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## Another Factor in the "Decisional Calculus": The Learned Intermediary Doctrine, The Physician-Patient Relationship, and Direct-to-Consumer Marketing

Jeffrey J. Wiseman

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# ANOTHER FACTOR IN THE "DECISIONAL CALCULUS": THE LEARNED INTERMEDIARY DOCTRINE, THE PHYSICIAN-PATIENT RELATIONSHIP, AND DIRECT-TO-CONSUMER MARKETING

## I. INTRODUCTION

Do you remember when drug commercials would not reveal exactly what the drugs were supposed to do? Those commercials depicted "wind-surfer[s] gliding over fields of wheat" or a group of swimmers at the beach.<sup>1</sup> But if you have paid attention, you have noticed drug commercials today are more specific, and there are many more of them.<sup>2</sup>

Now imagine you suffer from one of the many ailments for which these drugs are advertised, and you see one of these commercials. You become convinced that the drug is right for you. The advertisement ends, among a quick list of some of the drug's contraindications, with a message to consult your doctor.<sup>3</sup> You visit your doctor and ask her for the drug. After the doctor warns you about all the side effects and dangers of the drug, you still insist and receive a prescription. After taking the drug, you suffer a severe side effect and are injured. According to the learned intermediary doctrine, the pharmaceutical manufacturer only had a duty to warn the prescribing physician, who then had a duty to take that warning into her treatment considerations and pass it on to the patient.<sup>4</sup> Is that fair? The drug was marketed directly to you. You do not remember seeing a warning on the commercial or on the drug's package about the side effect you suffered, and you believe you should have recourse against the party who made the drug and marketed it to you. Why should the pharmaceutical manufacturer be insulated from liability when the drug was marketed *directly* to you?

The learned intermediary doctrine is a well-established exception to the duty to warn.<sup>5</sup> However, due to changes in the way the Food and Drug

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1. Andrew Somora, *Direct-to-Consumer Advertising: Are Consumers Being Informed?*, 8 KAN. J. L. & PUB. POL'Y 205, 205 (1998-99).

2. See William E. Holtz, *Consumer-Directed Prescription Drug Advertising: Effects on Public Health*, 13 J.L. & HEALTH 199, 200 (1998-99) ("Over the past two decades, and to a greater extent recently, society has been increasingly exposed to prescription drug advertisements aimed directly at the consumer.").

3. See Somora, *supra* note 1, at 205.

4. See *Brooks v. Medtronic Inc.*, 750 F.2d 1227, 1231 (4th Cir. 1984) (stating South Carolina law regarding the learned intermediary rule).

5. See Susan A. Casey, Comment, *Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine*, 19 WM. MITCHELL L. REV. 931, 936 (1993) (stating that the learned intermediary doctrine was "originally conceived" in a 1948 New York

Administration (FDA) regulates the industry, the marketing of prescription pharmaceuticals directly to consumers through broadcast media is a fairly recent development.<sup>6</sup> This new development has led to a debate over whether the learned intermediary doctrine should, in these situations, remain an exception to the manufacturer's duty to directly warn the consumer.<sup>7</sup> The *Restatement (Third) of Torts: Product Liability* only briefly addresses this issue and states that the issue is to be decided by "developing case law."<sup>8</sup>

This Comment explores both sides of this debate. Part II examines the FDA regulations, both past and present, regarding the advertising of prescription drugs directly to consumers. Part III examines the learned intermediary doctrine and discusses judicial exceptions which state that a pharmaceutical manufacturer has a duty to warn the prescription consumer and not just the medical care provider. Part IV of this Comment analyzes the current law regarding the learned intermediary doctrine, examines the physician-patient relationship and its effect on the doctrine, and weighs the benefits and drawbacks of direct-to-consumer (DTC) drug advertisements. This Comment concludes that the learned intermediary doctrine should remain in place even as pharmaceutical manufacturers increase their use of DTC drug advertisements.

## II. THE EVOLUTION OF DTC PHARMACEUTICAL ADVERTISEMENT REGULATION

### A. Regulation of Prescription Drug Advertisement Before 1997

The FDA regulates the promotion of pharmaceutical products.<sup>9</sup> Under 21 U.S.C. § 352, the regulations extend to "all advertisements" which naturally includes print and broadcast advertisements.<sup>10</sup> The FDA has been regulating the

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case).

6. See Tamar V. Terzian, *Direct-to-Consumer Prescription Drug Advertising*, 25 AM. J.L. & MED. 149, 150 (1999) ("On August 8, 1997, the FDA changed how it regulates DTC advertising by promulgating a new guidance, Guidance for Industry: Consumer-Directed Broadcast Advertisements . . . that clarifies existing prescription drug advertisement requirements for broadcast media.").

7. See Somora, *supra* note 1, at 206 (suggesting that, because pharmaceutical manufacturers have new freedom in direct-to-consumer advertising, they should not be shielded from liability behind the learned intermediary doctrine); see also Michael C. Allen, Comment, *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, 125-129 (1997) (arguing that the benefits of direct-to-consumer advertising by the pharmaceutical industry outweigh the drawbacks).

8. RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY § 6 cmt. e (1998).

9. See 21 U.S.C. § 352(n) (1988) (giving to the FDA the power to regulate the advertising and marketing of prescription drugs).

10. *Id.*

advertising of prescription drugs since 1963.<sup>11</sup> Initially, those regulations only addressed marketing and advertising directed towards the medical care provider.<sup>12</sup> When pharmaceutical manufacturers first began to float the idea of marketing their products directly to the consumers, the FDA had placed a moratorium on DTC advertising but had lifted it by 1985.<sup>13</sup> The Upjohn Company became the first to advertise its drugs directly to consumers when it advertised the hair-loss treatment Rogaine.<sup>14</sup>

Initially, any advertisement of a prescription drug was required to include all adverse information about the drug, its side effects and contraindications.<sup>15</sup> This requirement naturally led to confrontations between the pharmaceutical manufacturers and the FDA.<sup>16</sup> Much of the debate centered around exactly what sort of information was necessary to satisfy the regulations, although there were some challenges to the scope of the FDA's authority over the regulation of pharmaceuticals.<sup>17</sup>

In 1988 a "more workable format" was introduced that required all prescription drug advertisements to include: "1) a true statement of the established name for the drug and its formula; and 2) a brief summary of information about the drug relating to its side effects, contraindications for its use, and its effectiveness."<sup>18</sup> This regulation was known as the "brief summary" requirement.<sup>19</sup> The FDA further provided a special exception to this brief summary requirement.<sup>20</sup> Instead of requiring the advertisement to contain the brief summary of the drug's side effects, contraindications for its use, and its effectiveness, which actually was anything but "brief," the advertisement could omit the lengthy summary but would not be permitted to give the drug's indications at all.<sup>21</sup> Almost all manufacturers chose the advertisements that did not give the drug's indications<sup>22</sup> because including a long list of all the drug's adverse effects during a commercial simply was not "feasible."<sup>23</sup>

11. See Somora, *supra* note 1, at 206.

12. See *Perez v. Wyeth Lab. Inc.*, 734 A.2d 1245, 1258 (N.J. 1999).

13. See *id.*

14. See *id.* at 1251.

15. See Somora *supra* note 1, at 206.

16. See *id.*

17. See *id.* For an interesting discussion about the scope and nature of the FDA's authority to regulate statements about prescription drug products and whether they have overstepped their authority, as well as the implications on the First Amendment, see Charles J. Walsh & Alissa Pyrich, *FDA Efforts to Control the Flow of Information at Pharmaceutical Industry-Sponsored Medical Education Programs: A Regulatory Overdose*, 24 SETON HALL L. REV. 1325 (1994).

18. Somara, *supra* note 1, at 206 (quoting 21 U.S.C. § 352(n) (1988)).

19. 21 U.S.C. § 352(n); see also 21 C.F.R. § 202.1(e)(1)-(3)(iii) (2000) (requiring that the brief summary disclose all the information relating to the drug's adverse effects in the drug's approved package labeling).

