21. *Id.* at 419.

22. *Id.* at 421.

23. 370 F.2d 82, 85 (8th Cir. 1966); see Catherine A. Paytash, *The Learned Intermediary Doctrine and Patient Inserts: A Balanced Approach to Preventing Drug-Related Injury*, 51 STAN. L. REV. 1343, 1345 n.6 (1999).

24. *Sterling Drug*, 370 F.2d at 85.

25. *Id.*

duty to warn solely on the treating physician.<sup>26</sup> The manufacturers argued that the physician's failure to keep up with the medical literature, including information regarding the risks of the drug in question, was an intervening proximate cause of the plaintiff's injury and should relieve the drug company of liability.<sup>27</sup> The Eighth Circuit dismissed this argument, holding that the pharmaceutical manufacturer had a positive duty to inform the doctor of the risks associated with its product and that the drug manufacturer's breach of its duty to warn was sufficient for it to be held liable regardless of the doctor's failure to independently warn the patient.<sup>28</sup>

The court in *Sterling Drug* used the concept of the doctor as a learned intermediary between drug manufacturers and patients as a justification for imposing a duty on drug manufacturers to warn doctors of the risks of their products. Since *Sterling Drug*, however, the learned intermediary concept has been employed by drug manufacturers as a defense from being held liable to warn patients directly of the risks associated with their products.

The learned intermediary defense has been widely adopted under various rationales. The predominant rationale for the learned intermediary defense was explained in *Reyes v. Wyeth Laboratories*.<sup>29</sup> In *Reyes*, the Fifth Circuit explained that the learned intermediary doctrine is a sound rule because the nature of the product, prescription drugs, is so complicated that the patient/consumer does not have enough information to make an informed choice in assessing the risks associated with a particular drug.<sup>30</sup> By placing the doctor between the drug manufacturer and the patient, the doctor, who knows the patient's individual symptoms and needs as well as the benefits and risks associated with the drug, is able to assist the patient in making an informed decision.<sup>31</sup>

Another rationale cited in support of the learned intermediary defense is that doctors are in a better position to accurately warn patients than drug companies.<sup>32</sup> A warning from the drug manufacturer would have to be unduly complex to

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26. *Id.*

27. *Id.*

28. *Id.*; see also *Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143, 151-52 (Mo. 1967) (citing *Sterling Drug*, 370 F.2d at 85) (holding that the existence of a doctor as a learned intermediary was reason to require the drug company to warn the doctor of the risks of its product).

29. 498 F.2d 1264 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974).

30. *Id.* at 1276.

31. *Id.*

32. See *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 130 (9th Cir. 1968) (noting that a physician decides to prescribe drugs based on "an assessment of medical risks in the light of the physician's knowledge of his patient's needs and susceptibilities"); *Thomas v. Hoffmann-La Roche, Inc.*, 731 F. Supp. 224, 229 (N.D. Miss. 1989) ("[T]he physician through education, experience, and specialized training is in the best position to make a benefit/risk analysis in making the determination to prescribe a particular drug for a specific patient.")

cover all the potential risks a patient may have.<sup>33</sup> However, a doctor with knowledge of her patients' specific bodily conditions can make a more accurate diagnosis.<sup>34</sup> Moreover, patients are already protected by the doctor's duty to procure informed consent from the patient.<sup>35</sup> Courts are also concerned that a warning directly from the drug manufacturer may interfere with the doctor-patient relationship and deter a patient from taking a drug prescribed by her physician.<sup>36</sup>

Although the learned intermediary defense enjoys wide acceptance, there are some exceptions to the doctrine. The two major exceptions to the learned intermediary defense as it applies to pharmaceutical manufacturers occur when: (1) mass immunizations are given without the involvement of a physician,<sup>37</sup> or (2) statutory regulations require that drug companies warn patients directly.<sup>38</sup>

Drug manufacturers cannot rely on the learned intermediary doctrine when their products are distributed in a mass immunization because physicians are not in a position to adequately warn consumers. In *Davis v. Wyeth Laboratories, Inc.*,<sup>39</sup> the plaintiff sued a drug manufacturer for failure to warn of the risks associated with the company's polio vaccine that caused the plaintiff to suffer paralysis from the waist down.<sup>40</sup> The Ninth Circuit refused to accept the drug manufacturer's argument that its warning to the organization that conducted the mass immunization was sufficient to relieve the manufacturer of a further duty

33. See *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1232 (4th Cir. 1984) (arguing that warnings from drug companies, as opposed to physicians, will be "almost inevitably involved and longwinded"); Craig A. Marvinney, *How Courts Interpret a Manufacturer's Communications to Consumers: The Learned Intermediary Doctrine*, 47 FOOD & DRUG L.J. 69, 73 (1992) (arguing that the complexities of medical jargon make it almost impossible for pharmaceutical manufacturers to script a warning that the average consumer can understand).

