

January 2000

## How Many Times Must the Question Be Answered? The Application of the Learned Intermediary Doctrine in the Norplant Contraceptive Products Liability Litigation

Stacey Leffler Ravetta

Follow this and additional works at: <http://digitalcommons.law.ggu.edu/ggulrev>

 Part of the [Torts Commons](#)

---

### Recommended Citation

Stacey Leffler Ravetta, *How Many Times Must the Question Be Answered? The Application of the Learned Intermediary Doctrine in the Norplant Contraceptive Products Liability Litigation*, 30 Golden Gate U. L. Rev. (2000).  
<http://digitalcommons.law.ggu.edu/ggulrev/vol30/iss2/5>

This Note is brought to you for free and open access by the Academic Journals at GGU Law Digital Commons. It has been accepted for inclusion in Golden Gate University Law Review by an authorized administrator of GGU Law Digital Commons. For more information, please contact [jfischer@ggu.edu](mailto:jfischer@ggu.edu).

## NOTE

# HOW MANY TIMES MUST THE QUESTION BE ANSWERED? THE APPLICATION OF THE LEARNED INTERMEDIARY DOCTRINE IN THE *NORPLANT CONTRACEPTIVE PRODUCTS LIABILITY LITIGATION*

## I. INTRODUCTION

The *Norplant Contraceptive Products Liability Litigation*<sup>1</sup> (“Norplant Litigation”) was lengthy and complex multidistrict litigation involving the prescription Norplant Contraceptive Device (“Norplant”).<sup>2</sup> Since the introduction of the first oral contraceptives in the late 1960s, the first Intrauterine Devices (“IUDs”) in the 1970s, and Norplant in the 1990s, women experienced various adverse side effects when using any of these methods to prevent pregnancy.<sup>3</sup> Many women who suffered negative reactions brought lawsuits against the pharmaceuti-

---

<sup>1</sup> See *In re Norplant Contraceptive Products Liability Litigation*, 165 F.3d 374 (5th Cir. 1999) [hereinafter “*Norplant Litigation II*”].

<sup>2</sup> See *In re Norplant Contraceptive Products Liability Litigation*, 955 F. Supp. 700 (E.D. Tex. 1997) [hereinafter “*Norplant Litigation I*”]. See also *Norplant Litigation II*, 165 F.3d at 374.

<sup>3</sup> See generally *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65 (Mass. 1985); *Reaves v. Ortho Pharmaceutical Corp.*, 765 F. Supp. 1287 (E.D. Mich. 1991); *In re A.H. Robins Co. Inc., “Dalkon Shield” IUD Products Liability Litigation*, 505 F. Supp. 221 (J.P.M.L. 1981); *Perez v. Wyeth Laboratories, Inc.*, 734 A.2d 1245 (N.J. Sup. Ct. 1999).

## 332 GOLDEN GATE UNIVERSITY LAW REVIEW [Vol. 30:2

cal companies under products liability theories.<sup>4</sup> The results of the lawsuits varied depending on the jurisdictions in which the they were filed and the types of injuries the women sustained.<sup>5</sup> Similarly, in the *Norplant Litigation*, the plaintiffs alleged various side effects and claimed that the defendant did not provide adequate warnings of the potential risks.<sup>6</sup> The complaints against Norplant's manufacturer, Wyeth Laboratories, and its parent company, American Home Products (collectively "AHP") focused on twenty-six adverse reactions common to the majority of the plaintiffs.<sup>7</sup>

The primary issue presented in the *Norplant Litigation* was the federal district court's decision to apply the learned intermediary doctrine to the plaintiffs' failure to warn claims against AHP.<sup>8</sup> Since Norplant was a relatively new method of contraception at the time of the litigation, the court had limited binding precedent to apply to the facts of the plaintiffs' case.<sup>9</sup> Therefore, the court looked to similar cases involving prescription drugs and concluded that it should apply the learned intermediary doctrine to all of the plaintiffs' claims.<sup>10</sup> As a result of this determination, the court held that the de-

<sup>4</sup> See generally *MacDonald*, 475 N.E.2d 65; *Reaves*, 765 F. Supp. 1287; *Dalkon Shield*, 505 F. Supp. 221; *Perez*, 734 A.2d 1245.

<sup>5</sup> See generally *MacDonald*, 475 N.E.2d 65; *Reaves*, 765 F. Supp. 1287; *Dalkon Shield*, 505 F. Supp. 221; *Perez*, 734 A.2d 1245.

<sup>6</sup> See *Norplant Litigation I*, 955 F. Supp. at 702.

<sup>7</sup> See Defendant's No. 2 Memorandum in Support of Motion For Partial Summary Judgment Re Adequacy of the Norplant Labeling at 2, *Norplant Contraceptive Products Liability Litigation*, 955 F. Supp. 700 (E.D. Tex. 1997) (MDL 1038).

<sup>8</sup> See *Norplant Litigation I*, 955 F. Supp. at 702. The plaintiffs claimed that the defendant's failure to adequately warn of Norplant's side effects gave rise to liability under numerous theories including: strict liability, negligence, misrepresentation, breach of implied warranty of merchantability, and under the Texas Deceptive Trade Practices Act ("DTPA"). See *id.* at 703.

<sup>9</sup> See *id.* at 703. Since the federal district court's jurisdiction over the *Norplant Litigation* was based on diversity of citizenship, the court applied Texas law to the case. See *id.*

<sup>10</sup> See *id.* at 704. The court looked to Texas court decisions involving prescription drugs and the decisions of other states regarding the treatment of failure-to-warn claims specifically involving prescription contraceptives since the Texas courts had ruled on that issue. See *id.* at n.18.

fendant was insulated from liability to the plaintiffs for the adverse reactions they experienced as a result of using Norplant.<sup>11</sup> Subsequently, the court granted summary judgment in AHP's favor.<sup>12</sup> On appeal, the United States Court of Appeals for the Fifth Circuit affirmed the lower court's ruling.<sup>13</sup>

Part II of this Note begins with a general discussion of failure to warn causes of action and the application of the learned intermediary doctrine thereto. Further, Part II discusses cases essential to understanding the background of the *Norplant Litigation*. Next, Parts III and IV explain the facts and procedural history underlying the *Norplant Litigation*. Part V first examines the federal district court's analysis of the case. It then discusses the Fifth Circuit's analysis of the federal district court's summary judgment ruling in AHP's favor. Part VI examines the federal district court's pivotal decision to apply the learned intermediary doctrine to the plaintiffs' claims against AHP, and the Fifth Circuit's decision to affirm this ruling, thereby effectively ending the litigation. Further, Part VI also notes that direct-to-consumer advertising creates a new and unprecedented issue in failure to warn product liability cases involving prescription drugs.

## II. BACKGROUND

Norplant is comprised of synthetic hormones that prevent pregnancy.<sup>14</sup> These hormones potentially cause adverse side effects.<sup>15</sup> The *Norplant Litigation* began when women experiencing side effects sought to certify a nationwide class of persons who suffered or may suffer injury as a result of using Norplant against the device's manufacturer, Wyeth Laborato-

---

<sup>11</sup> See *id.* at 701.

<sup>12</sup> See *id.*

<sup>13</sup> See *Norplant Litigation II*, 165 F.3d at 375.

<sup>14</sup> See *In re Norplant Contraceptive Products Liability Litigation*, 165 F.3d 374, 376 (5th Cir. 1999) [hereinafter "*Norplant Litigation II*"].

<sup>15</sup> See *In re Norplant Contraceptive Products Liability Litigation*, 955 F. Supp. 700, 702 (E.D. Tex. 1997) [hereinafter "*Norplant Litigation I*"].

## 334 GOLDEN GATE UNIVERSITY LAW REVIEW [Vol. 30:2

ries, Inc., and its parent company, American Home Products (collectively "AHP").<sup>16</sup> The plaintiffs claimed that AHP was liable for failing to adequately warn them of the risks inherent in Norplant use.<sup>17</sup> Both the federal district court and the Fifth Circuit applied the learned intermediary doctrine to the plaintiffs' claims, thereby insulating AHP from liability for failing to warn the ultimate consumer.<sup>18</sup> An examination of the authority relied on by both courts in the *Norplant Litigation* illustrates the complexity and longevity of the central legal issue presented in this litigation: the application of the learned intermediary doctrine and its continuing impact on a pharmaceutical manufacturer's liability for failing to directly warn consumers of the risks associated with its products.<sup>19</sup>

## A. THE NORPLANT CONTRACEPTIVE DEVICE

In 1991, AHP introduced Norplant to the birth control market after more than two decades of development and testing.<sup>20</sup> Norplant consists of six thin, match-stick size, silicone-coated, capsules of synthetic progesterone, called levonorgestrel, inserted just below the skin of a woman's upper arm.<sup>21</sup> Norplant may remain in place for up to five years, and while implanted, constantly releases a small, continuous dose of levonorgestrel

---

<sup>16</sup> *See id.*

<sup>17</sup> *See id.*

<sup>18</sup> *See Norplant Litigation I*, 955 F. Supp. at 701. *See also Norplant Litigation II*, 165 F.3d at 375.

<sup>19</sup> *See Norplant Litigation I*, 955 F. Supp. at 704-705 (citing *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65 (Mass. 1985); *Reaves v. Ortho Pharmaceutical Corp.*, 765 F. Supp. 1287 (E.D. Mich. 1991); *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974)).

<sup>20</sup> *See Perez v. Wyeth Laboratories, Inc.*, 713 A.2d 588, 589 (N.J. Law Div. 1997). The Population Council, a non-profit organization committed to the advancement of reproductive health developed Norplant. The Population Council began development of Norplant in 1966 and tested it on over 55,000 women in forty-four countries over the following two decades. The Population Council granted Wyeth Laboratories, Inc. the exclusive right to market Norplant in the United States. *See id.*

<sup>21</sup> *See Planned Parenthood Federation of America, Inc., Fact Sheet: Norplant and You* (1997). Levonorgestrel is the term for synthetic progesterone hormone. *See id.*

into the blood stream.<sup>22</sup> Levonorgestrel prevents pregnancy by keeping the ovaries from releasing eggs and thickens the cervical mucus, which impedes sperm from joining with an egg.<sup>23</sup> In addition, some researchers believe that Norplant may also prevent a fertilized egg from attaching to the lining of a woman's uterus.<sup>24</sup> Norplant is a highly effective contraceptive, as demonstrated by statistics revealing that of every one hundred women who use the device for five years, fewer than four will become pregnant.<sup>25</sup>

Although Norplant is highly effective, women often experience various negative reactions due to the hormonal nature of the device.<sup>26</sup> A Norplant user's bloodstream carries the additional levonorgestrel to the pituitary gland in the brain and to the uterus and cervix.<sup>27</sup> Due to the increased level of progesterone in a woman's body, she may experience side effects including, but not limited to, various combinations of severe headaches, mood swings, depression, nausea, acne, arm pain, numbness, breast tenderness, weight gain, hair loss, cramps, and menstrual cycle irregularities.<sup>28</sup> Physicians prescribing a synthetic hormone-based contraceptive such as Norplant must inform their patients that using the device to prevent pregnancy may include the risk of experiencing other side effects.<sup>29</sup>

### *1. Failure to Warn Claims*

The general rule regarding failure to warn claims is that inadequate warnings by a pharmaceutical manufacturer render a product defective and may result in the manufacturer's

---

<sup>22</sup> See *id.*

<sup>23</sup> See *id.*

<sup>24</sup> See *id.*

<sup>25</sup> See *id.*

<sup>26</sup> See *Norplant Litigation I*, 955 F. Supp. at 702.

<sup>27</sup> See Planned Parenthood Federation of America, Inc., *Fact Sheet: Norplant and You* (1997).

<sup>28</sup> See *Norplant Litigation II*, 165 F.3d at 375.

<sup>29</sup> See *Norplant Litigation I*, 955 F. Supp. at 707.