20. See Terzian, *supra* note 6, at 149.

21. See *id.*

22. See *id.*

23. See PHRMA, FACTS AND FIGURES: DIRECT-TO-CONSUMER ADVERTISING, at <http://www.phrma.org/facts/bkgndr/advert.html> (last visited Feb. 1, 2001).

### B. *The Changing Health Care System*

The limitations on advertising for prescription drugs must be considered in light of the fact that pharmaceutical manufacturing is a business. Health care represents fourteen percent of the gross domestic product and is the “largest single area of non-government spending.”<sup>24</sup> The health care industry has experienced a major change in the way Americans pay for their health care.<sup>25</sup> Since the end of World War II, more and more Americans have relied on third-party health care providers.<sup>26</sup> Rising health care costs led to a “health care inflation rate” (annual percentage increase in health-benefit costs) that peaked in the late 1980s at nineteen percent.<sup>27</sup> These developments have changed the “delivery of health care services” and resulted in the concept of “managed care.”<sup>28</sup> Minimizing costs while still attempting to optimize service in the delivery of health care has come to the forefront in the health care industry.<sup>29</sup> With these changes, pharmaceutical manufacturers now find it necessary to compete to “position their products in the chain of delivery.”<sup>30</sup> One logical result was that pharmaceutical manufacturers began to market their products in new ways, such as creating alliances with insurers and health maintenance organizations.<sup>31</sup> However, the DTC advertisements have become “[a]mong the most controversial.”<sup>32</sup>

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24. Allen, *supra* note 7, at 113 (citation omitted).

25. See *id.* at 114. See generally Julie Rovner, *United States of America: The Healthcare System Evolves*, 348 THE LANCET 1001, 1001 (1996) (discussing the current state of health care in the United States).

26. See Rovner, *supra* note 25, at 1001. The author makes the interesting point that employer-provided insurance is “a quirk of history” that “began during World War II when companies were prohibited from raising wages to attract workers from a pool shrunken by the armed forces. Instead, companies began offering fringe benefits, and hospitalisation insurance became a popular job perk.” *Id.*

27. See Allen, *supra* note 7, at 114.

28. *Id.*; see also THE AMERICAN HERITAGE COLLEGE DICTIONARY 822 (3d. ed. 2000) (defining “Managed care” as “[a]n arrangement for health care in which an organization, such as an HMO or an insurance company, acts as an intermediate between the person seeking care and the physician”).

29. See Allen, *supra* note 7, at 114.

30. *Id.*

31. See *id.* at 114; see also Walsh & Pyrich, *supra* note 17 (discussing the pharmaceutical industry’s efforts, through educational seminars, to market drugs and the FDA’s increased scrutiny of these seminars).

32. Allen, *supra* note 7, at 115.

### C. The FDA's New "Guidance"

In August 1997 the FDA changed the way pharmaceutical manufacturers were able to advertise their product directly to the consumer.<sup>33</sup> Recognizing the confusion surrounding what information in an advertisement would satisfy the regulations, the new Guidance merely clarified the FDA's stance on the regulation of DTC drug advertisements.<sup>34</sup> The Guidance no longer required a pharmaceutical manufacturer to include the "brief summary."<sup>35</sup> The DTC drug advertisement now only requires a major statement "in either the audio or audio and visual parts of the presentation. Instead of presenting a 'brief summary' in connection with the broadcast advertisement, a sponsor may make adequate provision for the dissemination of the approved package labeling in connection with the broadcast presentation."<sup>36</sup> This "adequate provision" requirement has been understood to require the "major statement" of the DTC advertisement to include information regarding the product's most important risks.<sup>37</sup> Pharmaceutical manufacturers must also provide more detailed information by

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33. See Draft Guidance for Industry; Consumer Directed Broadcast Advertisements; Availability, 62 Fed. Reg. 43,171 (proposed Aug. 12, 1997). The Guidance provides: Section 502(n) (21 U.S.C. 352(n)) of the Federal Food, Drug, and Cosmetic Act (the act) requires that advertisements for prescription drugs . . . include information in brief summary relating to side effects, contraindications, and effectiveness. This is known as the "brief summary" requirement. The prescription drug advertising regulations . . . further require that the brief summary disclose all the risk-related information in a product's approved package labeling (package insert or product package insert).

The regulations for advertising prescription drugs through broadcast media, such as radio, television, or telephone communications systems, however, modify the disclosure requirements somewhat. All prescription drug broadcast advertisements must include information about the major risks of the advertised drug (the "major statement") in either the audio or audio and visual parts of the presentation. Instead of presenting a "brief summary" in connection with the broadcast advertisement, a sponsor may make adequate provision for the dissemination of the approved package labeling in connection with the broadcast presentation . . . . This alternative requirement is referred to as the "adequate provision" requirement.

The "adequate provision" requirement recognizes the inability of broadcast advertisements of reasonable length to present and communicate effectively the extensive information that would be included in a brief summary; it instead specifies that presentation of the advertised product's most important risk information as part of the "major statement," together with "adequate provision" for the dissemination of the approved labeling, can fulfill the risk information disclosure mandated by the act.

*Id.*

34. See *id.*

35. See *id.*

36. *Id.*

37. See *id.*

a toll-free number, Internet site, or other literature.<sup>38</sup> An important point about the FDA's Guidance is that, currently, the FDA does not require pharmaceutical manufacturers to send the commercials to the FDA for pre-release screening.<sup>39</sup> The FDA only reviews the commercials after they have been released.<sup>40</sup>

DTC drug advertisements have increased substantially every year since the release of the new Guidance.<sup>41</sup> It has been estimated that in 1998, pharmaceutical manufacturers spent \$1.4 billion on DTC drug advertisements.<sup>42</sup> It is estimated that in the next year, from January 1998 to January 1999, the yearly total climbed to \$1.9 billion.<sup>43</sup> Television commercials, reported to be the fastest growing "medium for advertising," comprised \$1.1 billion of the \$1.9 billion spent in 1999 on pharmaceutical advertisements.<sup>44</sup>

### III. THE LEARNED INTERMEDIARY DOCTRINE

#### A. *The Duty to Warn*

For a manufacturer, liability for failure to warn has generally been based on negligence or strict liability.<sup>45</sup> Instructions and warnings provide a consumer the opportunity to minimize risks through proper use of a product and to make an informed decision regarding whether to even encounter the risks associated with the product.<sup>46</sup> Instructions and warnings with pharmaceutical products will almost always impact whether the consumer chooses to take the drug and thus encounter the associated risks.<sup>47</sup> Nearly all jurisdictions do not impose strict liability on a pharmaceutical manufacturer, largely because it is difficult to

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38. See Allen, *supra* note 7, at 115; see also Susan Okie, *With TV Spots, Drug Firms Aim at Patients' Role: Strategy for Prescription Shifts Away from Doctors*, WASH. POST, May 22, 2000, at A1 ("The new guidance allowed TV and radio ads to mention only major risks and to list four sources—'your doctor,' a toll-free number, a Web site and a concurrent print ad—for people who wanted additional information.").

39. See Draft Guidance for Industry; Consumer Directed Broadcast Advertisements; Availability, 62 Fed. Reg. 43,171, at 43,172-43,173; see also Okie, *supra* note 38, at A1 (reporting that drug companies "must send a copy to the FDA whenever a new TV ad (or any other prescription drug ad) debuts" and quoting chief of the division of drug advertising at the FDA who said her "staff of 15 reviewers was responsible for screening about 30,000 pieces of promotional material last year, including more than 100 television commercials").

40. See Okie, *supra* note 38, at A1.

41. See Terzian, *supra* note 6, at 151 ("Drug companies spent \$595.5 million on DTC advertisements in 1996, a ninety percent increase from 1995. This figure exceeded \$1 billion in 1997." (footnotes omitted)); see also Okie, *supra* note 38, at A1 ("Direct-to-consumer advertising for prescription medicines increased nearly 20-fold during the 1990s.").