34. See Barbara Pope Flannagan, *Products Liability: The Continued Viability of the Learned Intermediary Rule as It Applies to Product Warnings for Prescription Drugs*, 20 U. RICH. L. REV. 405, 413 (1986) (suggesting that a doctor can both answer patient questions and gauge whether the patient understands the nature of the proposed drug therapy).

35. For an explanation of the doctrine of informed consent and its potential erosion in modern jurisprudence, see Robert Gatter, *Informed Consent Law and the Forgotten Duty of Physician Inquiry*, 31 LOY. U. CHI. L.J. 557 (2000).

36. See, e.g., *Dunkin v. Syntex Labs., Inc.*, 443 F. Supp. 121, 123 (W.D. Tenn. 1977) (noting that "attempts to give detailed warnings to patients could mislead patients and might also tend to interfere with the physician/patient relationship"); William J. Curran, *Package Inserts for Patients: Informed Consent in the 1980s*, 305 NEW ENG. J. MED. 1564 (1981) (arguing that warnings made directly to patients may instill patients with undue concern and deter them from taking their prescribed medication).

37. See *infra* notes 39-42 and accompanying text.

38. See *infra* notes 43-50 and accompanying text.

39. 399 F.2d 121 (9th Cir. 1968).

40. *Id.* at 122-25.

to warn.<sup>41</sup> The court reasoned that because the drug was not administered in a manner that allowed the patient to benefit from a physician's particularized medical judgment, the drug manufacturer should be held to a duty to directly warn the patient of the risks associated with its drugs.<sup>42</sup>

Drug companies are also unable to invoke the learned intermediary defense when they are required by statute to directly warn patients of the risks associated with their products. In *Edwards v. Basel Pharmaceuticals*,<sup>43</sup> the Oklahoma Supreme Court found that a drug manufacturer had a duty to adequately warn a patient directly because the manufacturer was not entitled to rely on the learned intermediary doctrine when the Food and Drug Administration ("FDA")<sup>44</sup> had promulgated regulations requiring a direct warning to patients.<sup>45</sup> The plaintiff in *Edwards* died from a nicotine overdose after smoking cigarettes while wearing two nicotine patches manufactured by the defendant.<sup>46</sup> Evidence demonstrated that the drug company warned the patient's prescribing physician of the possibility of a nicotine-induced heart attack.<sup>47</sup> Further, the manufacturer

41. *Id.* at 130-31.

42. *Id.* at 131; *see also* *Givens v. Lederle*, 556 F.2d 1341, 1345 (5th Cir. 1977); *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974).

43. 933 P.2d 298 (Okla. 1997).

44. The recorded decisions finding an exception to the learned intermediary defense in the face of governmental regulation of consumer warnings have all involved FDA regulations. For a description of the FDA regulatory scheme regarding prescription drug warnings, *see infra* notes 56-60 and accompanying text. States can also seek to regulate prescription drugs. In fact, Missouri has a fairly comprehensive regulatory scheme. *See* MO. REV. STAT. §§ 196.010-.180 (1994). It is unlikely, however, that Missouri's regulations may be used as a basis for imputing liability to a drug manufacturer when the manufacturer is in compliance with FDA regulations because a state law that has more stringent requirements for pharmaceutical warnings is likely to be viewed by courts as in conflict with the FDA's expansive regulation of the area, and thus preempted by federal law. *See generally* *Pharm. Soc'y of N.Y. v. Lefkowitz*, 586 F.2d 953, 958 (2d Cir. 1978) (noting that a state law that is in actual conflict with the Federal Food, Drug, and Cosmetic Act ("FDCA") will be preempted). The Missouri legislature has recognized the preemptive force of the FDCA. Section 196.050 of the Missouri Revised Statutes notes that the Missouri law should not be read to require more stringent controls than those enumerated by the federal law. Therefore, "if any product or commodity covered by [the Missouri law] shall comply with the definitions and standards proscribed by the federal act for such a product or commodity, such product or commodity shall be deemed in all respects to comply with [the Missouri law]." MO. REV. STAT. § 196.050 (1994).

45. *See Edwards*, 933 P.2d at 301. *But see* *Martin v. Ortho Pharm. Corp.*, 661 N.E.2d 352, 357 (Ill. 1996) (refusing to recognize an exception to the learned intermediary defense in the face of FDA regulations requiring direct-to-consumer warnings).