## 336 GOLDEN GATE UNIVERSITY LAW REVIEW [Vol. 30:2

liability for damages.<sup>30</sup> A prima facie failure to warn claim requires a plaintiff to prove: first, that a manufacturer failed to provide prescribing physicians and other healthcare providers with adequate warnings and instructions regarding its product; and second, that this failure to warn directly caused the plaintiff's injury.<sup>31</sup>

Therefore, warnings to physicians are adequate if the prescription drug manufacturer clearly conveys to the medical community any risk that it knows or should know are associated with a particular drug.<sup>32</sup> If warnings are deemed inadequate, a manufacturer may be liable directly to a patient for a breach of its duty to warn of the risks inherent in using its product.<sup>33</sup> However, in most failure to warn cases, prescription drug manufacturers are insulated from liability by the learned intermediary doctrine.<sup>34</sup>

## 2. *The Learned Intermediary Doctrine*

The learned intermediary doctrine insulates a prescription drug manufacturer from the legal duty to warn consumers directly of a product's risk if it adequately warns prescribing physicians.<sup>35</sup> This doctrine is based on the premise that physicians, who have an established and informed relationship with patients, are ultimately responsible for prescribing the manufacturer's products.<sup>36</sup> The foundation of the doctrine rests on the assumption that physicians are significantly more capable than the lay consumer of understanding the complex pharma-

---

<sup>30</sup> See Restatement (Third) of Torts §6A (Proposed Final Draft 1997).

<sup>31</sup> See *id.* The causation requirement in failure to warn claims is similar to the proximate cause requirement for ordinary negligence claims. See *id.*

<sup>32</sup> See Catherine A. Paytash, *The Learned Intermediary Doctrine and Patient Package Inserts: A Balanced Approach to Preventing Drug-Related Injury*, 51 Stan. L. Rev. 1343, 1345 (1999).

<sup>33</sup> See *id.*

<sup>34</sup> Restatement (Third) of Torts §6A (Proposed Final Draft 1997).

<sup>35</sup> Paytash, *supra* note 32 at 1345.

<sup>36</sup> See *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1967).

cology of a drug as it relates to the medical history of a particular patient.<sup>37</sup>

a. The Seminal Case: *Sterling Drug Inc. v. Cornish*

The United States Court of Appeals for the Eighth Circuit introduced the learned intermediary doctrine in *Sterling Drug, Inc. v. Cornish*<sup>38</sup> in 1966.<sup>39</sup> In *Sterling*, the plaintiff brought a failure to warn claim against the manufacturer of the arthritis drug Aralen.<sup>40</sup> She claimed that the defendant manufacturer failed to adequately warn her of the possible risks of taking the drug.<sup>41</sup> As a result of taking Aralen for four years, the plaintiff developed a condition known as chloroquine retinopathy.<sup>42</sup> This condition caused the plaintiff to suffer permanent vision impairment.<sup>43</sup> In 1960, two years after the plaintiff began taking the drug, the manufacturer distributed revised product information cards to physicians, which included warnings that Aralen may cause retinal damage.<sup>44</sup> Further, as studies linking the drug to retinal damage became more definitive, the manufacturer began sending letters to doctors to specifically call attention to the potential side effects.<sup>45</sup>

The question presented to the jury on appeal was whether the defendant manufacturer provided adequate warnings of the possible adverse side effects of Aralen to prescribing physicians, thereby making the doctors learned intermediaries be-

<sup>37</sup> Paytash, *supra* note 32 at 1345.

<sup>38</sup> *See Sterling*, 370 F.2d at 82.

<sup>39</sup> *See id.* at 83.

<sup>40</sup> *See id.* Aralen was used widely and effectively in the treatment of arthritis but produced chloroquine retinopathy in a small percentage of users. *See id.*

<sup>41</sup> *See id.*

<sup>42</sup> *See id.*

<sup>43</sup> *See Sterling*, 370 F.2d at 84. Chloroquine retinopathy is a degeneration or destruction of certain cells in the retina of the eye caused by the chloroquine chemical in Aralen. Chloroquine retinopathy often results in irreversible blindness. *See id.*

<sup>44</sup> *See id.*

<sup>45</sup> *See id.*



## 338 GOLDEN GATE UNIVERSITY LAW REVIEW [Vol. 30:2

tween it and consumers.<sup>46</sup> The Eighth Circuit held that the trial court correctly concluded that reasonable men could disagree as to the adequacy of the defendant manufacturer's warnings.<sup>47</sup> Therefore, whether the defendant manufacturer or pharmaceutical company provided adequate warnings to the prescribing physicians was a question of fact for the jury.<sup>48</sup> Thus, if the jury found that the defendant manufacturer provided adequate warnings to prescribing physicians, the learned intermediary doctrine applied and, therefore, the pharmaceutical company was not liable to the plaintiff for failing to directly warn her of the possible adverse side effects of its products.<sup>49</sup>

#### b. Judicial History of Prescription Drug Products Liability Litigation Involving the Learned Intermediary Doctrine

After *Sterling Drug, Inc. v. Cornish*, courts in other United States jurisdictions continued to apply the learned intermediary doctrine to failure to warn claims involving a variety of prescription drugs.<sup>50</sup> As the doctrine expanded, courts began to carve out exceptions to the doctrine.<sup>51</sup> These exceptions in-

---

<sup>46</sup> See *id.* at 85.

<sup>47</sup> See *id.*

<sup>48</sup> See *Sterling*, 370 F.2d at 84.

<sup>49</sup> See *id.* at 85.

<sup>50</sup> See generally *Reaves v. Ortho Pharmaceutical Corp.*, 765 F. Supp. 1287 (E.D. Mich. 1991); *Terhune v. A.H. Robins Co.*, 90 Wash 2d 9 (1978); *Spychala v. G.D. Searle & Co.*, 705 F. Supp. 1024 (D.N.J. 1988); *Lacy v. G.D. Searle & Co.*, 567 A.2d 398 (Del. 1989); *MacPherson v. Searle & Co.*, 775 F. Supp. 417 (D.D.C. 1991); *Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142 (D.Or. 1989); *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293 (D. Minn. 1988); *West v. Searle & Co.*, (304 Ark. 33 (1991); *Martin v. Ortho Pharmaceutical Corp.* 169 Ill.2d 234 (1996); *Humes v. Clinton*, 246 Kan. 590 (1990).

<sup>51</sup> See *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974). The *Reyes* court created an exception to the learned intermediary doctrine for mass vaccinations. See *id.* See also *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65 (Mass. 1985). The *MacDonald* court created an exception to the learned intermediary doctrine for prescription oral contraceptives. See *id.* See also *Perez v. Wyeth Laboratories, Inc.*, 734 A.2d 1245 (N.J. Sup. Ct. 1999). The *Perez* court created an exception to the doctrine when the manufacturer of Norplant advertised the device directly to consumers. See *id.*

clude mass vaccinations, prescription contraceptives and direct-to-consumer advertising.<sup>52</sup>

## B. EXCEPTION FOR MASS VACCINATIONS

In *Reyes v. Wyeth Laboratories*,<sup>53</sup> the United States Court of Appeals for the Fifth Circuit held that a polio vaccine manufacturer had a duty to warn recipients directly of the possible risks of its vaccine since it knew that physicians did not act as learned intermediaries.<sup>54</sup> In *Reyes*, the plaintiff's infant daughter contracted polio subsequent to receiving a few drops of Sabin oral polio vaccine at a Texas county health clinic.<sup>55</sup> A registered nurse administered the vaccine to the infant without a doctor present.<sup>56</sup> The defendant manufacturer provided a warning circular with each vial of the vaccine to warn doctors, hospitals or other health care providers of the potential dangers of ingesting the vaccine.<sup>57</sup> Although the nurse who administered the vaccine to the infant read the warning circular, she testified that she did not warn Mrs. Reyes of the risks of the vaccine since it was not the practice of the clinic nurses to pass the manufacturer's warnings on to the patients and their parents.<sup>58</sup>

---

<sup>52</sup> See *Reyes*, 498 F.2d 1264. See also *MacDonald*, 475 N.E.2d 65. See also *Perez*, 734 A. 2d 1245.

<sup>53</sup> See *Reyes*, 498 F.2d 1264.

<sup>54</sup> See *id.* at 1277.

<sup>55</sup> See *id.* at 1270. As a result of the polio, Anita Reyes was completely paralyzed from the waist down, her left arm became atrophied, and she was unable to control her bladder or bowel movements. See *id.*

<sup>56</sup> See *id.*

<sup>57</sup> See *id.* Each vial contained 10 doses of the vaccine. See *id.*

<sup>58</sup> See *Reyes*, 498 F.2d at 1270. Mrs. Reyes testified that she was not warned of the possible dangers of the polio vaccine. She had seventh grade education and spoke primarily Spanish. She signed a form releasing the State of Texas for all liability in connection with the vaccination which did not include any warning of potential risks of the vaccine. The Court of Appeal concluded she either did not read the form or did not have the linguistic ability to understand its significance. See *id.*

## 340 GOLDEN GATE UNIVERSITY LAW REVIEW [Vol. 30:2

The *Reyes* court determined that the defendant manufacturer knew that a great majority of its polio vaccines were administered in mass immunizations or at county health clinics staffed, at least in part, by volunteers.<sup>59</sup> Further, the court assumed that the defendant manufacturer knew that non-physician medical professionals administered the drug in an assembly line fashion, and thus did not dispense the vaccine in the same manner as ordinary prescription drugs.<sup>60</sup> The court emphasized that in such cases, the medical personnel dispensing the vaccine did not make individualized medical judgments as to whether the vaccine was appropriate for particular patients.<sup>61</sup> Therefore, in *Reyes*, a physician did not assume a learned intermediary role, since no physician actually passed along manufacturer warnings to parents before administering the vaccine.<sup>62</sup> Consequently, the Fifth Circuit held that the defendant manufacturer had a duty to directly warn vaccine recipients of the potential risks inherent in using its product.<sup>63</sup>

## C. EXCEPTION FOR ORAL CONTRACEPTIVES

In *MacDonald v. Ortho Pharmaceutical Corporation*,<sup>64</sup> the Massachusetts Supreme Court held that manufacturers of oral contraceptives owe a direct duty to consumers to warn of the dangers inherent in the use its products.<sup>65</sup> In *MacDonald*, the plaintiff suffered a stroke that left her permanently disabled after she used defendant's birth control pills for three years.<sup>66</sup> Although MacDonald testified that she read all of the manu-

---

<sup>59</sup> See *id.* at 1277. A witness for the defendant testified that it was common industry knowledge that county clinics were stocked primarily by sale of the vaccine to state health departments. See *id.*

<sup>60</sup> See *id.*

<sup>61</sup> See *id.*

<sup>62</sup> See *id.*

<sup>63</sup> See *Reyes*, 498 F.2d at 1277.

<sup>64</sup> See *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65 (1985).

<sup>65</sup> See *id.* at 65.

<sup>66</sup> See *id.* at 67.

facturer's warnings and received limited warnings from her physician, she maintained she was unaware that using oral contraceptives increased her risk of suffering a stroke.<sup>67</sup> Further, MacDonald claimed that she would not have used the birth control pill had she known of this associated risk.<sup>68</sup> The *MacDonald* court agreed that the learned intermediary doctrine should not apply to the plaintiff's claim, reasoning that oral contraceptives bear particular characteristics that warrant imposing a duty upon the manufacturer to directly warn users of associated risks.<sup>69</sup> These particular characteristics include the patient's active participation in the selection of a particular contraceptive method, the serious and substantial risks inherent in the nature of oral contraceptives, and the possibility of insufficient communication between patients and physicians regarding the risks of the drug.<sup>70</sup> Further, because of the unique nature of oral contraceptives, manufacturers cannot rely on solely doctors to provide patients with warnings of the risks inherent in the use of their products.<sup>71</sup> Thus, the Massachusetts Supreme Court held that pharmaceutical companies must provide consumers with direct written warnings of the potential risks of using oral contraceptives.<sup>72</sup> In addition, manufacturers must advise consumers to see a physician

---

<sup>67</sup> *See id.*

<sup>68</sup> *See id.* The plaintiff testified that her doctor warned her that the pills might cause bloating, but made no mention of the risk of stroke. *See id.* at 68. Each pill dispenser included a label with a warning that "oral contraceptives are powerful and effective drugs, which can cause side effects in some users and should not be used by some women" and that "the most serious known side effect is abnormal blood clotting which can be fatal". *See id.* at 66. Ortho's information booklet, provided by MacDonald's gynecologist contained additional information about blood clots but, failed to mention the word "stroke". The booklet included warnings that blood clots occasionally form in the blood vessels of the legs and pelvis of apparently healthy people and may threaten life if the clots break loose and then lodge in the lung or if clots form in other vital organs, such as the brain. Further, Ortho estimated that about one woman in 2,000 on the pill each year suffers blood clotting severe enough to require hospitalization. *See id.* at 67.

<sup>69</sup> *See MacDonald*, 475 N.E. 2d at 67.

<sup>70</sup> *See id.* at 69.

<sup>71</sup> *See id.* at 70.