42. See Terzian, *supra* note 6, at 151.

43. See Okie, *supra* note 38, at A1.

44. *Id.*

45. See Allen, *supra* note 7, at 117.

46. *See id.*

47. *See id.*

balance the dangers with the benefits of a pharmaceutical product.<sup>48</sup> Therefore, the liability of a pharmaceutical manufacturer is generally determined according to negligence principles and focuses on (1) who should receive the warning and (2) whether the warning was adequate.<sup>49</sup> This Comment will focus on who should receive the warning and its effect on the learned intermediary doctrine. The adequacy of a warning is beyond the scope of this Comment and will not be addressed.

*B. The Learned Intermediary Doctrine—An Exception to the Duty to Warn*

The idea that a prescription drug manufacturer only has a duty to warn the treating medical care provider, thus creating an exception to the duty to warn, can be traced as far back as the 1948 New York decision of *Marcus v. Specific Pharmaceuticals, Inc.*<sup>50</sup> In *Marcus* Judge Steuer set the foundation for what would later be called the learned intermediary doctrine:

The sole claim is not misrepresentation or even concealment, but a negligent failure to give adequate information, and in some instances a failure to use adequate means to call attention to the information given. It may be safely conceded that these allegations would be sufficient if the product were sold to the public generally as a drug for which no physician's prescription was necessary. The situation alleged is materially different. There is no reason to believe that a physician would care to disregard his own knowledge of the effects of drugs and hence of the quantity to be administered, and substitute for his own judgment that of a drug manufacturer. Nor is there any reason to expect that if a doctor did choose to rely on the information given by the manufacturer he would prescribe without knowing what that

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48. See *id.* at 117-18; see also RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965). Comment k provides:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs . . . . The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability . . . merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

*Id.*

49. See Allen, *supra* note 7, at 119.

50. 77 N.Y.S.2d 508 (App. Div. 1948).



information was. In the absence of any such grounds for belief there would be no negligence.<sup>51</sup>

The phrase “learned intermediary” was first used in *Sterling Drug, Inc. v. Cornish*.<sup>52</sup> Judge McManus, in his summary of the physician’s relationship to the patient and the pharmaceutical manufacturer, stated, “Moreover, in this case we are dealing with a prescription drug rather than a normal consumer item. In such a case the purchaser’s doctor is a *learned intermediary* between the purchaser and the manufacturer.”<sup>53</sup>

Today, the learned intermediary doctrine is well established in nearly all jurisdictions, including South Carolina.<sup>54</sup> Under the learned intermediary doctrine, if the treating medical care provider is adequately warned of the risks associated with the drug, the manufacturer cannot be said to be the proximate cause of any injuries that may arise from the patient’s use of the drug.<sup>55</sup> In *Odom* the plaintiff argued that the court should presume causation if the warning from the manufacturer was proven inadequate.<sup>56</sup> The Fourth Circuit Court of Appeals declined to follow this logic and stated:

There is no such presumption under South Carolina law, and we are unwilling to create one here. In *Thomas*, the Fifth Circuit distinguished between preventable risk warnings, which are commonly associated with mechanical products, and unavoidable risk warnings, which are often associated with prescription drugs or devices like the IUD. In the former category, a warning, if heeded, would diminish or eliminate the risk. In the latter context, however, an adequate warning “means only that the learned intermediary would have incorporated the ‘additional risk’ into his decisional calculus. The burden remains on the plaintiff to demonstrate that the additional non-disclosed risk was sufficiently high that it

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51. *Id.* at 509-510.

52. 370 F.2d 82, 85 (8th Cir. 1966).

53. *Id.* (emphasis added).

54. See *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992) (“[T]he manufacturer’s duty to warn extends only to the prescribing physician, who then assumes responsibility for advising the individual patient of risks associated with the drug or device.”); *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1231 (4th Cir. 1984) (concluding that the South Carolina Supreme Court would adopt the learned intermediary doctrine); see also *Amore v. G.D. Searle & Co.*, 748 F. Supp. 845, 850 (S.D. Fla. 1990) (applying Florida law); *Desmarais v. Dow Corning Corp.*, 712 F. Supp. 13, 17 (D. Conn. 1989) (applying Connecticut law); *Chambers v. G.D. Searle & Co.*, 441 F. Supp. 377, 381 (D. Md. 1975) (applying Maryland law).

55. See *Odom*, 979 F.2d at 1003.

56. *Id.*

would have changed the treating physician's decision to prescribe the product for the plaintiff."<sup>57</sup>

If the warnings to the treating medical care provider were not adequate, the issue of the learned intermediary does not arise, although the manufacturer may still avoid liability if causation is not shown.<sup>58</sup> It is important to note that the burden is on the plaintiff to prove that the non-disclosed risk was so serious that it would have changed the treating physician's decision to prescribe the drug to the plaintiff.<sup>59</sup> In other words, the plaintiff must show that the information that the drug manufacturer knew, or should have known, was material to the doctor's decision, and that if the doctor had been given the information, she would not have prescribed the drug.<sup>60</sup> If the warning to the medical care provider was adequate, but the drug is prescribed without the warnings being passed on to the patient, the failure by the medical care provider is viewed as the "proximate cause" of the patient's injury.<sup>61</sup>

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57. *Id.* (citations omitted) (quoting *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 814 (5th Cir. 1992)); see also *Thomas*, 949 F.2d 806, at 814 (applying Mississippi law) (holding plaintiff, injured after ingesting drug, was not entitled to a rebuttable presumption of causation after showing that the warnings provided to the physician by the manufacturer were inadequate). But see *Garside v. Osco Drug, Inc.*, 976 F.2d 77, 81 (1st Cir. 1992) (applying Massachusetts law) (holding that plaintiff was entitled to a rebuttable presumption that the manufacturer's inadequate warnings were the proximate cause of the plaintiff's injuries after the plaintiff was able to show that the warnings were inadequate); *Mampe v. Ayerst Lab.*, 548 A.2d 798, 801 (D.C. 1988). The Court of Appeals for the District of Columbia in *Mampe*, quoting *Payne v. Soft Sheen Prods., Inc.*, 486 A.2d 712, 725 (D.C. 1985), summarized the District of Columbia law regarding the presumption due to a plaintiff:

To succeed in her claim against Ayerst, Mrs. Mampe must show that some act or omission by Ayerst proximately caused her injuries. On the issue of causation in inadequate labeling cases, case law in the District of Columbia recognizes a rebuttable presumption "that the user"—in this case, the prescribing physician—"would have read an adequate warning, and that in the absence of evidence rebutting the presumption, a jury may find that the defendant's product was the producing cause of the plaintiff's injury."

*Mampe*, 548 A.2d at 801.

58. See *Brooks*, 750 F.2d at 1231.

59. See *Odom*, 979 F.2d at 1003.

60. See *id.*

61. See *Dyer v. Best Pharmacal*, 577 P.2d 1084, 1088 (Ariz. Ct. App. 1978). Affirming a summary judgment for the defendant, the court held that the alleged negligent conduct of the pharmaceutical manufacturer was not the proximate cause of the injury and stated:

The alleged negligence of the appellees was not the only force responsible for Mrs. Dyer's injuries. The active conduct of a physician was necessary in order for Mrs. Dyer to receive the injection of NOL-L.A. This act by the physician included a consideration of the recommended uses of the drug, the recommended forms of its administration, and whether any contraindications of the drug's use were present. In this case, when Dr. Stewart undertook these considerations, the efficiency of the appellees' alleged negligent course of conduct ended, and only the risk of harm created by that conduct remained.

*Id.* at 1087.