46. *See Edwards*, 933 P.2d at 299.

47. *Id.*

complied with the FDA regulations that required the manufacturer to provide a package insert.<sup>48</sup> The court held that because the FDA required the manufacturer to directly warn the consumer, the manufacturer could not invoke the learned intermediary defense.<sup>49</sup> The court further held that the question of whether the patient insert was sufficient to adequately warn the consumer of the risks associated with the drug was a question to be decided under state law. Thus, compliance with the FDA regulations was not found to be a per se reasonable warning.<sup>50</sup>

A third exception, embodied in the *Restatement (Third) of Torts*, has recently developed that could preclude drug manufacturers from relying on the learned intermediary defense when they have engaged in direct-to-consumer advertising.

### B. *Restatement (Third) of Torts, the FDA, and the Direct-to-Consumer Advertising Exception*

The *Restatement (Third) of Torts* codifies the common law learned intermediary doctrine.<sup>51</sup> Section 6(d) requires drug manufacturers to give “reasonable instructions or warnings regarding foreseeable risks of harm” to physicians or directly to the patients, if the physician will not be in a position to provide the warning to the patient.<sup>52</sup> The comment to Section 6(d) recognizes the arguments recently proffered in opposition to the learned intermediary defense in the situations where the government has regulated the manufacturer’s duty to warn or when the manufacturer has directly advertised its product to consumers.<sup>53</sup> The American Law Institute, however, expressly refrained from recognizing these arguments as amounting to viable exceptions to the learned

48. *Id.* at 299-300.

49. *Id.* at 301.

50. *Id.* at 303; *see also* *Odgers v. Ortho Pharm. Corp.*, 609 F. Supp. 867, 877-78 (E.D. Mich. 1985) (rejecting the defendant’s argument that compliance with FDA regulations should preclude tort liability); *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 70 (Mass. 1985) (holding that compliance with FDA regulations is not conclusive on the issue of the reasonableness of a drug manufacturer’s warning).

51. Although the RESTATEMENT (THIRD) OF TORTS codifies much of the existing law in the area of products liability, it does leave some questions open in the area of drug manufacturers’ duty to warn consumers. For instance, the RESTATEMENT (THIRD) OF TORTS outlines the instances when a drug manufacturer is obligated to warn patients, but does not articulate what constitutes a sufficient warning. For further discussion on this topic, *see* Jerry J. Phillips, *Products Liability: Beyond Warnings*, 26 N. KY. L. REV. 595, 603-09 (1999) and Justin T. Toth, *Prescription Drugs and Medical Devices: The Impending Impact of the Restatement (Third) of Torts in Texas*, 35 HOUS. LAW., Mar.-Apr. 1998, at 42-43.

52. RESTATEMENT (THIRD) OF TORTS § 6(d)(1)-(2) (1998).

53. *See* RESTATEMENT (THIRD) OF TORTS § 6 cmt. e (1998).



intermediary rule, deciding instead to “leave[] to developing case law whether exceptions to the learned intermediary rule in these or other situations should be recognized.”<sup>54</sup> At least one scholar has argued that the decision by the American Law Institute to not directly endorse the direct-to-consumer exception to the learned intermediary rule will cause courts to be reluctant to allow the exception.<sup>55</sup>

Although the *Restatement (Third) of Torts* does not speak to the propriety of directly advertising drugs to consumers, Congress has addressed this issue in the Federal Food, Drug, and Cosmetic Act (“FDCA”).<sup>56</sup> In the FDCA, Congress enacted general requirements for the advertisement of prescription drugs, including the requirement that advertisements include a true statement of the drug’s “established name,”<sup>57</sup> the drug’s ingredients, and information on the drug’s side effects.<sup>58</sup> Congress also granted the FDA power to “promulgate regulations for the efficient enforcement of the [FDCA].”<sup>59</sup> The FDA answered Congress’s charge, at least in the area of drug advertising, by enacting regulations that detail the requirements for prescription drug advertisements.<sup>60</sup>

With the recent trend of drug manufacturers advertising their products in the mass media, the direct-to-consumer advertising exception has garnered much attention from scholars.<sup>61</sup> The basic rationale for the exception is similar to the

54. RESTATEMENT (THIRD) OF TORTS § 6 cmt. e (1998).

55. See Paytash, *supra* note 23, at 1356.

56. See 21 U.S.C. §§ 301-397 (1994).

57. The “established name” of a drug is regulated by 21 U.S.C. § 352(e) (1994) and the statute’s accompanying regulations are located in 21 C.F.R. § 202.1(b)(1)-(2) (1999).