<sup>72</sup> *See id.*

## 342 GOLDEN GATE UNIVERSITY LAW REVIEW [Vol. 30:2

for additional information regarding the risks inherent in the use of oral contraceptives.<sup>73</sup>

However, despite the willingness of the Massachusetts Supreme Court to create an exception to the learned intermediary doctrine for prescription contraceptives, other courts are not willing to go that far.<sup>74</sup> For example, in *Reaves v. Ortho Pharmaceutical Corporation*,<sup>75</sup> the United States District Court for the Eastern District of Michigan held that the manufacturer of an oral contraceptive was not required to directly warn consumers of risks associated with the use of its product.<sup>76</sup> In *Reaves*, the plaintiff used the defendant's Ortho-Novum 1/50 oral contraceptive for almost 13 years.<sup>77</sup> Subsequently, the plaintiff developed arterial thromboembolism in her leg.<sup>78</sup> The plaintiff stopped using the drug after her doctor advised her that it was the likely cause of her condition.<sup>79</sup> Due to complications caused by the condition, the plaintiff's leg was eventually amputated just below her knee.<sup>80</sup> As a result, the plaintiff sued the manufacturer for failing to warn her of the potential side effects of the oral contraceptive.<sup>81</sup> Relying on *MacDonald*, the plaintiff argued that because of the particular characteristics of oral contraceptives, the defendant manufacturer had a duty to directly warn her of the risks inherent in using its product.<sup>82</sup>

---

<sup>73</sup> *See id.* The warnings must include notice of the nature, gravity and likelihood of known or knowable side effects. *See id.*

<sup>74</sup> *See MacDonald*, 475 N.E. 2d at 70.

<sup>75</sup> *See Reaves v. Ortho Pharmaceutical Corp.*, 765 F. Supp. 1287 (E.D. Mich. 1991).

<sup>76</sup> *See id.* at 1291.

<sup>77</sup> *See id.* at 1288. The plaintiff used an oral contraceptive manufactured by the defendant almost continuously from 1973 to 1986. A physician typically refilled her prescription for six months to one year without medical evaluation. *See id.*

<sup>78</sup> *See id.*

<sup>79</sup> *See id.* Arterial thromboembolism is a blood clotting disorder. *See id.*

<sup>80</sup> *See Reaves*, 765 F. Supp. at 1288.

<sup>81</sup> *See id.*

<sup>82</sup> *See id.*

Since the federal district court did not have any precedent to apply in this case, the court held an evidentiary hearing to determine whether the learned intermediary doctrine applied to oral contraceptives.<sup>83</sup> At the hearing, the defendant called a distinguished physician to support its argument that the learned intermediary doctrine should apply to the plaintiff's failure to warn claim.<sup>84</sup> The witness testified that a physician's participation in prescribing oral contraceptives is active since it is common practice to examine a patient prior to prescribing the drug to determine if she is likely to be a successful user of oral contraceptives.<sup>85</sup> In addition, the defendant's witness stated that physicians typically evaluate a patient's personal and family medical history to determine potential risk factors.<sup>86</sup> Further, physicians perform a physical examination and perform certain tests to ascertain any preexisting conditions that may preclude successful use, and counsel patients as to the side effects, risks and benefits of using oral contraceptives.<sup>87</sup> The physician concluded by stating that oral contraceptives are the same as any other prescription drug in that patients are unlikely to understand the technical medical information regarding the nature of the drug.<sup>88</sup>

In response, the plaintiff called an expert witness to support her argument that the learned intermediary doctrine should not apply to her failure to warn claim.<sup>89</sup> The plaintiff's physician witness testified that manufacturers are in the best position to know the potential risks of its products and thus are best able to warn patients.<sup>90</sup> However, based on the testimony presented at the evidentiary hearing, the federal district court disagreed with the plaintiff's argument that the learned

---

<sup>83</sup> See *id.* at 1290.

<sup>84</sup> See *id.*

<sup>85</sup> See *Reaves*, 765 F. Supp. at 1290.

<sup>86</sup> See *id.*

<sup>87</sup> See *id.*

<sup>88</sup> See *id.*

<sup>89</sup> See *id.*

<sup>90</sup> See *Reaves*, 765 F. Supp. at 1291.

## 344 GOLDEN GATE UNIVERSITY LAW REVIEW [Vol. 30:2

intermediary doctrine should not apply to her claim, and held that oral contraceptives are indistinguishable from other prescription drugs.<sup>91</sup> Thus, since physicians play an active role in prescribing prescription contraceptives, the *Reaves* court declined to follow *MacDonald's* exception to the doctrine.<sup>92</sup> Instead, the court held that the defendant manufacturer was not liable to plaintiff for failing to warn her directly of the risks associated with the use of its product.<sup>93</sup>

## D. EXCEPTION FOR DIRECT-TO-CONSUMER ADVERTISING

Although the issue of direct-to-consumer advertising was not directly addressed in the *Norplant Litigation*,<sup>94</sup> the New Jersey Supreme Court faced the issue in a later case against AHP regarding Norplant.<sup>95</sup> In 1999, in *Perez v. Wyeth Laboratories, Inc.*,<sup>96</sup> the New Jersey Supreme Court created an exception to the learned intermediary doctrine in failure to warn claims when the defendant manufacturer engaged in direct-to-consumer advertising.<sup>97</sup> In *Perez*, the plaintiffs argued that the learned intermediary doctrine should not apply to their failure to warn claim against AHP because the advertisement warnings were inadequate.<sup>98</sup> The defendant manufacturer, Wyeth Laboratories, Inc. ("Wyeth"), advertised Norplant in women's magazines such as *Glamour*, *Mademoiselle* and *Cosmopolitan*.<sup>99</sup> These advertisements praised the simplicity

---

<sup>91</sup> *See id.*

<sup>92</sup> *See id.*

<sup>93</sup> *See id.*

<sup>94</sup> *See Norplant Litigation I*, 955 F. Supp. at 708. The plaintiffs claimed that the learned intermediary doctrine does not apply when a manufacturer directly advertising its products to consumers. The Federal District Court did not address this issue because the plaintiffs admitted they did not see any of AHP's advertisements before the implantation with Norplant. *See id.*

<sup>95</sup> *See Perez v. Wyeth Laboratories, Inc.*, 734 A.2d 1245 (N.J. Sup. Ct. 1999).

<sup>96</sup> *See id.*

<sup>97</sup> *See id.* at 1245.

<sup>98</sup> *See id.* at 1248.

<sup>99</sup> *See id.*

and convenience of Norplant as a birth control method, but failed to mention the dangers inherent in using the actual device.<sup>100</sup> The plaintiffs claimed Norplant caused them to suffer adverse side effects, including weight gain, headaches, dizziness, nausea, diarrhea, acne, vomiting, fatigue, facial hair growth, numbness in the arms and legs, irregular menstruation, hair loss, leg cramps, anxiety, vision problems, anemia, mood swings and depression, high blood pressure and removal complications that resulted in scarring.<sup>101</sup>

Wyeth argued that the learned intermediary doctrine should apply to the plaintiffs' failure to warn claim despite its direct-to-consumer marketing campaign.<sup>102</sup> The trial court and the appellate division both ruled that the learned intermediary doctrine applied to the plaintiffs' claim because the plaintiffs failed to show that the manufacturer's provided inadequate warnings to the prescribing physicians.<sup>103</sup> Despite the fact that the plaintiffs conceded that they were not influenced by the defendant's advertisements, the New Jersey Supreme Court reversed and remanded the decisions of the lower courts, concluding that the consumer-directed advertising of pharmaceuticals undermines the foundational premises of the learned intermediary doctrine.<sup>104</sup> The court discussed several rationales to support its conclusion.<sup>105</sup> First, Wyeth's direct-to-consumer advertising of Norplant demonstrated that consumers participated directly in their health care decisions.<sup>106</sup> This patient participation invalidates the premise that it is the physician, rather than the patient, who decides which contraceptive method to use.<sup>107</sup> In addition, the court found it illogical to conclude that requiring manufacturers to provide direct

---

<sup>100</sup> See *Perez*, 734 A.2d at 1248.

<sup>101</sup> See *id.*

<sup>102</sup> See *id.* at 1260.

<sup>103</sup> See *id.* at 1249.

<sup>104</sup> See *id.* at 1256.

<sup>105</sup> See *Perez*, 734 A.2d at 1256.

<sup>106</sup> See *id.*

<sup>107</sup> See *id.*



## 346 GOLDEN GATE UNIVERSITY LAW REVIEW [Vol. 30:2

warnings to a consumer will undermine the patient-physician relationship.<sup>108</sup> The court held that by its very nature, consumer-directed advertising encroaches on the patient-physician relationship by encouraging patients to ask for products by name.<sup>109</sup> Next, the court noted that consumer-directed advertising rebuts the notion that prescription drugs and devices and their potential adverse effects are too complex to be effectively communicated to consumers.<sup>110</sup> Finally, the court concluded that since the Federal Drug Administration ("FDA") requires prescription drugs and devices to carry warnings, the consumer may reasonably presume that the advertiser guarantees the adequacy of its warnings.<sup>111</sup> Thus, the New Jersey Supreme Court held that the learned intermediary doctrine should not apply to the plaintiffs claim against AHP.<sup>112</sup>

### III. FACTS UNDERLYING THE NORPLANT CONTRACEPTIVE PRODUCTS LIABILITY LITIGATION

In 1995, the Norplant plaintiffs sought class certification, alleging that AHP failed to provide adequate warnings concerning the possible side effects from using Norplant.<sup>113</sup> Collectively, the various plaintiffs attributed over 950 different side

---

<sup>108</sup> *See id.*

<sup>109</sup> *See id.*

<sup>110</sup> *See Perez*, 734 A.2d at 1256

<sup>111</sup> *See id.*

<sup>112</sup> *See id.*

<sup>113</sup> *See In re Norplant Contraceptive Products Liability Litigation*, MDL 1038, 1996 WL 264731 at \*1 (E.D. Tex. May 17, 1996)

effects to their use of the device.<sup>114</sup> However, the majority of the plaintiffs complained of twenty-six adverse reactions.<sup>115</sup>

Prior to prescribing Norplant, the plaintiffs' prescribing physicians received informational brochures and package inserts directly from AHP, which warned of the possible risks of using Norplant.<sup>116</sup> Specifically, AHP listed the twenty-six adverse reactions alleged by the plaintiffs.<sup>117</sup> AHP listed the risk of irregular menstrual bleeding, the most common side effect alleged by the plaintiffs, first in its warning materials.<sup>118</sup> Specifically, AHP warned the prescribing physicians that 27.6% of women using Norplant may experience many bleeding days or prolonged bleeding during the first year of use.<sup>119</sup>

<sup>114</sup> See Defendant's No. 2 Memorandum in Support of Motion For Partial Summary Judgment Re Adequacy of the Norplant Labeling at 1, In re Norplant Contraceptive Products Liability Litigation, 955 F. Supp. 700 (E.D. Tex. 1997) (MDL 1038). The plaintiffs attributed over 950 conditions to the use of Norplant including, but not limited to: body odor, drug addiction, evil thoughts, change in finger nail color, loss of logical reasoning, stretch marks, tapeworms, toothache and tuberculosis. *See id.*

<sup>115</sup> *See id.* at 2. Nearly all of the 30,000 plaintiffs complained of irregular menstrual bleeding. The 26 core conditions included: bleeding irregularities including prolonged bleeding, spotting, amenorrhea (absence of menstruation), irregular onset of bleeding, frequent bleeding onsets, and scanty bleeding, infection at implant site, pain or itching at implant site, removal difficulties, headaches, nervousness, nausea, dizziness, adnexal enlargement, dermatitis (inflammation of the skin), acne, change in appetite, mastalgia (breast swelling and tenderness), weight gain, hair loss and hair growth, breast discharge, cervicitis (inflammation of the neck of the cervix), musculoskeletal pain, abdominal discomfort, leukorrhea (a white, thick vaginal discharge) and vaginitis (vaginal infection). *See id.*

<sup>116</sup> *See id.* at 3. The warning information provided by AHP included all of the 26 core adverse reactions, together with statistics as to how often the side effects occurred during controlled clinical studies involving Norplant. *See id.*

<sup>117</sup> *See id.* at 3.

<sup>118</sup> *See id.* at 12.