### C. Policy and Rationale Behind the Learned Intermediary Doctrine

In any analysis that questions whether the learned intermediary doctrine should apply, it becomes critical to understand the policy and rationale behind the learned intermediary rule. One basic policy is that pharmaceutical manufacturers provide valuable products that improve the “quality and duration of life.”<sup>62</sup> This is not to say that pharmaceutical manufacturers should not owe a duty of care to the general public and to the prescription consumers in particular. However, it is impossible to ignore the unique value that a prescription drug possesses. In *Reyes v. Wyeth Laboratories*<sup>63</sup> the Fifth Circuit Court of Appeals cited the decline in cases of polio as evidence of a pharmaceutical manufacturer’s value to society.<sup>64</sup> 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.<sup>65</sup>

A good example of the chilling effect on the pharmaceutical industry that can occur if this policy is not recognized and reasonably protected is the crisis that facilitated the passing of the National Childhood Vaccine Injury Act.<sup>66</sup> Between 1980 and 1986, the number of pharmaceutical manufacturers who produced the diphtheria-tetanus-pertussis (DPT) vaccine fell from eight to two.<sup>67</sup> This decline was the result of pharmaceutical manufacturers’ fears of

62. See Allen, *supra* note 7, at 130.

63. 498 F.2d 1264 (5th Cir. 1974).

64. *Id.* at 1269-70. The Fifth Circuit Court of Appeals stated:

Twenty or thirty years ago poliomyelitis was a dread disease that especially attacked the very young. In 1952 alone, there were 57,879 reported cases of polio in the United States; 21,269 of these resulted in crippling paralysis to the victims. By 1970, when Anita Reyes contracted polio, the number of those stricken by polio had diminished dramatically; she was one of just 33 individuals to be afflicted during that year. Credit for this precipitous decline must go primarily to the medical researchers who discovered the viral nature of the disease, and were able to isolate and reproduce the virus in an inactivated or an attenuated form. . . . But credit for this remarkable achievement must also be given to such laboratories as Wyeth, which processed the polio vaccine, and to massive federal-state public health programs for the administration of the vaccine.

*Id.* (footnotes omitted).

65. See RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965); see also *In re Norplant Contraceptive Prod. Liab. Litig.*, 165 F.3d 374, 379 (5th Cir. 1999) (“Our understanding of the rationale of the learned intermediary doctrine, at least in substantial part, is that it seeks to encourage the drug manufacturer to make available prescription drugs despite their potentially harmful side effects, by shielding the drug manufacturer from liability when the drug is prescribed by a properly trained physician.”).

66. See Allen, *supra* note 7, at 130-31.

67. *Id.*

product liability.<sup>68</sup> In 1986 Congress passed the National Vaccine Injury Act which limited the available legal theories a plaintiff could pursue, required a plaintiff to file any potential claim with the Secretary of Health and Human Services, and set a statutory compensation award through a no-fault system.<sup>69</sup>

Despite the reasons for protecting the manufacturers, some courts have suggested that the learned intermediary doctrine is necessary because warnings directed to patients may interfere with the treatment of the patient.<sup>70</sup> In *Reyes v. Wyeth Laboratories*, the court stated:

Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of the patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative.<sup>71</sup>

This rationale recognizes that the physician is well-trained and is probably in a better position to evaluate the patient's needs while at the same time taking into account the patient's wishes.<sup>72</sup> The physician is in a better position to more thoroughly and accurately convey any necessary warnings and will be able to do so in a way the patient is better able to understand.<sup>73</sup>

Patient's potential confusion or fear regarding a drug's adverse effects is another legitimate rationale for the learned intermediary doctrine.<sup>74</sup> In *McKee v. American Home Products Corp.* the Washington Supreme Court stated, "Some have argued that direct warnings to the consumer, once the patient has made the decision to use a drug and the physician is no longer available to counsel, may be counterproductive and are contrary to the rationale behind the learned intermediary doctrine."<sup>75</sup> Some scholars have theorized that a patient, frightened or confused by warnings given to her, whether or not such warnings

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68. *Id.*

69. *Id.* at 131.

70. *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974).

71. *Id.*

72. *See id.*

73. *See id.*; *see also* *Hill v. Searle Labs.*, 884 F.2d 1064, 1070 (8th Cir. 1989) ("[S]everal arguments support[ ] the application of this exception to prescription drug products. First, medical ethics and practice dictate that the doctor must be an intervening and independent party between patient and drug manufacturer. Second, the [risk] information . . . is often too technical for a patient to make a reasonable choice.")

74. *See* *Casey*, *supra* note 5, at 948.

75. *McKee v. Am. Home Prods., Corp.*, 782 P.2d 1045, 1055 (Wash. 1989) (citations omitted).

are material to that patient's particular situation, may cause the patient to forego treatment or conceal symptoms.<sup>76</sup>

Commentators have also argued that meaningful communication between the everyday prescription consumer and the pharmaceutical manufacturer would be best characterized as difficult.<sup>77</sup> Notwithstanding the difficulties an everyday prescription consumer would have in actually understanding any warnings from the manufacturer, there also remains a problem of actually getting the warning to the consumer.<sup>78</sup> Most prescription drugs are not disseminated in their original packaging.<sup>79</sup>

Considering the important role pharmaceutical manufacturers play in today's society along with the risks and difficulties of direct communication between the manufacturer and the consumer, there is solid policy behind the learned intermediary doctrine. This solid policy presents a formidable obstacle for opponents of the learned intermediary doctrine, and any attempt to create an exception warrants close scrutiny.

#### *D. Exceptions to the Learned Intermediary Doctrine*

Courts over the years have created several exceptions to the learned intermediary rule and have thus imposed upon a pharmaceutical manufacturer a duty to warn the prescription consumer directly.<sup>80</sup> The *Restatement (Third) of Torts: Product Liability* recognizes that courts have, at times, held that a manufacturer owes such a duty to the prescription consumer.<sup>81</sup> A fairly well-recognized exception to the learned intermediary doctrine is the "mass immunization" exception.<sup>82</sup> This exception appears to be recognized by sections 6(d) & (d)(2) of the *Restatement (Third)*, which provides:

A prescription drug . . . is not reasonably safe due to inadequate instructions or warnings if reasonable instructions

76. See Casey, *supra* note 5, at 948; see also Margaret Gilhooley, *Learned Intermediaries, Prescription Drugs, and Patient Information*, 30 ST. LOUIS U. L.J. 633, 642 (1986) (exploring current policies behind the learned intermediary doctrine and its effect on a patient's right to information).

77. See Casey, *supra* note 5, at 948.

78. See *id.*

79. See *id.*

80. See Allen, *supra* note 7, at 122.

81. RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY § 6 (d)(2) (1998).

82. See Davis v. Wyeth Labs., Inc., 399 F.2d 121, 131 (9th Cir. 1968) (applying Idaho law and holding that although the vaccine was designated as a prescription drug, it was not distributed as one, and the learned intermediary doctrine did not apply); Edwards v. Basel Pharms., 933 P.2d 298, 300-01 (Okla. 1997) (discussing the learned intermediary doctrine and its exceptions, including the mass immunization exception); Cunningham v. Charles Pfizer & Co., 532 P.2d 1377, 1381 (Okla. 1974) (finding that a manufacturer of a polo vaccine submitted to the city for a mass immunization program owed a duty to warn and that the learned intermediary doctrine did not apply).

or warnings regarding foreseeable risks of harm are not provided to . . . the patient when the manufacturer knows or has reason to know that the health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.<sup>83</sup>

This exception "operate[s] to remove the manufacturer from behind the shield of the learned intermediary doctrine."<sup>84</sup> In a mass-immunization setting, the pharmaceutical manufacturer owes a duty to warn the prescription consumer of the drug's dangers so that the consumer will be adequately informed.<sup>85</sup> The rationale behind this exception is that, in a mass immunization setting, the patient does not receive "individualized" attention from the medical care provider, and therefore, no professional calculation is made regarding what is best for the patient in that particular situation.<sup>86</sup> In *Edwards v. Basel Pharmaceuticals* the court described this "individualized attention" as follows:

Where a product is available only on prescription or through the services of a physician, the physician acts as a 'learned intermediary' between the manufacturer or seller and the patient. It is his duty to inform himself of the qualities and characteristics of those products which he prescribes for or administers to or uses on his patients, and to exercise independent judgment, taking into account his knowledge of the patient as well as the product. The patient is expected to and, it can be presumed, does place primary reliance upon that judgment. The physician decides what facts should be told to the patient. Thus, if the product is properly labeled and carries the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved, the manufacturer may reasonably assume that the physician will exercise the informed judgment thereby gained in conjunction with his own independent learning, in the best interest of the patient.<sup>87</sup>

The mass immunization exception is not the only time courts have held that the learned intermediary doctrine should not shield a manufacturer from liability.<sup>88</sup> Courts have created other limited exceptions to this doctrine.<sup>89</sup>

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83. RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY § 6(d)(2) (1998).