58. See 21 U.S.C. § 352(n) (1994).

59. 21 U.S.C. § 371(a) (1994).

60. See 21 C.F.R. § 202.1 (1999). The FDA’s regulations on prescription drug advertisements are extensive. For a detailed explanation of the FDA’s regulations in this area, see Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141 (1997). Violation of the FDCA, or its accompanying regulations, is deemed to be a “false advertisement” under the Federal Trade Commission Act (“FTCA”). 21 U.S.C. § 353(a) (1994) (noting that violations of the section’s provisions will “be subject to the provisions of sections 52 to 57 of Title 15”). “False advertisement” under the FTCA is a misdemeanor, punishable by a fine of not more than \$5,000 and/or not more than six months imprisonment. 15 U.S.C. § 54(a) (1994). A violation may also prompt a civil action brought by the Federal Trade Commission. See 15 U.S.C. § 57b(a) (1994). Though some may argue that these penalties are sufficient to deter drug manufacturers from falsely advertising, Congress intended consumers to be able to individually seek reparations as well. See 15 U.S.C. § 57b(e) (1994) (“Remedies provided [by the FTCA] are in addition to, and not in lieu of, any other remedy or right of action provided by State or Federal law.”).

61. See, e.g., Tim S. Hall, *Bypassing the Learned Intermediary: Potential Liability for Failure to Warn in Direct-to-Consumer Prescription Drug Advertising*, 2 CORNELL J.L. & PUB. POL’Y 449 (1993); Jack B. Harrison & Mina J. Jerrerson, “[S]ome [A]ccurate [I]nformation is [B]etter than [N]o [I]nformation [A]t [A]ll”: Arguments Against an

rationale behind the exceptions regarding mass immunizations and statutory regulations.<sup>62</sup> In all three instances, there is reason to believe that the doctor-patient relationship, on which the learned intermediary theory is grounded, is not sufficient to protect the patient/consumer. The basic argument for the direct-to-consumer advertising exception is that the autonomy of the physician in the drug prescription process is undermined by the drug manufacturers' advertisements.<sup>63</sup> One purpose of advertising prescription drugs in the mass media is to encourage potential consumers to approach their physicians and request a prescription for the advertised drug. This situation seems to unseat the decision-making balance between the doctor and patient, where the doctor was previously viewed as a gate-keeper, protecting the patient from potential harm. When the patient is the party requesting a particular drug, the doctor would be seen as nothing more than an intermediary between the drug company and the consumer. However, despite the rationale behind the direct-to-consumer exception, courts have not been receptive to adopting it.<sup>64</sup>

While most courts have not been receptive to the direct-to-consumer advertising exception to the learned intermediary doctrine, some courts have recognized the exception. In *Stephens v. G.D. Searle & Co.*,<sup>65</sup> the United States District Court, applying Michigan law,<sup>66</sup> held that manufacturers of oral

*Exception to the Learned Intermediary Doctrine Based on Direct-to-Consumer Advertising*, 78 OR. L. REV. 605 (1999); Jack E. Karns, *Direct Advertising of Prescription Drugs: The Duty to Warn and the Learned Intermediary Rule*, 3 DEPAUL J. HEALTH CARE L. 273 (2000); Joel Slawotsky, *The Learned Intermediary Doctrine: The Employer as Intermediary*, 30 TORT & INS. L.J. 1059 (1995).

62. See Michael C. Allen, *Medicine Goes Madison Avenue: An Evaluation of the Effect of Direct-to-Consumer Pharmaceutical Advertising on the Learned Intermediary Doctrine*, 20 CAMPBELL L. REV. 113, 123-24 (1997).

63. See Paytash, *supra* note 23, at 1355.

64. See Paytash, *supra* note 23, at 1355-56.

65. 602 F. Supp. 379 (E.D. Mich. 1985); see also *Hill v. Searle Labs.*, 884 F.2d 1064, 1070-71 (8th Cir. 1989) (holding that manufacturers of contraceptives are required to warn the consumers of their products based, in part, on the fact that they directly advertise the product to consumers); *Garside v. Osco Drug, Inc.*, 764 F. Supp. 208, 211 n.4 (D. Mass. 1991) (recognizing the validity of the direct-to-consumer advertising exception to the learned intermediary doctrine), *rev'd on other grounds*, 976 F.2d 77 (1st Cir. 1992). But see *Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142, 1148 (D. Or. 1989) (holding that there is no exception to the learned intermediary doctrine in direct-to-consumer advertising cases because doctors are still in a position to exercise individual medical judgment).