<sup>119</sup> *See Defendant's No. 2 Memorandum in Support of Motion For Partial Summary Judgment Re Adequacy of the Norplant Labeling at 3, In re Norplant Contraceptive Products Liability Litigation, 955 F. Supp. 700 (E.D. Tex. 1997) (MDL 1038).* AHP emphasized the possibility of irregular menstrual bleeding because the Norplant clinical trials revealed that irregular menstrual bleeding was the most common reason for women discontinuing the use of the device. *See id.*

## IV. PROCEDURAL HISTORY

On December 6, 1994, the Judicial Panel on Multidistrict Litigation<sup>120</sup> assigned all pending federal claims against AHP to the United States District Court for the Eastern District of Texas, Beaumont Division as Multidistrict Litigation 1038 ("MDL 1038") for consolidated and coordinated discovery and pretrial proceedings.<sup>121</sup> After the initial consolidation in the Eastern District of Texas, four hundred additional cases were also added to MDL 1038.<sup>122</sup> During the coordination of the pretrial proceedings, the plaintiffs filed a Motion for Class Certification on behalf of all women in the United States who experienced problems associated with their use of Norplant.<sup>123</sup>

On May 17, 1996, the federal district court stayed the plaintiffs' Motion for Class Certification pending the Fifth Circuit's

---

<sup>120</sup> See 28 U.S.C.A. § 1407(d). Section 1407(d) states: The Judicial Panel on Multidistrict Litigation shall consist of seven circuit and district judges designated from time to time by the Chief Justice of the United States, no two of whom shall be from the same circuit. The concurrence of four members shall be necessary to any action by the panel. *See id.*

<sup>121</sup> See *In re Norplant Contraceptive Products Liability Litigation*, 878 F. Supp. 972, 973 (E.D. Tex. 1995). See also 28 U.S.C.A. § 1407(a). Section 1407(a) specifically states: When civil actions involving one or more common questions of fact are pending in different districts, such actions may be transferred to any district for coordinated or consolidated pretrial proceedings. Such transfers shall be made by the Judicial Panel on Multidistrict Litigation authorized by this section upon its determination that transfers for such proceedings will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions. Each action so transferred shall be remanded by the panel at or before the conclusion of such pretrial proceedings to the district from which it was transferred unless it shall have been previously terminated. *See id.*

<sup>122</sup> See *In re Norplant Contraceptive Products Liability Litigation*, MDL 1038, 1996 WL 264731 at \*1 (E.D. Tex. May 17, 1996).

<sup>123</sup> See *id.* Plaintiffs filed their Motion for Class Certification on March 9, 1995. See *id.* See also Fed. R. Civ. P. 23(a). Rule 23(a) outlines the prerequisites for a class action lawsuit: One or more members of a class may sue or be sued as representative parties on behalf of all only if (1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class. *See id.*

decision in *Castano v. American Tobacco Company*,<sup>124</sup> concerning the necessary court procedures prior to granting class certification under the Federal Rules of Civil Procedure (“FRCP”).<sup>125</sup> Following *Castano*, the federal district court dismissed the plaintiffs’ Motion for Class Certification, and instead held that it would first conduct bellwether<sup>126</sup> trials to determine the appropriateness of class certification for the *Norplant Litigation* plaintiffs.<sup>127</sup> Upon the completion of the bellwether trials, the plaintiffs could refile their Class Certification Motion.<sup>128</sup>

---

<sup>124</sup> See *Castano v. American Tobacco Company*, 84 F.3d 734 (5th Cir. 1996). The Fifth Circuit Court of Appeal held that individual trials are necessary prior to applying the predominance test under Rule 23(b)(3) of the FRCP. Individual trials are necessary so as to allow the court to make an informed decision regarding whether common issues predominate and whether class certification is superior to other methods for handling the litigation. See *id.*

<sup>125</sup> See *In re Norplant Contraceptive Products Liability Litigation*, MDL 1038, 1996 WL 264731 at \*1 (E.D. Tex. May 17, 1996). The Federal District Court knew that the Fifth Circuit was considering many class certification issues similar to those presented in the *Norplant* litigation in *Castano v. American Tobacco Company*. See also *Castano*, 84 F.3d at 734. Specifically, *Castano* addressed issues related to the viability of a nationwide class in a products liability case in the Fifth Circuit, and the proper method for applying the predominance test under Rule 23(b)(3) of the Federal Rules of Civil Procedure. See *id.* at 750. See also Fed. R. Civ. P. 23(b)(3). Rule 23(b)(3) is called into question if the prerequisites to a class action are met as set forth in 23(a) and the provisions of 23(b)(1) and 23(b)(2) are also satisfied. Following Rule 23(b)(3), an action may be maintained as a class action if: the court finds that questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy. See *id.*

<sup>126</sup> See *In re Chevron U.S.A., Inc.*, 109 F.3d 1016, 1019 (5th Cir. 1997). The term bellwether derives from the ancient practice of belling a wether (a male sheep) selected to lead his flock. The ultimate success of the wether selected to wear the bell was determined by the confidence of the flock that the wether would not lead them astray. The same notion applies to the class action concept. A bellwether trial helps the court to determine if the claims tried are representative of a larger group of claims from which they are selected. The bellwether trial is meant to permit the court to reach a sufficient level of confidence that the results obtained in the bellwether trial would be obtained from trial involving the whole class. See *id.*

<sup>127</sup> See *In re Norplant Contraceptive Products Liability Litigation*, 168 F.R.D. 577, 578 (E.D. Tex. 1996) (citing *Castano*, 84 F.3d at 734).

<sup>128</sup> See *id.*

## 350 GOLDEN GATE UNIVERSITY LAW REVIEW [Vol. 30:2

The federal district court determined that in the interest of fairness and to comply with FRCP 23(c)(1),<sup>129</sup> which mandates that decisions regarding class certification be made as soon as practicable, the bellwether trials should take priority over the court's other business.<sup>130</sup> On October 28, 1996, Chief Judge Richard A. Schell issued an Order Regarding Selection of Plaintiffs for Trial.<sup>131</sup> In the Order, Judge Schell selected three groups, each consisting of five plaintiffs, for the bellwether trials scheduled to take place during 1997.<sup>132</sup> The court scheduled the first group for trial commencing on February 24, 1997.<sup>133</sup> The additional two groups would follow at later dates.<sup>134</sup>

AHP filed a Motion for Summary Judgment before the commencement of the first bellwether trial.<sup>135</sup> The defendant argued that the learned intermediary doctrine insulated it from liability to the plaintiffs for failing to warn of the risks of Norplant use because it provided adequate warnings to prescribing physicians.<sup>136</sup> Subsequent to the defendant's motion, the federal district court issued its Preliminary Order on Application of the Learned Intermediary Doctrine as it Pertains

---

<sup>129</sup> See *Norplant Litigation*, 168 F.R.D. at 579. FRCP 23(c)(1) requires a decision regarding class certification to be made as soon as practicable. See *id.* See also Fed. R. Civ. P. (23)(c)(1). Rule 23(c)(1) states:

As soon as practicable after the commencement of an action brought as a class action, the court shall determine by order whether it is to be so maintained. An order under this subdivision may be conditional, and may be altered or amended before the decision on the merits. *Id.*

<sup>130</sup> See *Norplant Litigation*, 168 F.R.D. at 578.

<sup>131</sup> See *In re Norplant Contraceptive Products Liability Litigation*, MDL 1038, 1996 WL 631727, at \*1 (E.D. Tex. October 28, 1996).

<sup>132</sup> See *id.*

<sup>133</sup> See *id.*

<sup>134</sup> See *id.*

<sup>135</sup> See *In re Norplant Contraceptive Products Liability Litigation*, 955 F. Supp. 700, 702 (E.D. Tex. 1997) [hereinafter "*Norplant Litigation I*"].

<sup>136</sup> See *id.*

to Defendant's Motion for Summary Judgment (the "Order").<sup>137</sup> This Order advised the parties that based on the weight of the authorities in Texas, the federal district court would apply the learned intermediary doctrine to the plaintiffs' claims.<sup>138</sup>

In response, the plaintiffs argued that the learned intermediary doctrine should not apply to their claims against AHP.<sup>139</sup> Specifically, they maintained that prescription contraceptives such as Norplant are unlike other prescription drugs because physicians do not stand as learned intermediaries between consumers and the device's manufacturer.<sup>140</sup> Further, they argued that AHP's actions displaced those physicians as learned intermediaries.<sup>141</sup> These actions included engaging in direct-to-consumer advertising, and distributing informational and promotional materials to patients through prescribing physicians.<sup>142</sup> The federal district court disagreed with the plaintiffs' arguments and consequently granted AHP's Motion for Summary Judgment.<sup>143</sup>

The plaintiffs appealed the federal district court's ruling to the Fifth Circuit, again claiming that the learned intermediary doctrine should not apply to all of their claims against AHP.<sup>144</sup> Specifically, the plaintiffs argued that the learned intermediary doctrine should not apply to its claims for misrepresentation and its statutory claim under the Texas Deceptive Trade

<sup>137</sup> See *id.* The Federal District Court issued its Preliminary Order on Application of the Learned Intermediary Doctrine as it Pertains to Defendant's Motion for Summary Judgment on February 20, 1997. See *id.*

<sup>138</sup> See *id.* Federal courts sitting in diversity jurisdiction must apply the substantive laws of the state in which they are located. In cases involving a drug manufacturer's duty to warn, Texas courts apply the learned intermediary doctrine. See *id.* at 701.

<sup>139</sup> See *id.*

<sup>140</sup> See *Norplant Litigation I*, 955 F. Supp. at 704.

<sup>141</sup> See *id.* at 705.

<sup>142</sup> See *id.* at 707-708.

<sup>143</sup> See *id.* at 702.

<sup>144</sup> See *In re Norplant Contraceptive Products Liability Litigation*, 165 F.3d 374, 375 (5th Cir. 1999) [hereinafter "*Norplant Litigation II*"]

## 352 GOLDEN GATE UNIVERSITY LAW REVIEW [Vol. 30:2

Practices Act ("DTPA").<sup>145</sup> Further, the plaintiffs argued the defendant's direct-to-consumer marketing campaign demonstrated that by providing information directly to consumers, it assumed a duty to warn consumers directly of its products risks.<sup>146</sup>

In response, the defendant argued that the plaintiffs' DTPA claims were also based on its failure to warn of the risks associated with Norplant, and that the learned intermediary doctrine should continue to apply.<sup>147</sup> In addition, the defendant argued that the plaintiffs' argument concerning their advertising campaign was irrelevant because the plaintiffs admitted that they had not seen the advertisements prior to using Norplant.<sup>148</sup> After hearing the parties' arguments, the Fifth Circuit affirmed the federal district court's decision to apply the doctrine to all of the plaintiffs' claims.<sup>149</sup>

Despite the Fifth Circuit's ruling in its favor, AHP recently agreed to pay over fifty million dollars to settle the claims of former Norplant users pending in other United States jurisdictions in order to end time-consuming and expensive litigation.<sup>150</sup> As a result, on September 23, 1999, the federal district court issued an order establishing a schedule for non-settling plaintiffs to respond to four motions filed by AHP in May, 1999.<sup>151</sup> In November, 1999, the parties asked the court to extend the deadlines for submitting responses since the identities of the settling plaintiffs will not be known until

<sup>145</sup> See *id.* at 377.

<sup>146</sup> See *id.* at 379.

<sup>147</sup> See *id.* at 378.

<sup>148</sup> See *id.* at 379.

<sup>149</sup> See *Norplant Litigation II*, 165 F.3d at 375. The Fifth Circuit Court of Appeal denied a rehearing of the January 1999 decision on March 9, 1999. See *id.*

<sup>150</sup> See Charles Orstein, *Norplant company agrees to settle suits*, THE DALLAS MORNING NEWS, Aug. 6, 1999. Each claimant who filed suit before March 1, 1999 will receive a cash payment of \$1,500, and attorney's fees will be deducted from each woman's settlement. See *id.*

<sup>151</sup> See Order Establishing Schedule for Responses of Non-Settling Plaintiffs, In re Norplant Contraceptive Products Liability Litigation, MD 1038.