84. *Edwards*, 933 P.2d at 301.

85. *See id.*

86. *See id.*

87. *Id.* at 300-01.

88. *See Allen, supra* note 7, at 122.

89. *See id.*

A second exception occurs when the FDA mandates that warnings be given directly to the ultimate consumer on certain prescription drugs (most notably birth control pills) and medical devices.<sup>90</sup> Courts, at times, have held that the learned intermediary doctrine is inapplicable in these situations.<sup>91</sup> A discussion about whether the FDA's mandated requirements regarding warnings on prescriptions pre-empts state tort law is beyond the scope of this Comment. However, it is sufficient for this discussion to note that neither the FDA's safety regulations nor the Food, Drug, and Cosmetic Act expressly or impliedly pre-empt state civil tort actions in failure to warn cases.<sup>92</sup>

Further, courts generally view the FDA guidelines as a minimum standard.<sup>93</sup> Courts have also held, where the warnings given to the consumer complied with FDA guidelines, mere compliance with the FDA may still not be sufficient to shield the pharmaceutical manufacturer from liability for a failure to adequately warn the consumer.<sup>94</sup> However, courts have not been

90. *See id.*

91. *See id.* at 301; *see also* MacDonald v. Ortho Pharm. Corp., 475 N.E.2d 65, 70 (Mass. 1985) (holding that the learned intermediary doctrine does not apply in the case of oral contraceptives where the FDA has mandated warnings be given directly to the consumer).

92. *See* Graham v. Wyeth Labs., 666 F. Supp. 1483, 1500 (D. Kan. 1987). The district court discussed the preemption issue and stated:

In order to find congressional intent to preempt state tort remedies, this court would have to conclude that the federal regulations were promulgated with the intent to *exempt* drug manufacturers from tort liability. This court cannot find that such an intent is implicit in the regulatory scheme governing the manufacture and distribution of DPT. To the contrary, Congress has recently clarified its intent that regulations should *not* preempt state tort remedies for victims of vaccine-related injuries. Such intent was manifested in the "National Childhood Vaccine Injury Act" . . . . Moreover, FDA regulations of prescription drugs are generally viewed as setting *minimum* standards, both as to design and warning.

*Id.* at 1491 (citations omitted); *see also* Medtronic, Inc. v. Lohr, 518 U.S. 470, 485-86 (1996) (holding that the states have long possessed dominion over the right to protect the safety of their citizens and that this state right is not preempted unless Congress clearly expresses the intent to do so); Hill v. Searle Labs., 884 F.2d 1064, 1068 (8th Cir. 1989) ("FDA regulations are generally minimal standards of conduct unless Congress intended to preempt common law, which Congress has not done in this area."). *But cf.* Meyer v. Int'l Playtex, Inc., 724 F. Supp. 288, 293 (D.N.J. 1988) (holding that the Medical Device Act precludes a state tort action when FDA requirements satisfied).

93. *See* Edwards v. Basel Pharms., 933 P.2d 298, 302 (Okla. 1997).

94. *See id.* In *Edwards* the plaintiff sued the pharmaceutical manufacturer of nicotine patches for wrongful death after her husband suffered a fatal heart attack due to smoking cigarettes while wearing two prescribed nicotine patches. *Id.* at 299. The Supreme Court of Oklahoma concluded that the issue concerning the adequacy of a warning was not preempted by the FDA requirements and noted that the duty to warn is still governed by state law. *See id.* at 303. The court concluded:

It is the widely held view that the FDA sets minimum standards for drug manufacturers as to design and warnings. We conclude that compliance with these minimum standards does not necessarily complete the manufacturer's duty . . . . Even the FDA agrees, as noted by the FDA Commissioner who observed that civil tort liability for failure to warn is

consistent in their application of this rule, and some have held that satisfaction of FDA requirements will satisfy the duty to warn the consumer.<sup>95</sup> Regardless, satisfaction of the FDA guidelines is, at the very least, an important factor in considering whether the manufacturer satisfied its duty to warn.<sup>96</sup>

This exception to the learned intermediary doctrine has been applied primarily in cases dealing with intrauterine devices, nicotine patches, and especially with contraceptives.<sup>97</sup> Additionally, one recent, state court case

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governed by state law.

*Id.* at 302-03 (citations omitted). The court continued:

Although the common law duty we today recognize is to a large degree coextensive with the regulatory duties imposed by the FDA, we are persuaded that, in instances where a trier of fact could reasonably conclude that a manufacturer's compliance with the FDA labeling requirements or guidelines did not adequately apprise [prescription-drug] users of inherent risks, the manufacturer should not be shielded from liability by such compliance.

*Id.* at 302-03 (quoting *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65 (Mass. 1985)).

95. *See In re Norplant Contraceptive Prods. Liab. Litig.*, 165 F.3d 374, 379 (5th Cir. 1999); *Reaves v. Ortho Pharm. Corp.*, 765 F. Supp. 1287, 1291 (E.D. Mich. 1991); *Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142, 1148 (D. Or. 1989).

*In re Norplant*, the Court of Appeals for the Fifth Circuit criticized the *Edwards* decision:

The [*Edwards*] court reached this somewhat counter-intuitive result by concluding that, where the potential side effects of a prescription drug are so serious that the FDA places a requirement on the manufacturer to warn the end user, the rationale of the learned intermediary doctrine no longer applies.

At the outset, we find this conclusion to be puzzling. Our understanding of the rationale of the learned intermediary doctrine, at least in substantial part, is that it seeks to encourage the drug manufacturer to make available prescription drugs despite their potentially harmful side effects, by shielding the drug manufacturer from liability when the drug is prescribed by a properly trained physician. Why the learned intermediary doctrine should somehow be less applicable when the severity of the side effects encourages the FDA to promote additional labeling escapes us.

*In re Norplant*, 165 F.3d at 379; *see also* *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245, 1259 (N.J. 1999) (holding that satisfaction of the FDA guidelines creates a presumption that the warnings are adequate).

96. *See Edwards*, 933 P.2d at 302.

97. *See Hill v. Searle Lab.*, 884 F.2d 1064, 1071 (8th Cir. 1989) (holding that the learned intermediary doctrine did not apply for intrauterine-device case); *Stephens v. G.D. Searle & Co.*, 602 F. Supp. 379, 381 (E.D. Mich. 1985) (adopting language from the dissenting opinion in *In re Certified Questions, Odgers v. Ortho Pharm. Corp.*, 358 N.W.2d 873 (Mich. 1984) and holding that the manufacturer of an oral contraceptive had a duty to warn the consumer despite the learned intermediary); *Lukasiewicz v. Ortho Pharm. Corp.*, 532 F. Supp. 211, 213 (E.D. Wis. 1981) (holding that the learned intermediary doctrine does not apply to oral contraceptive manufacturer in failure to warn case); *Perez v. Wyeth Lab., Inc.*, 734 A.2d 1245, 1247 (N.J. 1999) (holding that the learned intermediary doctrine did not apply in a Norplant birth control failure to warn case); *Edwards v. Basel Pharm.*, 933 P.2d 298, 301 (Okla. 1997) (holding that learned intermediary doctrine is not applicable in a wrongful death action arising from prescription of nicotine-patches). *But see In re Norplant Contraceptive Products Liability Litigation*, 165 F.3d 374, 380 (5th Cir. 1999) (applying the learned intermediary doctrine in a class-action case involving the manufacturer of the surgically implanted contraceptive,