66. In *Grainger v. Sandoz Pharmaceuticals*, 358 N.W.2d 873, 874 (Mich. 1984), the Michigan Supreme Court chose not to rule whether the learned intermediary doctrine contained an exception for direct-to-consumer advertising, holding that it was a question for the legislature. Three judges dissented from the opinion, advocating that the court should have ruled on the issue and recognized a direct-to-consumer advertising exception to the learned intermediary doctrine. *Id.* at 878-79. The district court in *Stephens* relied

contraceptives have a duty to directly warn consumers of the risks associated with their products.<sup>67</sup> The court noted that drug companies are usually protected by the learned intermediary doctrine, but found that an exception in the case of oral contraceptives was needed because of the marketing practices employed by the drug manufacturers.<sup>68</sup> The district court noted, "As a result of [the drug manufacturers' marketing practices'], patients eager to take the pill have specifically requested it as the most effective means of preventing unwanted pregnancies, and doctors have responded to these requests by prescribing it."<sup>69</sup>

In *Perez v. Wyeth Laboratories Inc.*,<sup>70</sup> the New Jersey Supreme Court held that a manufacturer of a contraceptive implant system was not entitled to rely on the learned intermediary defense when the manufacturer engaged in direct marketing of the product to consumers.<sup>71</sup> The court explained:

[W]hen mass marketing of prescription drugs seeks to influence a patient's choice of a drug, a pharmaceutical manufacturer that makes direct claims to consumers for the efficacy of its product should not be unqualifiedly relieved of a duty to provide proper warnings of the dangers or side effects of the product.<sup>72</sup>

The New Jersey Supreme Court based its decision to make an exception to the learned intermediary defense on the ground that direct marketing of prescription drugs undermines the rationale behind the learned intermediary rule.<sup>73</sup> The court recognized that the basic rationales behind the learned intermediary rule are "(1) reluctance to undermine the doctor-patient relationship; (2) absence in the era of 'doctor knows best' of [the] need for the patient's informed consent; (3) inability of drug manufacturer[s] to communicate with patients; and (4) complexity of the subject . . ."<sup>74</sup> Furthermore, the court noted that these justifications were no longer compelling.<sup>75</sup> First, the traditional doctor-patient relationship, which was characterized by the doctor's paternalistic decision-making authority, has given way to an approach that, through the doctrine of informed consent, emphasizes the patient's decision-making authority.<sup>76</sup> The court also noted that "because managed care has reduced the

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entirely on the dissenting opinion in *Grainger* to determine what Michigan law was on this issue. See *Stephens*, 602 F. Supp. at 380-81.

67. See *Stephens*, 602 F. Supp. at 381.

68. *Id.* at 380.

69. *Id.* at 380-81 (quoting *Grainger*, 358 N.W.2d at 884-85).

70. 734 A.2d 1245 (N.J. 1999).

71. *Id.* at 1263.

72. *Id.* at 1247.

73. *Id.* at 1255.

74. *Id.*

75. *Id.*

76. *Id.*

time allotted per patient, physicians have considerably less time to inform patients of the risks and benefits of a drug.<sup>77</sup> Further, the court recognized that drug companies do have the means to successfully communicate with patients, a fact evidenced by the companies' ability to launch successful advertising campaigns.<sup>78</sup> For these reasons, the New Jersey Supreme Court held that drug manufacturers cannot rely on the learned intermediary defense when they engage in direct-to-consumer advertising of their products.<sup>79</sup>

### *C. Learned Intermediary Doctrine in Missouri*

The first case in Missouri to apply the learned intermediary doctrine to a products liability action against a drug manufacturer was *Krug v. Sterling Drug, Inc.*<sup>80</sup> In *Krug*, the plaintiff took a drug called chloroquine prescribed by her doctor to treat discoid lupus erythematosus.<sup>81</sup> Krug later developed a condition called chloroquine retinopathy, which results in the gradual onset of blindness.<sup>82</sup> This ailment is a side-effect of chloroquine.<sup>83</sup> Krug's doctor wrote a letter to Sterling Drug, the manufacturer of chloroquine, inquiring whether the side-effects his patient was experiencing were the result of her taking chloroquine.<sup>84</sup> Sterling Drug replied that eyesight impairment was a side-effect of chloroquine, but that there had not been any evidence that the effect was irreversible.<sup>85</sup> When Krug subsequently brought suit against Sterling Drug, the Missouri Supreme Court, instituting the learned intermediary rule, stated:

‘There is no question of intervening proximate cause in this case. The sole issue was whether appellant negligently failed to make reasonable efforts to warn appellee’s doctors. If appellant did so fail, it is liable regardless of anything the doctors may or may not have done. If it did not so fail, then it is not liable for appellee’s injury.’<sup>86</sup>

This statement of the learned intermediary doctrine left unanswered the question whether the drug manufacturer has a duty to warn a physician when the physician has independent knowledge of the risks associated with the manufacturer's drug. This question, in actuality a proximate cause issue, was

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77. *Id.*

78. *Id.*

79. *Id.* at 1263.