March 31, 2000, due to the time permitted under the settlement agreement.<sup>152</sup> The court agreed to the extension and ordered that the plaintiffs file their responses no later than May 15, 2000.<sup>153</sup> Thus, the plaintiffs' response to the defendant's motions are not available at the time of this writing.<sup>154</sup>

## V. COURTS' ANALYSIS

The *Norplant Litigation* plaintiffs argued against the application of the learned intermediary doctrine to their failure to warn claims against AHP, citing authorities from various United States jurisdictions which created exceptions to the doctrine's application.<sup>155</sup> Since the plaintiffs were unable to convince the federal district court, the doctrine ultimately applied to their failure to warn claims against AHP.<sup>156</sup> Consequently, the plaintiffs appealed to the Fifth Circuit.<sup>157</sup> On appeal, the plaintiffs again failed to convince the court that the learned intermediary doctrine should not apply to their failure to warn claims involving Norplant.<sup>158</sup>

### A. DEFENDANT'S SUMMARY JUDGMENT MOTION

In response to AHP's motion, the plaintiffs argued that the learned intermediary doctrine should not apply to their various claims against the defendant manufacturer.<sup>159</sup> First, the plaintiffs argued that a special exception to the doctrine should ap-

---

<sup>152</sup> *See id.*

<sup>153</sup> *See id.*

<sup>154</sup> *See id.*

<sup>155</sup> *See In re Norplant Contraceptive Products Liability Litigation*, 955 F. Supp. 700, 704-705 (E.D. Tex. 1997) [hereinafter "*Norplant Litigation I*"] (citing *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65 (Mass. 1985); *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974)).

<sup>156</sup> *See Norplant Litigation I*, 955 F. Supp. at 709.

<sup>157</sup> *See Norplant Litigation*, 165 F.3d at 374.

<sup>158</sup> *See id.* at 375.

<sup>159</sup> *See In re Norplant Contraceptive Products Liability Litigation*, 955 F. Supp. 700, 705 (5th Cir. 1999) [hereinafter "*Norplant Litigation II*"].



## 354 GOLDEN GATE UNIVERSITY LAW REVIEW [Vol. 30:2

ply to failure to warn claims since it involves a prescription contraceptive.<sup>160</sup> Next, the plaintiffs argued that AHP's actions, including distributing brochures through physicians and engaging in direct-to-consumer advertising, effectively displaced physicians as learned intermediaries, rendering the application of the doctrine improper.<sup>161</sup> Finally, the plaintiffs argued that even if the learned intermediary doctrine applied to their claims based on failure to warn, it should not apply to their claims for misrepresentation and violations of the Texas Deceptive Trade Practices Act ("DTPA").<sup>162</sup>

*1. Should the Learned Intermediary Doctrine Apply to Failure to Warn Claims Involving Prescription Contraceptives?*

The plaintiffs failed to convince the federal district court that it should create a special exception to the learned intermediary doctrine for prescription contraceptives.<sup>163</sup> They relied principally on *MacDonald v. Ortho Pharmaceutical Corp.*<sup>164</sup> to support their contention that prescription contraceptives bear particular characteristics that warrant imposing a duty on drug manufacturers to directly warn consumers of associated risks.<sup>165</sup> The plaintiffs argued that prescribing physicians are relegated to a passive role when a woman makes the ultimate decision to select Norplant as her contraceptive method, and therefore, manufacturers are in a better position than physicians to directly warn consumers of the risks inherent in using

---

<sup>160</sup> See *id.* at 706.

<sup>161</sup> See *id.* at 705-708.

<sup>162</sup> See *id.* at 709.

<sup>163</sup> See *id.* at 707.

<sup>164</sup> See *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E. 2d 65 (1985).

<sup>165</sup> See *Norplant Litigation I*, 955 F. Supp. at 706 (citing *MacDonald*, 475 N.E.2d at 65). According to *MacDonald*, these peculiar characteristics include patient's active involvement in making the decision to use prescription contraceptives, the substantial risks associated with using the drug, the feasibility of direct warnings by the manufacturer to the user, the limited participation of the physician (annual prescription), and the possibility that communications between the physician and patient may be too scanty standing alone to fully warn patients of the risks. See *id.*

its product.<sup>166</sup> In response, the court found that physicians consistently advise patients of the various advantages and disadvantages of prescription contraceptives even though the drugs are elective.<sup>167</sup> The court rejected the plaintiffs' argument, reasoning that the fact that the patient makes the final decision as to which contraceptive method to use does not render the doctrine inapplicable.<sup>168</sup> The federal district court concluded that the learned intermediary doctrine applies to failure to warn claims regarding prescription contraceptives whenever a physician is involved, a relationship that is inherent in the surgical nature of Norplant.<sup>169</sup>

## *2. Did the Defendant's Conduct Result in the Displacement of the Prescribing Physician?*

Next, the plaintiffs relied on *Reyes v. Wyeth Laboratories*<sup>170</sup> to support their argument that the learned intermediary doctrine should not apply to Norplant because AHP's distribution of informational materials through prescribing physicians abrogated the physicians' roles as learned intermediaries.<sup>171</sup> In *Reyes*, the Fifth Circuit Court of Appeal held that the defendant pharmaceutical manufacturer was not insulated from liability for the adverse side effects of its polio vaccine because a physician did not assume a learned intermediary role.<sup>172</sup> Rather, a nurse dispensed the polio vaccine to children and a physician did not confer with parents about the possible side effects of the vaccine.<sup>173</sup> The federal district court distin-

---

<sup>166</sup> See *Norplant Litigation I*, 955 F. Supp. at 706. In the twelve years following the *MacDonald* decision, no other United States jurisdiction followed the Massachusetts Supreme Court ruling. See *id.*

<sup>167</sup> See *id.* at 707.

<sup>168</sup> See *id.*

<sup>169</sup> See *id.*

<sup>170</sup> See *Norplant Litigation I*, 955 F. Supp. at 705 (citing *Reyes v. Wyeth Laboratories, Inc.*, 498 F.2d 1264 (5th Cir. 1974)).

<sup>171</sup> See *id.*

<sup>172</sup> See *id.*

<sup>173</sup> See *id.*

## 356 GOLDEN GATE UNIVERSITY LAW REVIEW [Vol. 30:2

guished *Reyes*, where the learned intermediary doctrine was inapplicable because the physician-patient relationship was non-existent.<sup>174</sup> In contrast, the physicians in the *Norplant Litigation* were clearly involved in the prescribing and implanting of Norplant.<sup>175</sup> The court elaborated further, holding that although AHP provided physicians with a Norplant Patient Brochure to review with their patients, this brochure did not abrogate the patient-physician relationship.<sup>176</sup> Instead, the brochure reinforced the existence of that relationship by encouraging patients to discuss the contents of the brochure with a doctor before deciding to use Norplant.<sup>177</sup> The federal district court concluded that, as was the case in *Reyes*, only a doctor can remove himself from the role of learned intermediary.<sup>178</sup> The information AHP provided to physicians clearly did not create such situation.<sup>179</sup>

### 3. Did the Marketing Campaign Impose a Direct Duty on AHP to Warn Norplant Users of Possible Adverse Side Effects?

The federal district court did not resolve whether AHP's direct-to-consumer advertising campaign created an exception to the learned intermediary doctrine.<sup>180</sup> The plaintiffs argued that AHP had a duty to directly warn consumers of both the benefits and possible risks of its product since it elected to bypass physicians by advertising products directly to consumers.<sup>181</sup> However, although AHP printed several "puff pieces" in consumer magazines that did not include warnings of side effects, the plaintiffs admitted that they had not seen any of the advertisements before using Norplant.<sup>182</sup> The fed-

---

<sup>174</sup> See *id.*

<sup>175</sup> See *Norplant Litigation I*, 955 F. Supp. at 705.

<sup>176</sup> See *id.*

<sup>177</sup> See *id.* at 706.

<sup>178</sup> See *id.* at 706.

<sup>179</sup> See *id.*

<sup>180</sup> See *Norplant Litigation I*, 955 F. Supp. at 708.

<sup>181</sup> See *id.* at 707-708.

<sup>182</sup> See *id.*

eral district court determined that on this basis, the plaintiffs' argument concerning AHP's direct marketing efforts was without merit.<sup>183</sup>

*4. Did Defendant's Distribution of Promotional Materials Through a Physician Displace the Learned Intermediary Doctrine?*

The federal district court ruled that AHP's efforts to distribute promotional materials to consumers through physicians did not displace the physicians as learned intermediaries.<sup>184</sup> AHP provided promotional videotapes and pamphlets to physicians "disguised" as objective and factual patient informational brochures.<sup>185</sup> The plaintiffs argued that these promotional materials were deceptive because they highlighted the benefits of Norplant, but not the potential side effects.<sup>186</sup> Further, the plaintiffs argued that since their decisions to use Norplant were made after reviewing these deceptive materials, physicians did not act as learned intermediaries.<sup>187</sup> Therefore, AHP assumed a duty to directly warn consumers of its product's risks.<sup>188</sup> The court disagreed and instead concluded that the promotional materials merely facilitated communication between physicians and patients.<sup>189</sup> AHP's distribution of these materials did not reflect a voluntarily assumption of a duty to directly warn patients of Norplant's potential side effects.<sup>190</sup> Since AHP distributed the materials to physicians, as learned intermediaries, they have a duty to review materials to ensure that the materials provide accurate information before passing them on to patients.<sup>191</sup> Thus, the court declined to conclude

---

<sup>183</sup> See *Norplant Litigation*, 955 F. Supp. at 708.

<sup>184</sup> See *id.* at 708-709.

<sup>185</sup> See *id.* at 708.

<sup>186</sup> See *id.*

<sup>187</sup> See *id.*

<sup>188</sup> See *Norplant Litigation*, 955 F. Supp. at 708.

<sup>189</sup> See *id.*

<sup>190</sup> See *id.*

<sup>191</sup> See *id.*

that the promotional materials distributed by AHP displaced the role of prescribing physicians as learned intermediaries.<sup>192</sup>

*5. Does the Learned Intermediary Doctrine Apply to Each of the Plaintiffs' Claims?*

The federal district court determined that failure to warn was the foundation for all of the plaintiffs' claims against AHP.<sup>193</sup> As a result, the learned intermediary doctrine applied to all the claims.<sup>194</sup> Therefore, to avoid summary judgment, the plaintiffs were required to satisfy a two-prong test.<sup>195</sup> The first prong required the plaintiffs to prove that AHP's warnings to prescribing physicians failed to adequately warn of the side effects they each experienced.<sup>196</sup> To satisfy the second prong, the plaintiffs had to prove that but for the inadequacies of AHP's warnings, their treating physicians would not have prescribed Norplant to them.<sup>197</sup>

AHP argued that the plaintiffs could not avoid summary judgment since the court did not need to reach the first-prong issue concerning the adequacy of its warnings to physicians because the plaintiffs could not satisfy the second prong.<sup>198</sup> Rather, the undisputed evidence showed that the plaintiffs' physicians were fully aware of the alleged potential side effects and their severity before prescribing Norplant.<sup>199</sup> The plaintiffs unsuccessfully argued that their physicians would not have prescribed Norplant if they had received additional information contained in studies, internal AHP memoranda and

---

<sup>192</sup> See *id.* at 709.

<sup>193</sup> See *Norplant Litigation I*, 955 F. Supp. at 709.

<sup>194</sup> See *id.* The plaintiffs alleged a number of causes of action including strict liability, negligence, misrepresentation, implied warranty and a claim under the DTPA. See *id.*

<sup>195</sup> See *id.*

<sup>196</sup> See *id.*

<sup>197</sup> See *id.*

<sup>198</sup> See *Norplant Litigation I*, 955 F. Supp. at 710.

<sup>199</sup> See *id.*

letters unavailable to the physicians.<sup>200</sup> At trial, all of the plaintiffs' prescribing physicians testified that none of the additional information would have changed their minds about prescribing Norplant to the plaintiffs.<sup>201</sup> Since the plaintiffs were unable to prove that AHP's warnings were inadequate, the plaintiffs were not able to satisfy the second-prong of the two-prong test.<sup>202</sup> Thus the federal district court did not need to reach the second prong causation question.<sup>203</sup>

As a last resort, the plaintiffs argued that their claims for misrepresentation and violations of the DTPA were not actually based on failure to warn, and therefore, the learned intermediary doctrine should not apply.<sup>204</sup> Further, the plaintiffs claimed that they should be able to sue AHP directly on these two theories because AHP voluntarily distributed deceptive and misleading patient information materials to physicians.<sup>205</sup> The federal district court rejected the plaintiffs' argument and ruled that the alleged misrepresentation or the allegedly false, misleading and deceptive nature of these materials was not that the information was inaccurate, but rather that AHP failed to adequately warn of Norplant's side effects.<sup>206</sup> Thus, the court concluded that failure to warn was definitely the basis of all of the plaintiffs' various claims against AHP.<sup>207</sup>

#### 6. *The District Court's Conclusion*

The court concluded that prescription contraceptives should be treated the same as any other prescription drug regarding the application of the learned intermediary doctrine as a pharmaceutical manufacturer's defense to failure to warn

---

<sup>200</sup> *See id.*

<sup>201</sup> *See id.* at 710-711.