deserves particular mention among these “exception cases.” In *Perez v. Wyeth Laboratories, Inc.*,<sup>98</sup> the New Jersey Supreme Court held that the learned intermediary doctrine should not apply when a drug is marketed directly to the consumer through DTC advertising.<sup>99</sup> However, *Perez*, a warning case involving the contraceptive Norplant, ignored the Tenth Circuit Court of Appeals’ decision in *In re Norplant Contraceptive Products Liability Litigation*,<sup>100</sup> which held that the learned intermediary doctrine should be applied in failure to warn cases involving Norplant.<sup>101</sup> In *Perez* the Supreme Court of New Jersey stated that it preferred the reasoning in *Edwards v. Basel Pharmaceuticals, Inc.*,<sup>102</sup> which held that the learned intermediary doctrine did not apply in a failure to warn case involving a prescription nicotine patch,<sup>103</sup> over the Fifth Circuit’s reasoning in *In re Norplant*,<sup>104</sup> even though the Fifth Circuit specifically criticized *Edwards* in *In re Norplant*.<sup>105</sup> Although *Perez* has not yet been rejected by any court, it has also not been relied on to hold the learned intermediary doctrine inapplicable because of DTC advertising. These cases illuminate the inconsistencies among courts in finding exceptions to the learned intermediary doctrine and demonstrate their resistance to dislodge this well established doctrine. Furthermore, at least one court has called these birth control, failure-to-warn, learned-intermediary-exception cases the “minority” rule.<sup>106</sup>

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Norplant); *Reaves v. Ortho Pharm. Corp.*, 765 F. Supp. 1287, 1291 (E.D. Mich. 1991) (holding that the learned intermediary doctrine applied because oral contraceptives were prescription drugs and could only be obtained from a physician); *Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 401 (Del. 1989) (holding that the learned intermediary doctrine applied in a failure to warn claim involving intrauterine-devices); *Martin v. Ortho Pharm. Corp.*, 661 N.E.2d 352, 356 (Ill. 1996) (holding that the learned intermediary doctrine relieves the manufacturer of the duty to warn the consumer regarding oral contraceptive prescriptions); *Freeman v. Hoffman-LaRouche, Inc.*, 618 N.W.2d 827, 842 (Neb. 2000) (holding that the learned intermediary doctrine would apply in a failure to warn case regarding the drug Accutane); *Tracy v. Merrell Dow Pharm. Inc.*, 569 N.E.2d 875, 879 (Ohio 1991) (holding that the learned intermediary doctrine relieved the manufacturer of Nicorette tablets from a duty to warn).

98. 734 A.2d 1245 (N.J. 1999).

99. *Id.* at 1247.

100. *Id.* at 1256.

101. *In re Norplant Contraceptive Prods. Liab. Litig.*, 165 F.3d 374, 379-80 (5th. Cir. 1999).

102. 933 P.2d 298 (Okla. 1997).

103. *See id.* at 303.

104. *See Perez*, 734 A.2d at 1256.

105. *See In re Norplant*, 165 F.3d at 379.

106. *Martin v. Ortho Pharm. Corp.*, 661 N.E.2d 352, 356 (Ill. 1996).

#### IV. ANALYSIS: THE LEARNED INTERMEDIARY DOCTRINE IN CONNECTION WITH DTC ADVERTISEMENTS

##### A. *The Alteration of the Physician-Patient Relationship*

The central theme, consistent among all of the cases finding an exception to the learned intermediate doctrine, is that the physician-patient relationship is not the same as in typical treatment scenarios. All of the cases that impose a duty upon the pharmaceutical manufacturer to warn the consumer do so relying in substantial part on some type of significant change in the physician-patient relationship.<sup>107</sup> Comment b to § 6(b)(2) of the *Restatement (Third)* recognizes this change in the physician-patient relationship exception by providing, "[I]n certain limited therapeutic relationships the physician or other health-care provider has a much-diminished role as an evaluator or decisionmaker. In these instances it may be appropriate to impose on the manufacturer the duty to warn the patient directly."<sup>108</sup>

The most obvious change in this relationship is viewed in the mass-immunization setting. In these settings very little to no physician-patient relationship exists.<sup>109</sup> The individualized medical judgment, the cornerstone of the learned intermediary doctrine,<sup>110</sup> is glaringly absent in situations where the drug is administered to a large group of patients with only a single physician, or even only a nurse, acting more as an overseer of the process and less like a physician who examines and makes an individualized judgment about each patient.<sup>111</sup>

The issue is not as clear in the non-mass-immunization setting because the patient actually does meet with a doctor. However, the substantial lack of a physician-patient relationship is still reasonably evident.

In *Hill v. Searle Laboratories*<sup>112</sup> the court noted several factors that indicate a change in the physician-patient relationship.<sup>113</sup> First, the court pointed out that the decision to take the prescription, an intrauterine device (IUD) in this case, was almost entirely the patient's to make and not the physician's.<sup>114</sup> The court also noted that the patient had no contact with the physician after the prescription had been given, the product was marketed directly to the

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107. See *Odgers v. Ortho Pharm. Corp.*, 609 F. Supp. 867, 878 (E.D. Mich.1985); *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 69-70 (Mass. 1985).

108. RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY § 6 cmt. b (1998) (citation omitted).

109. See Teresa Moran Schwartz, *Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule*, 46 FOOD DRUG COSM. L. J. 829, 832 (1991).

110. See RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY § 6 cmt. b.

111. See Allen, *supra* note 7, at 122.

112. 884 F.2d 1064 (8th Cir. 1989).

113. *Id.* at 1070-71.

114. *Id.*

consumer, and that the FDA required the warnings be given directly to the consumer.<sup>115</sup>

In *MacDonald v. Ortho Pharmaceutical Corp.*<sup>116</sup> the only state court case currently known to hold that the learned intermediary doctrine did not shield the manufacturer of an oral contraceptive from the duty to warn the consumer, the court noted that the physician's role was reduced to a "passive" one regarding the patient's choice to begin using "the Pill."<sup>117</sup> Similar to *Hill*, the court's decision in *MacDonald* to not apply the learned intermediary doctrine centered on the following factors: (1) the minimal amount of input necessary from the physician in the patient's decision to actually take the prescription (an oral contraceptive in this case); (2) the physician only examines the patient once before prescribing the contraceptive; (3) the physician will only examine the patient on an annual basis after the prescription has been given; and (4) the extensive regulations imposed on the oral contraceptive manufacturer by the FDA.<sup>118</sup> This change in the physician-patient relationship is conspicuous in all of the cases that find the learned intermediary doctrine inapplicable.<sup>119</sup>

In these cases the courts have also mentioned the distinction between a therapeutic drug and a non-therapeutic drug.<sup>120</sup> A therapeutic drug is a drug "[h]aving or exhibiting healing powers."<sup>121</sup> Obviously many of the prescriptions, the contraceptives for instance, that have been the center of controversy in the cases that have held the learned intermediary doctrine inapplicable, fall on the side of non-therapeutic.<sup>122</sup> The decisional calculus that is so essential to the rationale behind the learned intermediary doctrine is much more evident when the patient visits the physician for therapeutic reasons, such as treatment of an illness, as opposed to non-therapeutic reasons, such as to receive "the Pill."<sup>123</sup> When prescribing a non-therapeutic drug, the physician may be transformed from an advisor to a "supporting role."<sup>124</sup> Essentially, the decision is almost entirely the patient's, not the physician's.

It is important to keep in mind that these exception cases are by no means the settled law.<sup>125</sup> Almost all of those cases that have held the learned intermediary doctrine to be inapplicable have been highly criticized by other

115. *Id.*

116. 475 N.E.2d 65 (Mass. 1985).

117. *Id.* at 69.