80. 416 S.W.2d 143 (Mo. 1967).

81. *Id.* at 146.

82. *Id.*

83. *Id.*

84. *Id.* at 150.

85. *Id.* at 150-51.

86. *Id.* at 151 (quoting *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966)).

resolved in favor of drug manufacturers by the Missouri Supreme Court in *Callahan v. Cardinal Glennon Hospital*.<sup>87</sup>

*Callahan* involved a medical malpractice claim brought against Cardinal Glennon Hospital for the negligent acts of one of its doctors.<sup>88</sup> In explaining the extent of causation necessary to substantiate a finding of liability, the court noted that the plaintiff must demonstrate that the actions of the defendant were the proximate cause of the injury suffered.<sup>89</sup> The court explained this rule by noting that if a doctor had independent knowledge of information that could have been used to prevent the patient's injury, then a failure to warn by the nurse or a pharmaceutical company could not be the proximate cause of the patient's injuries.<sup>90</sup>

Subsequent cases have extended the learned intermediary doctrine to apply to medical devices in liability cases. For example, in *Kirsch v. Picker International, Inc.*,<sup>91</sup> the Eight Circuit, applying Missouri law, held that a company that produces X-ray equipment was protected by the learned intermediary defense and was only obligated to warn the physician of the risks associated with its product.<sup>92</sup> The court reasoned that because the company's X-ray equipment was only sold to qualified professionals and not to the general public, the manufacturer was entitled to rely on the doctor to warn the patients of the risks associated with use of the equipment.<sup>93</sup>

87. 863 S.W.2d 852 (Mo. 1993).

88. *Id.* at 857.

89. *Id.* at 862.

90. *Id.*; see also *Arnold v. Ingersoll-Rand Co.*, 834 S.W.2d 192, 193-94 (Mo. 1992) (holding that, in failure to warn cases, the plaintiff has the burden of showing that the manufacturer's failure to warn was the proximate cause of the plaintiff's injuries). But see *Beer v. Upjohn Co.*, 943 S.W.2d 691, 693 (Mo. Ct. App. 1997) (finding that the testimony of the prescribing physician that a warning by the drug manufacturer would probably not have changed his decision to prescribe the drug was not sufficient to entitle the drug company to a directed verdict because the court could not "conclude as a matter of law that a more positive or forceful warning would not have affected [the doctor's] treatment of [the patient]").

91. 753 F.2d 670 (8th Cir. 1985).

92. *Id.* at 671.

93. *Id.* Missouri courts, however, have been reluctant to extend the learned intermediary defense to manufactures of non-medical products. See *Menschik v. Mid-America Pipeline Co.*, 812 S.W.2d 861 (Mo. Ct. App. 1991). In *Menschik*, the court held that the learned intermediary doctrine does not apply outside the medical context to a bulk supplier of gas, noting:

Missouri courts have developed another exception, known as the 'learned intermediary' doctrine, for the special case involving a drug manufacturer that supplies prescription drugs to a doctor, who then prescribes them to a patient[.] The rationale for that exception, that a patient may obtain the product only through a qualified professional who presumably will explain the dangers of the product to the patient, cannot sensibly be stretched to apply

## IV. INSTANT DECISION

On appeal, the plaintiffs in *Alpha Therapeutic* contended that the trial court erred in submitting instructions to the jury on the learned intermediary doctrine.<sup>94</sup> The plaintiffs argued that the learned intermediary instructions were not proper because Alpha Therapeutic engaged in direct-to-consumer advertising, which triggered an exception to the learned intermediary doctrine, thus precluding the defense.<sup>95</sup> The plaintiffs also argued that because of the erroneous advertising sent to them, the trial court erred in not giving an instruction to the jury that outlined Alpha Therapeutic's duty to warn the plaintiffs' doctors.<sup>96</sup> Finally, the plaintiffs argued that the learned intermediary doctrine was generally not a viable defense under Missouri law.<sup>97</sup>