<sup>202</sup> *See Norplant Litigation I*, 955 F. Supp. at 711.

<sup>203</sup> *See id.*

<sup>204</sup> *See id.*

<sup>205</sup> *See id.* at 709.

<sup>206</sup> *See id.*

<sup>207</sup> *Norplant Litigation I*, 955 F. Supp. at 709.

## 360 GOLDEN GATE UNIVERSITY LAW REVIEW [Vol. 30:2

claims.<sup>208</sup> Although the plaintiffs argued that AHP's efforts to distribute product information brochures to consumers through physicians displaced the medical professionals as learned intermediaries, the court did not find the argument compelling.<sup>209</sup> In addition, the applicability of the learned intermediary doctrine when manufacturers engage in direct-to-consumer advertising remains unanswered by the *Norplant Litigation*.<sup>210</sup> Further, AHP's efforts to distribute promotional materials through prescribing physicians did not render the doctrine inapplicable since the court found that these materials actually facilitated dialogues between physicians and patients.<sup>211</sup> Finally, the court concluded that failure to warn was the basis of each of the plaintiffs' claims against AHP.<sup>212</sup> Thus the learned intermediary doctrine protected the defendant from liability on all counts.<sup>213</sup> As a result of its findings, the federal district court granted AHP's Summary Judgment Motion, despite the plaintiffs many arguments against applying the learned intermediary doctrine.<sup>214</sup>

#### B. PLAINTIFFS' APPEAL TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

On appeal, the plaintiffs argued that the federal district court erred in granting AHP's Motion for Summary Judgment.<sup>215</sup> Specifically, the plaintiffs contended that the court erred by applying the learned intermediary doctrine to their DTPA claim against AHP.<sup>216</sup> Further, the plaintiffs argued that because AHP's direct-to-consumer advertising cam-

---

<sup>208</sup> See *id.* at 707.

<sup>209</sup> See *id.* at 706.

<sup>210</sup> See *id.* at 708.

<sup>211</sup> See *id.* at 708.

<sup>212</sup> See *Norplant Litigation I*, 955 F. Supp. at 709.

<sup>213</sup> See *id.*

<sup>214</sup> See *id.* at 711.

<sup>215</sup> See *Norplant Litigation II*, 165 F.3d at 376.

<sup>216</sup> See *id.* at 377.

paign abrogated the role of their prescribing physicians, it assumed a duty to directly warn consumers of Norplant's inherent risks.<sup>217</sup> Finally, the plaintiffs introduced a new theory for imposing liability on AHP by arguing that the learned intermediary doctrine should not apply when the Federal Drug Administration recommends manufacturer warnings for a particular drug.<sup>218</sup> The Fifth Circuit ultimately disagreed, affirming the federal district court's decision to grant summary judgment in favor of AHP.<sup>219</sup>

*1. Should the Learned Intermediary Doctrine Apply to the Plaintiffs' Claims Under the DTPA?*

The Fifth Circuit rejected the plaintiffs' argument that the learned intermediary doctrine should not apply to their claim under the DTPA.<sup>220</sup> The plaintiffs claim relied specifically on DTPA Section 17.46(b), which makes it unlawful to misrepresent the nature of goods sold in Texas.<sup>221</sup> The plaintiffs alleged that AHP violated the DTPA by representing that Norplant had certain attributes that it does not,<sup>222</sup> and representing that Norplant was of a particular standard or quality when it was not.<sup>223</sup> Moreover, the *Norplant Litigation* plaintiffs claimed that AHP violated Section 17.46(b)(23) of the DTPA, which makes it unlawful for manufacturers to fail to disclose information it knows at the time of the transaction that, if disclosed, would cause the consumer not to enter into the transac-

---

<sup>217</sup> *See id.*

<sup>218</sup> *See id.*

<sup>219</sup> *See id.* at 380.

<sup>220</sup> *See Norplant Litigation II*, 165 F.3d at 377. The Federal District Court did not address the issue because the court concluded that the DTPA claim was equivalent to the other common law claims and therefore the learned intermediary doctrine applied.

<sup>221</sup> *See id.* Section 17.46(b) of the DTPA makes it unlawful to misrepresent that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have. *See id.*

<sup>222</sup> *See id.*

<sup>223</sup> *See id.* *See also* Texas Business and Commerce Code, Chapter 17 § 17.46(b)(7) (1967). Section 17.46(b)(7) prohibits representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another.



## 362 GOLDEN GATE UNIVERSITY LAW REVIEW [Vol. 30:2

tion.<sup>224</sup> When the defendant engages in the false, misleading or deceptive practices specifically set forth in subsection 17.46(b), a Texas consumer may maintain an action for economic or mental anguish damages.<sup>225</sup> The *Norplant Litigation* plaintiffs claimed to have a cause of action under the DTPA for AHP's deceptive practices, without the burden of proof requirements and common law defenses normally applicable to common law claims.<sup>226</sup>

The plaintiffs contended that the learned intermediary doctrine should not apply to their statutory DTPA claims because it is a defense to common law failure to warn claims.<sup>227</sup> Therefore, the doctrine does not apply to a statutory DTPA claim.<sup>228</sup> AHP responded by arguing that the learned intermediary doctrine is not actually a defense, but rather a rule of law defining a pharmaceutical manufacturer's duty to provide adequate warnings to prescribing physicians regarding its product.<sup>229</sup> The court found evidence to support AHP's argument, as lower Texas courts applied the doctrine to DTPA claims in the past.<sup>230</sup> On the basis of these Texas decisions, the Fifth Circuit

---

<sup>224</sup> See Texas Business and Commerce Code, Chapter 17 § 17.46(b)(23) (1967). Section 17.46(b)(23) prohibits failing to disclose information concerning goods or services which was known at the time of the transaction if such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed.

<sup>225</sup> See Texas Business and Commerce Code, Chapter 17 § 17.50 (1967). In order to recover damages under the DTPA, consumers must also show that they relied on the false, misleading or deceptive practice to their detriment.

<sup>226</sup> See *Norplant Litigation II*, 165 F.3d at 377 (citing *Smith v. Baldwin*, 611 S.W. 2d 611, 616 (Tex. 1980)).

<sup>227</sup> See *Norplant Litigation II*, 165 F.3d at 377.

<sup>228</sup> See *id.* The plaintiffs argued that the DTPA is not a codification of the common law. Rather, its purpose is to provide consumers with a cause of action for deceptive practices without the burden of proof and defenses encountered in a common law fraud or breach of warranty suit. See *id.*

<sup>229</sup> See *id.* at 378.

<sup>230</sup> See *id.* (citing *Rivers v. American Home Products Corp.*, No. 342-160538-95 dated April 9, 1998.)). In *Rivers*, a lower Texas state court applied the learned intermediary doctrine in the context of a *Norplant* claim under the DTPA.

held that the learned intermediary doctrine also applied to the plaintiffs' DTPA claim.<sup>231</sup>

### *2. Do Public Policy Considerations Require Imposing a Duty to Warn?*

The plaintiffs unsuccessfully argued that AHP should have a duty to directly warn consumers of the risks inherent in Norplant use because physicians play a reduced role in selecting the contraceptive for their patients.<sup>232</sup> The court concluded that although patients participate with physicians in their contraceptive choices, Norplant is nevertheless a prescription drug.<sup>233</sup> The court found the plaintiffs' argument unpersuasive since the record clearly established that physicians played a significant role in prescribing Norplant and educating patients about the risks and benefits of the device.<sup>234</sup>

### *3. Did AHP's Direct-to-Consumer Marketing of Norplant Impose a Duty to Directly Warn Consumers?*

The Fifth Circuit disagreed with the plaintiffs' argument that AHP's direct-to-consumer marketing efforts displaced their prescribing physicians as learned intermediaries.<sup>235</sup> The plaintiffs claimed that since AHP engaged in aggressive marketing of Norplant, it should be held liable for failing to provide adequate warnings in conjunction with that marketing.<sup>236</sup> The court held that even if an exception to the learned intermediary doctrine applied in this case, summary judgment was proper because the plaintiffs never saw any of AHP's Norplant advertisements before implantation.<sup>237</sup> Additionally, the Fifth Circuit reasoned that even if the plaintiffs had seen the adver-

---

<sup>231</sup> See *id.*

<sup>232</sup> See *Norplant Litigation II*, 165 F.3d 374 at 379.

<sup>233</sup> See *id.*

<sup>234</sup> See *id.*

<sup>235</sup> See *id.*

<sup>236</sup> See *id.*

<sup>237</sup> See *Norplant Litigation II*, 165 F.3d at 379.

## 364 GOLDEN GATE UNIVERSITY LAW REVIEW [Vol. 30:2

tisements, their argument would still fail because two courts, applying Texas law, concluded that the learned intermediary doctrine applies as long a physician-patient relationship exists.<sup>238</sup>

*4. Does the Learned Intermediary Doctrine Continue to Apply Even When the Federal Drug Administration Recommends Manufacturer Warnings?*

The plaintiffs further argued that the warnings on Norplant packaging recommended by the FDA created an exception to the learned intermediary doctrine.<sup>239</sup> Citing an Oklahoma Supreme Court decision, the plaintiffs contended that when potential side effects of prescription drugs are so serious that the FDA requires warnings, the doctrine should not apply.<sup>240</sup> The Fifth Circuit called this rationale “counter-intuitive” because one reason for the learned intermediary doctrine is to encourage pharmaceutical companies to make drugs available to consumers.<sup>241</sup> Despite the potentially harmful side effects of certain products, pharmaceutical manufacturers are shielded from liability when the drug is prescribed by a properly trained physician.<sup>242</sup> Further, the court found that it had no reason to believe that Texas would be inclined to follow Oklahoma’s exception to the learned intermediary doctrine in this situation.<sup>243</sup> Finally, the court noted that the FDA has explicitly stated that labeling requirements should not affect civil tort liability.<sup>244</sup> Ultimately, the court found the plaintiffs’ ar-

---

<sup>238</sup> See *id.* (citing *Hurley v. Lederle Laboratories*, 863 F.2d 1173 (5th Cir. 1988); *Swayze v. McNeil Laboratories*, 807 F.2d 464 (5th Cir. 1987)).

<sup>239</sup> See *Norplant Litigation II*, 165 F.3d at 379.

<sup>240</sup> See *id.* (citing *Basel v. Edwards Pharmaceuticals*, 933 P.2d 298 (Okla. 1997)).

<sup>241</sup> See *Norplant Litigation II*, 165 F.3d at 379.

<sup>242</sup> See *id.*

<sup>243</sup> See *id.*

<sup>244</sup> See *id.*

gument unpersuasive since the FDA did not actually mandate any particular labeling for Norplant.<sup>245</sup>

### 5. *The Fifth Circuit's Conclusion*

The Fifth Circuit affirmed the lower court's granting of AHP's Motion for Summary Judgment.<sup>246</sup> The court held that the learned intermediary doctrine applied to all of the plaintiffs claims against AHP, including their claims under the DTPA.<sup>247</sup> Further, the court disagreed with the plaintiffs' argument that public policy considerations require imposing a duty to warn on AHP.<sup>248</sup> Since the plaintiffs did not see any of AHP's Norplant advertisements before implantation, the court did not directly address the issue concerning the applicability of the learned intermediary doctrine when drug manufacturers engage in direct-to-consumer advertising.<sup>249</sup> Notably, the court mentioned in dictum that the learned intermediary doctrine would likely apply even if the plaintiffs had seen the advertisements.<sup>250</sup> Finally, the court held that it should not carve out another exception to the learned intermediary doctrine in cases where the FDA requires warning labels, especially since no such warnings were ever required for Norplant.<sup>251</sup>

## VI. CRITIQUE

The federal district court and the Fifth Circuit issued opinions in the lengthy *Norplant Litigation* that followed common law precedent regarding failure to warn claims involving prescription contraceptives.<sup>252</sup> Both courts appropriately applied

---

<sup>245</sup> See at 379-380.

<sup>246</sup> See *Norplant Litigation II*, 165 F.3d at 375.

<sup>247</sup> See *id.* at 378.

<sup>248</sup> See *id.* at 379.

<sup>249</sup> See *id.* at 379.

<sup>250</sup> See *id.* at 379.

<sup>251</sup> See *Norplant Litigation II*, 165 F.3d at 379-380.