118. *Id.*

119. *Id.*; see also *Stephens v. G.D. Searle & Co.*, 602 F. Supp. 379, 381 (E.D. Mich. 1985) (noting that the patient sought and received the prescription contraceptive with little input from the prescribing physician); *Odgers v. Ortho Pharm. Corp.*, 609 F. Supp. 867, 874-75 (E.D. Mich. 1985) (noting that patients who receive prescriptions for oral contraceptives play a much different role than in traditional prescription settings).

120. See *Stephens*, 602 F. Supp. at 380-81; *Odgers*, 609 F. Supp. at 874-75.

121. THE AMERICAN HERITAGE COLLEGE DICTIONARY 1406 (3d ed. 2000).

122. See *id.*

123. See *Stephens*, 602 F. Supp. at 380-81.

124. *Odgers*, 609 F. Supp. at 875.

125. See *Martin v. Ortho Pharm. Corp.*, 661 N.E.2d 352, 356 (Ill. 1996).

courts.<sup>126</sup> At least one court has called these exception cases the "minority" rule.<sup>127</sup> *MacDonald* is the only state court case currently known to have held that the learned intermediary doctrine did not apply to a failure to warn case regarding oral contraceptives.<sup>128</sup> The learned intermediary doctrine is a well-established doctrine and any exception to this doctrine is narrowly construed.<sup>129</sup>

*B. DTC Advertisements and the Physician-Patient Relationship: Is there Enough Change to Warrant an Exception to the Learned Intermediary Rule?*

After understanding why the courts, although not consistently, have held the learned intermediary doctrine inapplicable in some cases, the issue of the learned intermediary doctrine and DTC pharmaceutical advertising arises. The question still remains: since manufacturers are now able to market their product directly to the consumer,<sup>130</sup> should the courts create another exception to the learned intermediary doctrine and hold drug manufacturers who advertise their products through DTC advertisements liable for a failure to warn the prescription consumer? Based on the rationale applied in the cases discussed earlier, the answer appears to depend on whether the physician-patient relationship is substantially changed by these advertisements.<sup>131</sup>

Critics of DTC advertising who propose that such advertising warrants an exception to the learned intermediary doctrine suggest that the physician-patient relationship is altered by DTC advertising.<sup>132</sup> As one doctor stated, "I have seen an increase in patients coming into this office and requesting a specific brand of drug that they saw on television."<sup>133</sup> One reported study showed that DTC advertising can lead to the physician having to spend more time with the patient reviewing the pros and cons of the requested drug and explaining formulary restrictions when the requested drug is outside the health

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126. See *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1305-06 (D. Minn. 1988) (disagreeing with *Odgers v. Ortho Pharm. Corp.* and *Stephens v. G.D. Searle & Co.*); *Humes v. Clinton*, 792 P.2d 1032, 1040-41 (Kan. 1990) (declining to follow *Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp. 961 (E.D. Wis. 1981)); see also Schwartz, *supra* note 109, at 834 ("With the few exceptions noted above, courts have chosen not to abandon the learned intermediary rule in prescription drug cases.")

127. See *Martin v. Ortho Pharm. Corp.*, 661 N.E.2d 352, 356 (Ill. 1996).

128. See *supra* note 119 and accompanying text.

129. See Schwartz, *supra* note 109, at 831.

130. See *supra* text accompanying notes 33-40.

131. See *supra* text accompanying notes 107-29.

132. See Terzian, *supra* note 6, at 157; see also *Patient Requests for Brand Name Rx on Rise*, 21 CHAIN DRUG REV., Jan. 18, 1999, at Rx7 ("Two new studies by IMS Health find that half of United States-based physicians and managed care organizations report a significant increase in the number of consumers requesting prescription drugs by brand name . . .").

133. Interview with Kevin Griggs, M.D., Family Physician at Lexington Family Practice, in Columbia, S.C. (Sept. 14, 2000).

plan's formulary.<sup>134</sup> Another survey of 5,000 patients and 5,000 physicians found that almost 75% of the doctors discussed, in one way or another, the contents of a DTC advertisement and almost 90% of the 5,000 patients had asked for the drug by its brand name.<sup>135</sup>

Undeniably, DTC drug advertising has led to an increase in patients asking their doctors for a particular drug by name. Thus there has been some type of change in the physician-patient relationship. The question remains: Do DTC advertisements alter the physician-patient relationship enough to warrant an exception to the learned intermediary doctrine? More importantly, has the relationship been "diminished"?<sup>136</sup>

Managed care has put a strain on the amount of time a physician can spend with a patient.<sup>137</sup> A reality of managed care programs is that the physician spends less time with the patient.<sup>138</sup> Commentators argue that the "overall health of a patient may be compromised" when the physician has to spend more time with a patient answering questions about a drug the patient saw on television and less time actively examining and treating the patient.<sup>139</sup>

Commentators have also suggested that physicians may prescribe a drug to a patient even when the physician does not feel that particular drug is in the patient's best interest.<sup>140</sup> One survey found that one-half of the physicians surveyed feel pressured to prescribe a prescription to the patient when the patient asks for a particular prescription.<sup>141</sup>

Courts have not shown a particular deference towards this line of thinking. In *Incollingo v. Ewing*<sup>142</sup> the physician claimed he was pressured by "detail men" (better characterized as sales representatives) from the pharmaceutical manufacturer to prescribe a drug that he otherwise would not have prescribed.<sup>143</sup> The court responded to this assertion by stating:

We decline to accept the proposition that a qualified doctor can so easily turn himself into a dupe. As indicated [before], the [drug manufacturer's] warnings were there to read if he would, and the dangers of the drug were . . . also revealed in other medical literature to which the doctor had access and which he said he read. . . . The court below was correct in

134. Terzian, *supra* note 6, at 158.

135. Paul D. Colford, *DTC Ads: Just what the Doctor Ordered*, MEDIAWEEK, Oct. 20, 1997, at 46, 47.

136. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6 cmt. b.

137. See Holtz, *supra* note 2, at 214.

138. See *id.*

139. *Id.*

140. See Somora, *supra* note 1, at 212.

141. *Direct-to-Consumer Ads: Influence Doctor's RX Behavior*, AM. HEALTH LINE, Nov. 10, 1999.

142. 282 A.2d 206 (Pa. 1971).

143. *Id.* at 218.

not permitting him to take refuge behind the asserted liability of the manufacturer.<sup>144</sup>

When asked if he felt doctors were being pressured to prescribe drugs for their patients merely because the patient asked for a drug advertised on television, one physician simply stated, "It all depends on the doctor."<sup>145</sup>

Critics of DTC drug advertising, and there are many, also argue that DTC ads tend to mislead the consumer.<sup>146</sup> Critics charge that television commercials and other forms of advertisements are designed to sell and therefore are not reliable sources of information.<sup>147</sup> These critics are concerned that the patient will have misconceived notions of the drug's benefit and potential, and this could lead to a further strain on the physician-patient relationship.<sup>148</sup> Patients may begin to substitute advertising promises and misrepresentations for the judgment of their physicians.

While this concern is valid, the FDA monitors these DTC drug advertisements,<sup>149</sup> employs a staff that reviews them for misleading information,<sup>150</sup> and is known to act swiftly on any advertisements that have even a subtle tendency to mislead.<sup>151</sup> One example is a television commercial where Schering-Plough "touted" the benefits of its product in slow and easy to understand language but when the adverse effects to the drug were read by the announcer, the commercial displayed a competing message that gave the manufacturer's Internet site.<sup>152</sup> The FDA quickly had Schering-Plough pull the ad.<sup>153</sup>

It is important to note that the FDA is a "science-based law enforcement agency" designed to improve customer protection.<sup>154</sup> Whether there are problems with the way the FDA enforces its own regulations is beyond the scope of this Comment. However, courts have recognized that it may be beyond the realm of the courts' duties to hand down decisions that, either in whole or in part, are motivated by a desire to make broad legislative-type

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144. *Id.*

145. Interview with Kevin Griggs, M.D., Family Physician at Lexington Family Practice, in Columbia, S.C. (Sept. 14, 2000).