The Missouri Court of Appeals for the Eastern District of Missouri noted that in order to preserve an issue for appeal, a party must make specific objections to a jury instruction either in the jury instruction conference or in a motion for new trial.<sup>98</sup> At trial, the plaintiffs did not object to the language of the jury instructions on the learned intermediary doctrine, nor did the plaintiffs ask for an instruction on the direct-to-consumer advertising exception.<sup>99</sup> The only timely objection made to the jury instructions at issue was made in the plaintiffs' motion for a new trial, where the plaintiffs argued that the instruction was improper because the doctrine of learned intermediary was not a viable defense in Missouri.<sup>100</sup> Because the only objection that the plaintiffs made at trial was that the learned intermediary doctrine was not an affirmative defense in Missouri, the only issues before the appellate court were whether the instruction was in accord with Missouri law and whether there was sufficient evidence to support submitting the instruction to the jury.<sup>101</sup>

The court held that the learned intermediary doctrine is a viable defense in Missouri.<sup>102</sup> The court noted that the duty of a drug manufacturer is "'to properly warn the doctor of the dangers involved and it is incumbent upon the

to this case. Whatever else [the pipeline company] may be, it is not a 'learned intermediary' within the meaning of the Missouri doctrine.

*Id.* at 864 (quoting *Donahue v. Phillips Petroleum Co.*, 866 F.2d 1008, 1013 n.9 (8th Cir. 1989)).

94. *See Doe v. Alpha Therapeutic Corp.*, 3 S.W.3d 404, 419 (Mo. Ct. App. 1999). For the text of one of the instructions at issue, see *supra* note 19.

95. *Alpha Therapeutic*, 3 S.W.3d at 419. For a description of Alpha Therapeutic's direct-to-consumer advertising, see *supra* text accompanying notes 6-7.

96. *Alpha Therapeutic*, 3 S.W.3d at 419.

97. *Id.*

98. *Id.*

99. *Id.*

100. *Id.*

101. *Id.*

102. *Id.*

manufacturer to bring the warning home to the doctor."<sup>103</sup> The manufacturer's duty to warn is discharged when it provides the physician with information regarding the risks of its products.<sup>104</sup> Further, if the prescribing physician had independent knowledge of the risks of the product, the failure of a drug manufacturer's warning would do nothing to improve the patient's position as the doctor already had the information and failed to warn the patient.<sup>105</sup>

The court also found that there was sufficient evidence presented at trial to support the submission of the instruction on the learned intermediary defense to the jury.<sup>106</sup> The court pointed to evidence that the plaintiffs' treating physicians went to great lengths to educate themselves about the AIDS crisis.<sup>107</sup> The plaintiffs' physicians testified that they relied principally on research that was being conducted by the Center for Disease Control and not on the literature provided by Alpha Therapeutic.<sup>108</sup> And while they were at least somewhat aware of the risks associated with Factor VIII, the physicians decided to keep their patients on Factor VIII treatment.<sup>109</sup> Because the learned intermediary doctrine was supported by Missouri law and there was evidence that the plaintiffs' treating physicians had substantially the same knowledge as Alpha Therapeutic regarding the risks of contracting AIDS through the use of blood products, the court held that the instructions on the learned intermediary doctrine were proper.<sup>110</sup> The court, therefore, affirmed the trial court's decision to instruct the jury on the learned intermediary defense.<sup>111</sup>

## V. COMMENT

Missouri, to date, has not recognized the direct-to-consumer advertising exception to the learned intermediary doctrine. This issue was raised in *Alpha Therapeutic*, but was dismissed because of a procedural error by the plaintiffs' counsel.<sup>112</sup> Although this exception has not been widely adopted by courts, it is

103. *Id.* (quoting *Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143, 146 (Mo. Ct. App. 1967)).

104. *Id.*

105. *Id.* at 420.

106. *Id.* at 421.

107. *Id.* at 420.

108. *Id.*

109. *Id.* at 420-21.

110. *Id.* at 421.

111. *Id.*

112. See *supra* text accompanying notes 98-101. This issue was again raised in *Doe v. Miles, Inc.*, No. ED 75100, 2000 WL 667383 (Mo. Ct. App. May 23, 2000). The facts in *Miles* are very similar to those in *Alpha Therapeutic*. The plaintiff in *Miles* alleged that a company that manufactured blood products for the treatment of hemophilia had a duty to directly warn patients, because the company, in a newsletter to consumers, made alleged misrepresentations about the safety of its product. *Id.* at \*17. The trial

well supported by public policy considerations and should be adopted in Missouri. 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.