<sup>252</sup> See *In re Norplant Contraceptive Products Liability Litigation*, 955 F. Supp. 700 (E.D. Tex. 1997) [hereinafter "*Norplant Litigation I*"]. See also *In re Norplant Contra-*

## 366 GOLDEN GATE UNIVERSITY LAW REVIEW [Vol. 30:2

the learned intermediary doctrine to insulate AHP from a duty to directly warn the plaintiffs of the risks inherent in using Norplant.<sup>253</sup> However, both courts left unanswered the question regarding whether the learned intermediary doctrine applies when pharmaceutical manufacturers engage in direct-to-consumer advertising.<sup>254</sup>

#### A. THE LEARNED INTERMEDIARY DOCTRINE SHOULD APPLY TO NORPLANT BECAUSE A DOCTOR MUST SURGICALLY IMPLANT THE DEVICE

Both the federal district court and Fifth Circuit correctly rejected the plaintiffs' argument, based on *Reyes v. Wyeth Laboratories*,<sup>255</sup> that prescribing physicians do not play an active role in selecting Norplant as a patient's contraceptive method.<sup>256</sup> The plaintiffs argued that an exception to the learned intermediary doctrine should apply to Norplant prescriptions because, in *Reyes*, the Fifth Circuit created an exception to the learned intermediary doctrine when a defendant manufacturer clearly knows that a physician does not administer its vaccines.<sup>257</sup> Therefore, these physicians do not in fact stand as learned intermediaries between the manufacturer and those receiving its polio vaccines.<sup>258</sup> The physician-patient relationship in *Reyes*, however, is distinguished from the physician-patient relationship in the *Norplant Litigation* where the physicians actually participated in prescribing and im-

---

ceptive Products Liability Litigation, 165 F.3d 374 (5th Cir. 1999) [hereinafter "*Norplant Litigation II*"]

<sup>253</sup> See *Norplant Litigation I*, 955 F. Supp. at 701. See also *Norplant Litigation II*, 165 F.3d at 380.

<sup>254</sup> See *Norplant Litigation I*, 955 F. Supp. at 708. See also *Norplant Litigation II*, 165 F.3d at 379.

<sup>255</sup> See *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974).

<sup>256</sup> See *Norplant Litigation I*, 955 F. Supp. at 707. See also *Norplant Litigation II*, 165 F.3d at 379.

<sup>257</sup> See *Reyes*, 498 F.2d at 1277.

<sup>258</sup> See *id.* The vaccine causing the plaintiff's infant daughter to contract polio was dispensed by a nurse in a county health clinic without any warning of possible adverse side effects. See *id.*

planting Norplant.<sup>259</sup> Unlike that in *Reyes*, the existence of a physician-patient relationship was undisputed in the *Norplant Litigation*.<sup>260</sup>

The plaintiffs argued that physicians played a diminished role in prescribing the device because AHP distributed patient information brochures through physicians.<sup>261</sup> However, unlike the parents in *Reyes*, who received no warnings and had no contact with a physician, AHP distributed brochures to physicians who gave them to patients.<sup>262</sup> These brochures urged women to discuss the risks and benefits of the device with their doctors.<sup>263</sup> Further, physicians dispensed Norplant to the plaintiffs only in the context of a physician-patient relationship, as evidenced by the fact that Norplant must be surgically inserted.<sup>264</sup> For these reasons, the Fifth Circuit correctly affirmed the federal district court decision to apply the learned intermediary doctrine to Norplant.<sup>265</sup>

#### B. THE LEARNED INTERMEDIARY DOCTRINE APPLIES TO NORPLANT BECAUSE PRESCRIPTION CONTRACEPTIVES ARE INDISTINGUISHABLE FROM OTHER PRESCRIPTION DRUGS

The *Norplant Litigation* plaintiffs argued that the unique nature of prescription contraceptives warrants creating an exception to the learned intermediary doctrine.<sup>266</sup> The plaintiffs relied primarily on *MacDonald v. Ortho Pharmaceutical Corp.*<sup>267</sup> to support their argument.<sup>268</sup> The *MacDonald* excep-

<sup>259</sup> See *Norplant Litigation I*, 955 F. Supp. at 705.

<sup>260</sup> See *id.*

<sup>261</sup> See *id.*

<sup>262</sup> See *id.*

<sup>263</sup> See *id.*

<sup>264</sup> See *Norplant Litigation I*, 955 F. Supp. at 705.

<sup>265</sup> See *Norplant Litigation I*, 955 F. Supp. at 711. See also *Norplant Litigation II*, 374 F.3d at 380.

<sup>266</sup> See *Norplant Litigation I*, 955 F. Supp. at 707.

<sup>267</sup> See *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65 (Mass. 1985).

## 368 GOLDEN GATE UNIVERSITY LAW REVIEW [Vol. 30:2

tion to the learned intermediary doctrine requires manufacturers of prescription contraceptives to provide warnings directly to patients because physicians play a diminished role in prescribing these drugs to their patients.<sup>269</sup> However, both courts rejected the plaintiffs' argument that they should create an exception to the doctrine under *MacDonald*, concluding that the Massachusetts Supreme Court based its exception on flawed reasoning.<sup>270</sup> The federal district court decided not to follow the *MacDonald* exception to the learned intermediary doctrine for the following reasons.<sup>271</sup> First, *MacDonald* is not a widely followed opinion and, thus, does not provide compelling support for the plaintiffs' argument.<sup>272</sup> Second, *MacDonald* did not present a situation similar to the *Norplant Litigation* because the warnings AHP provided to physicians were adequate, undermining the basis for the *MacDonald* exception to the doctrine.<sup>273</sup> Finally, an Eighth Circuit case, *Reaves v. Ortho Pharmaceutical Corp.*, further undermined the plaintiffs' argument because it represents the majority view regarding the continuing application of the doctrine to prescription contraceptives in United States jurisdictions.<sup>274</sup> Thus, both courts in the *Norplant Litigation* correctly followed the majority view for applying the learned intermediary doctrine to failure to warn claims as outlined in the *Reaves* opinion.<sup>275</sup>

---

<sup>268</sup> See *Norplant Litigation I*, 955 F. Supp. at 706.

<sup>269</sup> See *MacDonald*, 475 N.E.2d at 69.

<sup>270</sup> See *Norplant Litigation I*, 955 F. Supp. at 707. See also *Norplant Litigation II*, 165 F.3d at 375.

<sup>271</sup> See *Norplant Litigation I*, 955 F. Supp. at 706-707.

<sup>272</sup> See *id.* at 706.

<sup>273</sup> See *id.* at 711.

<sup>274</sup> See *id.* at 704.

<sup>275</sup> See *id.* at 707.

*1. MacDonald Did Not Provide an Adequate Basis for the Plaintiffs' Argument Because it is Not a Widely Followed Opinion*

The Fifth Circuit correctly determined that the plaintiffs' reliance on *MacDonald v. Ortho Pharmaceutical Corp.* was misplaced.<sup>276</sup> The federal district court's analysis of the plaintiffs' argument began by emphasizing that no state or federal court had adopted the *MacDonald* rationale for creating an exception to the learned intermediary doctrine for prescription contraceptives in the twelve years following the decision.<sup>277</sup> In *MacDonald*, the learned intermediary doctrine did not apply because the Massachusetts Supreme Court concluded that the patient's active participation in the decision to use oral contraceptives diminished the role of the prescribing physician as a learned intermediary.<sup>278</sup> However, the courts in the *Norplant Litigation* reasoned that they could draw no principled distinction between Norplant and other prescription drugs.<sup>279</sup> The fact that a woman plays an active role in electing to use Norplant to prevent pregnancy does not diminish the physician's role in determining each patient's suitability for using the device and counseling her as to its risks and benefits.<sup>280</sup> As such, the court correctly disagreed with the plaintiffs' diminished role argument, noting that the fact that Norplant is elective and other prescription drugs are therapeutic should not affect the application of the learned intermediary doctrine.<sup>281</sup> Considering the court's reasoning that prescription contraceptives such as Norplant are indistinguishable from other prescription drugs, the plaintiffs' diminished role argument under *Mac-*

---

<sup>276</sup> See *Norplant Litigation I*, 955 F. Supp. at 706 (citing *MacDonald*, 475 N.E.2d at 65).

<sup>277</sup> See *Norplant Litigation I*, 955 F. Supp. at 706.

<sup>278</sup> See *id.*

<sup>279</sup> See *id.* at 707.

<sup>280</sup> See *id.* at 707.

<sup>281</sup> See *id.* at 707



## 370 GOLDEN GATE UNIVERSITY LAW REVIEW [Vol. 30:2

*Donald* was particularly unpersuasive since a physician must surgically implant the device.<sup>282</sup>

*2. Norplant's Warnings Were Adequate and Did Not Warrant Imposing a Duty to Directly Warn the Plaintiffs' on AHP*

The *MacDonald* facts differ from those in the *Norplant Litigation* in another crucial way.<sup>283</sup> In the *Norplant Litigation*, AHP clearly warned prescribing physicians of the common, well-known, and reversible side effects that the plaintiffs alleged as a result of using Norplant.<sup>284</sup> Conversely, in *MacDonald*, the information booklet included with each pill dispenser warned of the risks of life threatening blood clotting in some women, but failed to warn specifically of the possibility of stroke.<sup>285</sup> MacDonald testified that she did not know that the risk of blood clotting included this serious risk, and that she would not have used the drug if she had known.<sup>286</sup> The *MacDonald* jury held the defendant manufacturer liable to MacDonald because its pills caused her injury and its failure to adequately and directly warn MacDonald was the proximate cause of her injury.<sup>287</sup>

In contrast, the product information booklet distributed to Norplant users and their prescribing physicians clearly warned

<sup>282</sup> See *Norplant Litigation I*, 955 F. Supp. at 707.

<sup>283</sup> See *id.* at 706 (citing *MacDonald*, 475 N.E.2d at 65).

<sup>284</sup> See *Norplant Litigation II*, 165 F.3d at 374. Side effects suffered by the plaintiffs in the *Norplant Litigation* included severe headaches, mood swings, depression, nausea, acne, arm pain, numbness, breast tenderness, weight gain, hair loss, cramps and bleeding irregularities. See *id.* at 376. See also Defendant's No. 2 Memorandum in Support of Motion For Partial Summary Judgment Re Adequacy of the Norplant Labeling at 3, *Norplant Litigation*, 955 F. Supp. 700 (E.D. Tex. 1997) (MDL 1038).

<sup>285</sup> See *MacDonald*, 475 N.E.2d at 67.

<sup>286</sup> See *id.*

<sup>287</sup> See *id.* at 72. The Massachusetts Supreme Court reasoned that the jury's verdict on the inadequacy of the warnings was reasonable. In light of their common experience and MacDonald's testimony, the absence of reference to the word "stroke" in the warning may have unduly minimized the warnings impact or failed to make the nature of the risk reasonably comprehensible to the average consumer. See *id.* at 71.

users of the side effects alleged by the plaintiffs.<sup>288</sup> For example, all five of the bellwether plaintiffs claimed they suffered irregular menstrual bleeding.<sup>289</sup> Moreover, AHP listed this risk as the first potential adverse reaction in its Norplant patient information materials.<sup>290</sup> Despite the risks, all five of the first bellwether plaintiffs' prescribing physicians testified that they received adequate warning of possible side effects and still believed that Norplant was a safe and effective product.<sup>291</sup> Unlike the defendant in *MacDonald* who received inadequate warnings, AHP explicitly provided adequate warnings of potential side effects in its Norplant brochure.<sup>292</sup> Thus, since the Norplant warnings to physicians were accurate, both courts correctly determined that the learned intermediary doctrine should apply to the plaintiffs' claims against AHP.<sup>293</sup>

### *3. Both Courts Correctly Followed Reaves v. Ortho Pharmaceutical Corporation Because it Represents the Majority View*

The *Norplant* litigation holding is further supported by *Reaves v. Ortho Pharmaceutical Corporation*.<sup>294</sup> In *Reaves*, the plaintiff lost her leg as a result of a serious condition she developed while taking oral contraceptives.<sup>295</sup> Despite the severe nature of her injury, the court in *Reaves* declined to create a

<sup>288</sup> See also Defendant's No. 2 Memorandum in Support of Motion For Partial Summary Judgment Re Adequacy of the Norplant Labeling, *Norplant Litigation* at 3, 955 F. Supp. 700 (E.D. Tex. 1997) (MDL 1038).