146. *See* Somora, *supra* note 140, at 211.

147. *See id.*

148. *See* Terzian, *supra* note 6, at 158.

149. *See* Draft Guidance for Industry; Consumer Directed Broadcast Advertisements; Availability, 62 Fed. Reg. 43,171 (proposed Aug. 12, 1997); Okie, *supra* note 38, at A1.

150. *See* Okie, *supra* note 38, at A1.

151. *See* Somora, *supra* note 1, at 211.

152. *See id.*

153. *See id.*

154. *See generally* David A. Kessler, *Remarks by the Commissioner of Food and Drugs at the Association of Food and Drug Officials' Annual Conference*, 46 FOOD DRUG COSM. L. J. 773 (1991) (emphasizing the FDA's role as a science-based law enforcement agency).

decisions.<sup>155</sup> In *Odgers v. Ortho Pharm. Corp.*<sup>156</sup> the court addressed this issue and stated, “The allocation of the duty to warn patients is a public policy question involving the marketing system and economics of a major industry and the everyday practice of an essential profession. We believe that the Legislature is in a better position to allocate those duties.”<sup>157</sup> In *Haverly v. United States*<sup>158</sup> the Court of Appeals for the Seventh Circuit expressed this rationale by stating, “[i]t is not for the courts to quarrel with an agency’s rational allocation of its administrative resources.”<sup>159</sup> Simply put, although defining the scope of tort liability has traditionally been within the scope of the judiciary,<sup>160</sup> the notion that the judiciary oversteps its boundaries when it encroaches on areas of law heavily regulated by the federal government is probably more sound.

While there is some evidence that the physician-patient relationship may be altered, the severity of this alteration remains, at best, unclear. A gap appears when contrasting this unclear and seemingly slight interference with the physician-patient relationship from DTC ads,<sup>161</sup> with the more absolute change of relationship in the recognized exceptions to the doctrine discussed above.<sup>162</sup> The lack of a meaningful physician-patient relationship is more evident in the recognized exceptions. Having to take more time to explain a drug or to clear up a misconception about that drug seems to actually enhance, rather than diminish, the physician’s “role as an evaluator or decisionmaker.”<sup>163</sup> Even if answering questions, however, diminishes examination and treatment time,<sup>164</sup> the diminution still does not compare to the absolute lack of a physician-patient relationship found in a mass-immunization setting. Furthermore, DTC drug advertising does not give rise to a situation in which the doctor assumes a passive role as is done in non-therapeutic settings.<sup>165</sup> The physician still has the absolute duty to examine and advise the patient.<sup>166</sup> Perhaps the best answer to this problem is simply to recognize that the advertisements and their effects on the prescription consumer may be one additional factor a doctor has to consider in his decisional calculus when

155. *Odgers v. Ortho Pharm. Corp.*, 358 N.W.2d 873 (Mich. 1984).

156. *Id.*

157. *Id.* at 874. *But see* *Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245, 1254 (N.J. 1999) (rejecting the notion that the court should await legislative action before ruling on the applicability of the learned intermediary doctrine, which in New Jersey had been relegated to statutory law).

158. 513 F.2d 224 (7th Cir. 1975).

159. *Id.* at 227.

160. *See Perez*, 734 A.2d at 1254.

161. *See supra* text accompanying notes 139-53.

162. *See supra* text accompanying notes 80-129.

163. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCT LIABILITY § 6 cmt. b.

164. *See Holtz, supra* note 2, at 214.

165. *See Perez v. Wyeth Lab. Inc.*, 734 A.2d 1245, 1260 (N.J. 1999).

166. *See Terzian, supra* note 6, at 157.

treating a patient. However, before coming to a conclusion on this issue, there are several general policy issues that must be first considered.

### C. Policy Considerations

The serious nature of the law regarding prescription drugs is obvious. "Adverse drug reactions are a major cause of hospitalization, prolonged hospital stays, and frequently death in the United States."<sup>167</sup> The availability of prescription drugs is critical to public health, and public policy strongly favors fostering a legal and social environment that encourages the continued production and research of pharmaceutical products.<sup>168</sup> The noted Dean Prosser discussed this policy and stated:

'The argument that industries producing potentially dangerous products should make good the harm, distribute it by liability insurance, and add the cost to the price of the product, encounters reason for pause, when we consider that two of the greatest medical boons to the human race, penicillin and cortisone, both have their dangerous side effects, and that drug companies might well have been deterred from producing and selling them.'<sup>169</sup>

The policy considerations behind the learned intermediary doctrine discussed in Part III of this Comment are also clearly applicable in this section. The importance of not discouraging pharmaceutical manufacturers from research and production of useful products along with the risks and difficulties of direct warnings to the prescription consumers clearly apply to this portion of the analysis. However, at this point in the discussion, there are further considerations that support the notion that DTC advertisements should not create another exception to the learned intermediary doctrine.

DTC drug advertisements have various educational benefits.<sup>170</sup> One such tangible benefit is that information about new treatments is easily distributed to the general public.<sup>171</sup> Television commercials obviously reach an enormous number of people, and the benefit of distributing information almost instantaneously about a new drug that can improve millions of lives is undeniable. Tied in with this benefit is the idea that information about established treatments is also easily disseminated to millions. Commercials that

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167. Holtz, *supra* note 2, at 209 (footnote omitted).

168. See JOHN W. WADE ET. AL., PROSSER, WADE AND SCHWARTZ'S CASES AND MATERIALS ON TORTS 749 (9th ed. 1994) (quoting DEAN PROSSER, TORTS § 99, at 661 (4th ed. 1971)) (footnotes omitted).

169. *Id.*

170. See Terzian, *supra* note 6, at 156.

171. See Kathy L. Woodard, *New Choices, New Responsibilities*, BUSINESS FIRST-COLUMBUS, June 23, 2000, at 4a.



list various symptoms to an ailment may alert a viewer to a problem they did not know existed.<sup>172</sup> Recognizing warning signs to diseases like hypertension or depression can alert a consumer at the early stages of an ailment.<sup>173</sup>

DTC drug commercials have also helped lift some social barriers to problems that patients at one time hesitated to discuss with their doctors. One doctor stated:

The biggest change I have seen stemming from these commercials is the inquiries I have about Viagra. Impotency was not a commonly discussed problem with my patients in the past. Now, the most common conversation I have with my patients that stems from a drug they saw on TV is a conversation about Viagra.<sup>174</sup>

Prescription products for depression are also commonly advertised products.

Critics of DTC drug advertising cite the rising costs of prescriptions and question whether it is appropriate for prescription prices to rise, partly because pharmaceutical companies are spending more money each year on advertising budgets.<sup>175</sup> This issue, however, is beyond the scope of this Comment except to note that the FDA regulates the pharmaceutical industry,<sup>176</sup> and it is not for courts to mandate industry regulation to the FDA implicitly through tort decisions. If the FDA decides that the pharmaceutical industry should change the way its products are marketed, it is the FDA's duty to take such appropriate action.<sup>177</sup>

## V. CONCLUSION

The learned intermediary doctrine is a well-established legal doctrine and should not be discarded simply because the governmental agency charged with the protection of the prescription consumer saw fit to loosen its restrictions on advertising. Exceptions to this doctrine have been narrowly construed and have only been accepted in cases where there was a substantial change in the physician-patient relationship. No clear, substantial change in this relationship has evidenced itself as a result of DTC drug advertising. Physicians are still the final gatekeepers and there is not enough evidence to show that the keys have been handed to the patients. Courts should approach this issue with the

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172. See Terzian, *supra* note 6, at 156-57.

173. See *id.*

174. Interview with Kevin Griggs, M.D., Family Physician at Lexington Family Practice, in Columbia, S.C. (Sept. 14, 2000).

175. See Woodard, *supra* note 171, at 4a.

176. See 21 U.S.C. § 352(n) (1988).

177. See *id.*

recognition that DTC advertising is simply another factor in the physician's decisional calculus in the treatment of the patient.

*Jeffrey J. Wiseman*