It is true that the FDA has adopted regulations to oversee direct-to-consumer drug advertising.<sup>113</sup> However, the regulations only provide a limited scheme of penalties and do not provide victims of drug manufacturers' failure to warn with any process for reparations.<sup>114</sup> Further, Congress intended the FDA regulations to be a supplement to common law actions, not an alternative to them.<sup>115</sup> However, without the direct-to-consumer advertising exception to the learned intermediary doctrine, a plaintiff harmed by a drug who relied on the advertising provided by the drug's manufacturer cannot recover damages because the responsibility to warn rests on physicians. This result is irrational in light of the justifications for the learned intermediary defense.

Many commentators, in arguing against revising the learned intermediary doctrine, rely on the primary rationale behind the rule.<sup>116</sup> Courts and commentators continue to find compelling the argument that doctors are in a better position than drug companies to warn consumers of the risks associated with prescriptions drugs.<sup>117</sup> One reason that doctors are viewed as better conduits of information than drug companies is that prescription drugs, and the risks associated with them, are so complicated that patients need doctors to provide them with a particularized warning.<sup>118</sup> This argument, however, is rebutted by the actions of drug companies in directly marketing their products to consumers. By engaging in direct-to-consumer advertising, drug manufacturers are implicitly admitting that consumers can understand how a prescription drug will benefit them.<sup>119</sup> If consumers are able to understand the benefits of a prescription drug, then certainly, they are capable of understanding the associated risks.

Further, the direct-to-consumer advertising exception is a limited exception to the otherwise sound learned intermediary rule. The exception recognizes the inherent inconsistency of the policy justifications for the learned intermediary

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court held that because the plaintiff did not actually read the newsletter provided by the drug manufacturer, she was not entitled to argue for the direct-to-consumer advertisement exception to the learned intermediary rule. *Id.* The court, therefore, refused to rule whether such an exception is cognizable under Missouri law. *Id.*

113. See *supra* note 60 and accompanying text.

114. See *supra* notes 60-64 and accompanying text.

115. See *supra* note 60.

116. See *supra* text accompanying notes 29-31.

117. See *supra* text accompanying notes 29-31.

118. See *supra* text accompanying notes 29-31.

119. See *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245, 1255 (N.J. 1999); Noah, *supra* note 60, at 157-59.



rule when applied in the context of directly marketed drugs. The exception, therefore, should not have an undue chilling effect on the development of prescription drugs, because the exception is limited to those instances when manufacturers directly market their drugs to consumers. If the risks associated with a particular prescription drug are too complicated for manufacturers to effectively explain directly to consumers, then courts should recognize that it is negligent to directly advertise that drug to consumers.

Courts also adhere to the view that the traditional doctor-patient relationship continues to justify the learned intermediary rule.<sup>120</sup> Recent trends in the medical profession, including the rise of managed care and the direct marketing of medical services, have undermined this rationale.<sup>121</sup> Medicine is a less personal industry than it was forty years ago when the learned intermediary rule was first announced. Patients are now expected to take a more active role in their own health care decisions. Further, the exponential growth of medical technology, including prescription drug development, calls into question the ability of doctors to educate themselves about all of the potential drugs their patients may request or require.<sup>122</sup> Drug manufacturers have recognized this problem and have sought to directly educate the public about their products. Because the purpose of direct-to-consumer advertising is to remove the physician as the sole source of treatment information, drug manufacturers who utilize these methods should be responsible, just as physicians are, for informing the patient/consumer of the risks associated with their recommendations.

## VI. CONCLUSION

Although the learned intermediary doctrine is based on sound public policy, Missouri courts must recognize that, as with all common law concepts, this doctrine must be revised to meet the changing face of the market in which it operates. The advent of direct-to-consumer advertising by drug manufacturers has caused a need for a revision of the learned intermediary doctrine. Missouri courts should not apply the learned intermediary defense on behalf of a drug company when the company has sought to influence the doctor-patient treatment

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120. See *supra* note 36.

121. See *supra* text accompanying notes 77-79.

122. "In a 1997 survey of 1,000 patients, the F.D.A. found that only one-third had received information from their doctors about the dangerous side effects of drugs they were taking." *Perez*, 734 A.2d at 1255 (quoting Sheryl Gay Stolberg, *Faulty Warning Labels Add to Risk in Prescription Drugs*, N.Y. TIMES, June 4, 1999, at A27).

decision with commercial advertising. Continuing to apply the learned intermediary defense in the face of direct-to-consumer advertising of drug products will result in a violation of the very policy justifications on which the rule is based.

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