<sup>289</sup> See *id.* at 12. Most of the women experienced irregular bleeding when using Norplant. See *id.*

<sup>290</sup> See *id.* at 12.

<sup>291</sup> See *Norplant Litigation I*, 955 F. Supp. at 710-711. Plaintiffs claimed that AHP withheld information from physicians about Norplant side effects. The physicians examined medical studies, Wyeth internal memoranda and letters that contained information that was not available at the time they inserted Norplant into the plaintiffs. The physicians claimed that none of the new information would have changed their minds about prescribing Norplant. See *id.*

<sup>292</sup> See *id.* at 711.

<sup>293</sup> See *Norplant Litigation I*, 955 F. Supp. at 701. See also *Norplant Litigation II*, 165 F.3d at 375.

<sup>294</sup> See *Reaves v. Ortho Pharmaceutical Corp.*, 765 F. Supp. 1287 (E.D. Mich. 1991).

<sup>295</sup> See *id.* at 1288.

## 372 GOLDEN GATE UNIVERSITY LAW REVIEW [Vol. 30:2

special exception to the learned intermediary doctrine for oral contraceptives, finding the drugs indistinguishable from other prescription drugs.<sup>296</sup> The court held that the role of physicians in prescribing contraceptives is identical to their role in prescribing other drugs, because with both types of drugs physicians play an active role in determining whether their patients will be successful users of a particular product.<sup>297</sup>

However, the *Norplant Litigation* presents a less persuasive situation than *Reaves* for creating an exception to the learned intermediary doctrine.<sup>298</sup> In *Reaves*, the plaintiff became permanently disabled as a result of using oral contraceptives.<sup>299</sup> The plaintiffs in the *Norplant Litigation*, however, alleged uncomfortable, but basically reversible side effects, including, headaches, mood swings, depression, nausea, acne, arm pain, numbness, breast tenderness, weight gain, hair loss, cramps and menstrual cycle irregularities.<sup>300</sup> The *Reaves* court was unwilling to create an exception to the doctrine, despite the serious injuries *Reaves* suffered, because a physician still acted as an learned intermediary when prescribing the drug.<sup>301</sup> Similarly, despite the numerous side effects alleged by the plaintiffs, the courts in the *Norplant Litigation* concluded that although prescription contraceptives are elective and have potentially serious side effects, these characteristics do not diminish the role of the prescribing physician as a learned intermediary.<sup>302</sup> Therefore, the elective nature of *Norplant* does not warrant placing a duty on manufacturers to directly warn consumers of the device's inherent risks.<sup>303</sup> Both courts in the *Norplant Litigation* correctly followed the majority view outlined in *Reaves*, as the applicability of the learned intermedi-

---

<sup>296</sup> See *id.* at 1291.

<sup>297</sup> See *id.* at 1290.

<sup>298</sup> See *Norplant Litigation II*, 165 F.3d at 375.

<sup>299</sup> See *Reaves*, 765 F. Supp. at 1288.

<sup>300</sup> See *Norplant Litigation II*, 165 F.3d at 375.

<sup>301</sup> See *Reaves*, 765 F. Supp. at 1291.

<sup>302</sup> See *Norplant Litigation I*, 955 F. Supp. at 707.

<sup>303</sup> See *id.*

ary doctrine is determined according to role of prescribing physicians, and not by the severity of the alleged side effects.<sup>304</sup>

C. THE LEARNED INTERMEDIARY DOCTRINE SHOULD CONTINUE TO APPLY WHEN PHARMACEUTICAL MANUFACTURERS ADVERTISE PRODUCTS TO CONSUMERS

A few months after the Fifth Circuit determined that the learned intermediary doctrine should apply to the plaintiffs' claims in the *Norplant Litigation*, the New Jersey Supreme Court specifically rejected the *Norplant Litigation* holding in *Perez v. Wyeth Laboratories, Inc.*<sup>305</sup> The court in *Perez* held that the learned intermediary doctrine should not shield a pharmaceutical company from liability for failure to warn of Norplant's risks since it engaged in direct-to-consumer advertising.<sup>306</sup> The *Perez* majority concluded that direct-to-consumer advertising undermines the very foundation of the learned intermediary doctrine.<sup>307</sup> The court based its conclusion on its assumption that AHP's direct-to-consumer advertising of Norplant demonstrated that consumers participated directly in their health care decisions, invalidating the premise that the physician plays an active role in selecting a woman's contraceptive method.<sup>308</sup> Further, the court held that consumer-directed advertising infringes upon the patient-physician relationship by encouraging patients to ask for products by name.<sup>309</sup> In addition, the court noted that consumer-directed advertising undermines the view that prescription drugs and devices and their potential adverse effects are too complex to be effectively communicated to consumers.<sup>310</sup> Conversely, if presented with a legitimate claim involving the direct-to-

---

<sup>304</sup> See *id.* at 701. See also *Norplant Litigation II*, 165 F.3d at 375.

<sup>305</sup> See *Perez v. Wyeth Laboratories, Inc.*, 734 A.2d 1245 (N.J. Sup. Ct. 1999).

<sup>306</sup> See *Perez*, 734 A.2d at 1249.

<sup>307</sup> See *id.* at 1256.

<sup>308</sup> See *id.*

<sup>309</sup> See *id.*

<sup>310</sup> See *Perez*, 734 A.2d at 1256

## 374 GOLDEN GATE UNIVERSITY LAW REVIEW [Vol. 30:2

consumer advertising issue addressed in *Perez*, the courts in the *Norplant Litigation* would have applied the learned intermediary doctrine to the plaintiffs' claims against AHP.<sup>311</sup>

In the *Norplant Litigation*, the Fifth Circuit noted in dictum that the learned intermediary doctrine should continue to apply when pharmaceutical manufacturers engage in direct-to-consumer advertising.<sup>312</sup> The court based its statement on the premise that the doctrine continues to apply as long as the physician-patient relationship exists.<sup>313</sup> Throughout the *Norplant Litigation* opinions, the courts held contrary to *Perez*, concluding that even if women make the ultimate decision about their method of contraception, physicians still consistently advise patients of the various advantages and disadvantages of a particular method.<sup>314</sup>

The learned intermediary doctrine should continue to despite the fact that AHP engaged in direct-to-consumer advertising of Norplant, since physicians remain actively involved in prescribing and implanting the device.<sup>315</sup> In the *Norplant Litigation*, the courts concluded that AHP's efforts to distribute informational and promotional materials through physicians did not undermine the applicability of the doctrine because, despite these efforts, physicians played an active role in prescribing Norplant.<sup>316</sup> As such, the courts in the *Norplant Litigation* concluded that even if patients are actively involved in choosing to use Norplant, the device is nevertheless only available by prescription and, therefore, physicians must be involved in the contraceptive selection process.<sup>317</sup> In addition to prescribing the device, physicians must surgically implant

---

<sup>311</sup> See *id.* at 1268.

<sup>312</sup> See *Norplant Litigation II*, 165 F.3d at 379.

<sup>313</sup> See *id.* at 379.

<sup>314</sup> See *id.* at 379.

<sup>315</sup> See *Norplant Litigation I*, 955 F. Supp. at 709.

<sup>316</sup> See *id.* at 706.

<sup>317</sup> See *Norplant Litigation II*, 165 F.3d 374 at 379.

Norplant under the skin of a woman's upper arm.<sup>318</sup> Consequently, even if the patient learned about Norplant from a magazine advertisement, the prescribing physician remains responsible for educating each patient about Norplant, assessing whether she will be a successful Norplant user, and performing the surgical insertion procedure.<sup>319</sup> Further, like the *Norplant Litigation* opinion, the dissenting opinion in *Perez* concluded that even if the advertisements influenced a woman's ultimate choice to use Norplant, the physician-patient relationship remains implicit in prescribing the drug and performing the surgical procedure.<sup>320</sup> Therefore, the reasoning presented in the *Norplant Litigation*, as the dissenting opinion in *Pere*, correctly characterizes a physician's active involvement in prescribing Norplant.<sup>321</sup> As such, if permitted to answer the question presented by AHP's direct-to-consumer marketing campaign, the courts should have applied the learned intermediary doctrine to the plaintiffs' claim.<sup>322</sup>

## VII. CONCLUSION

The Fifth Circuit affirmed the application of the learned intermediary doctrine to the plaintiffs' failure to warn claims, excusing AHP from the duty to directly warn Norplant users of the possible risks of its product.<sup>323</sup> The court based its conclusion on the fact that prescribing physicians clearly played an active role in prescribing and implanting the device.<sup>324</sup> Thus,

---

<sup>318</sup> See *id.*

<sup>319</sup> See *id.*

<sup>320</sup> See *Perez*, 734 A.2d at 1268.

<sup>321</sup> See *Norplant Litigation*, 165 F.3d at 379.

<sup>322</sup> See *id.*

<sup>323</sup> See *In re Norplant Contraceptive Products Liability Litigation*, 165 F.3d 374, 380 (5th Cir. 1999) [hereinafter "*Norplant Litigation II*"].

<sup>324</sup> See *id.* at 379

## 376 GOLDEN GATE UNIVERSITY LAW REVIEW [Vol. 30:2

because the learned intermediary doctrine applied, the first bellwether trial ended before it reached a jury.<sup>325</sup>

The decision reached by the federal district court and the Fifth Circuit in the *Norplant Litigation* were consistent with the common law of most United States jurisdictions.<sup>326</sup> These decisions to apply the learned intermediary doctrine to the plaintiffs' claims reinforces the position of pharmaceutical companies with regard to their duty to directly warn consumers of the side effects of prescribed products.<sup>327</sup> Simply stated, the rule remains that if a pharmaceutical company provides adequate warnings to physicians who prescribe its drugs, it is not directly liable to consumers for failure to warn of the risks inherent in using their products.<sup>328</sup>

Although AHP admits no fault or responsibility for the plaintiffs' suffering, it is attempting to end this long and expensive litigation by settling with the plaintiffs in the *Norplant Litigation*.<sup>329</sup> It remains unclear as of this writing whether all of the plaintiffs involved in the *Norplant Litigation* will agree to settle their claims against AHP.<sup>330</sup> Until the uncertainty

<sup>325</sup> See *In re Norplant Contraceptive Products Liability Litigation*, 955 F. Supp. 700, 711 (E.D. Tex. 1997) [hereinafter "*Norplant Litigation I*"]. See also *Norplant Litigation II*, 165 F.3d at 380.

<sup>326</sup> See *Norplant Litigation I*, 955 F. Supp. at 707 (citing *Reaves v. Ortho Pharmaceutical Corp.*, 765 F. Supp. 1287 (E.D. Mich. 1991); *Terhune v. A.H. Robins Co.*, 90 Wash 2d 9 (1978); *Spychala v. G.D. Searle & Co.*, 705 F. Supp. 1024 (D.N.J. 1988); *Lacy v. G.D. Searle & Co.*, 567 A.2d 398 (Del. 1989); *MacPherson v. Searle & Co.*, 775 F. Supp. 417 (D.D.C. 1991); *Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142 (D.Or. 1989); *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293 (D. Minn. 1988); *West v. Searle & Co.*, (304 Ark. 33 (1991); *Martin v. Ortho Pharmaceutical Corp.* 169 Ill.2d 234 (1996); *Humes v. Clinton*, 246 Kan. 590 (1990)).

<sup>327</sup> See *Norplant Litigation II*, 165 F.3d at 379.

<sup>328</sup> See *id.* at 376.

<sup>329</sup> See Charles Orstein, *Norplant company agrees to settle suits*, THE DALLAS MORNING NEWS, Aug. 6, 1999. Each plaintiff should receive around \$1,500 less attorney's fees.

<sup>330</sup> See Order Establishing Schedule for Responses of Non-Settling Plaintiffs, *In re Norplant Contraceptive Products Liability Litigation*, MD 1038.

\*Golden Gate University School of Law J.D. Candidate, Class of 2001; B.S. Political Science, University of Montana. I would like to thank my journal editor, faculty advisors and associate editors for all of their assistance and encouragement while writing

2000]      *LEARNED INTERMEDIARY DOCTRINE*      377

regarding the applicability of the learned intermediary doctrine to failure to warn claims against pharmaceutical companies is eliminated, complex and expensive litigation such as that involving Norplant will continue to address these issues.

*Stacey Leffler Ravetta\**

---

this article. I would also like to thank my family and friends for their unconditional love and support in all that I do. Last but not least, a special thank you to my husband, Paul Ravetta, for always holding my hand and encouraging me to do what makes me happy.