Hormone Replacement Therapy in the Wake of the Women's Health Initiative Study: An Opportunity to Reexamine the Learned Intermediary Doctrine

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HORMONE REPLACEMENT THERAPY IN THE WAKE OF THE WOMEN’S HEALTH INITIATIVE STUDY: AN OPPORTUNITY TO REEXAMINE THE LEARNED INTERMEDIARY DOCTRINE

INTRODUCTION

Litigation resulting from recent data published about the adverse risks of hormone replacement therapy has brought the learned intermediary doctrine to the surface of products liability jurisprudence. On July 9, 2002, the Women’s Health Initiative (WHI) of the National Institute of Health (NIH) announced that it was stopping its massive study after five years of hormone replacement therapy use because the risks associated with the drugs greatly exceeded the benefits. This news prompted more bad press about hormone replacement therapies as well as litigation by women against Wyeth, the manufacturer of Prempro, a popular hormone replacement drug.

Hormone replacement therapy is the use of conjugated estrogens, progesterone, and sometimes androgen to substitute the body’s loss of natural hormones in women who have undergone menopause. Estrogen replacement therapy, of which Wyeth’s drug Premarin is a popular example, is intended for the same use in women who have undergone a surgical removal of their uterus.

In one of the resulting cases that plaintiffs have brought against Wyeth for its manufacturing of Prempro, the Pennsylvania Court of Common Pleas, among other claims, dismissed the plaintiff’s claim under the Pennsylvania Unfair Trade Practices and Consumer Protection Law (UTPCPL) for failure to warn of the drug’s risks. The court concluded that the learned intermediary doctrine barred recovery and held that there should be no exception for drugs that are promoted directly to consumers through advertising. It is the only court thus far to have reached a decision in such a case against Wyeth.

The learned intermediary doctrine, first pronounced approximately forty years ago, precludes plaintiffs from holding pharmaceutical companies liable for failure to warn consumers of drugs’ adverse effects if
the manufacturers have adequately warned the prescribing physicians. The learned intermediary doctrine essentially states that pharmaceutical companies have no duty to warn consumers of the possible risks and side effects of drugs because it is the duty of the doctor prescribing the drugs to relay the side effects to consumers.

"The overwhelming majority of states have adopted the learned intermediary doctrine." In the last few years, however, a number of courts have recognized exceptions to the doctrine for particular types of pharmaceutical drugs. Several courts have recognized an exception with mass immunizations and drugs that have Food and Drug Administration (FDA) mandated warnings such as contraceptives. One court found an exception because the drug had been overly promoted by the manufacturer. In 1999, another court found that direct-to-consumer advertising barred the learned intermediary doctrine from shielding pharmaceutical companies from a negligent consumer warning claim.

Upon examining the current laws and arguments for and against the learned intermediary doctrine, this note argues that the failure of hormone replacement therapy’s manufacturers to adequately warn consumers directly of the risks of hormone replacement therapy necessitates the expansion of the exception for direct-to-consumer advertising. In the alternative, it is argued that hormone replacement therapy fits into the exception for contraceptives.

Part I provides a brief summary of background information on estrogen and hormone replacement therapy, with an emphasis on how Wyeth was able to amass significant numbers of female prescribers through its advertising campaign. The summary will


12. Stevens v. Parke, Davis & Co., 507 P.2d 653, 663 (Cal. 1973) (concluding that the jury could find that the manufacturer's over-promotion of the drug influenced physicians so that over-prescription was a foreseeable consequence).

13. Perez, 734 A.2d. at 1257.
culminate with a description of the recent class action lawsuit filed in Pennsylvania and the judge's decision that the learned intermediary doctrine barred recovery by the plaintiffs on a negligent warning claim. Part II discusses the learned intermediary doctrine, established in 1966 and still followed in most jurisdictions, along with the few exceptions that have been carved in the last several years. Part III considers the pros and cons of the doctrine and argues that the hormone replacement therapy disaster demonstrates why the learned intermediary doctrine should be overruled. Part IV argues that hormone replacement therapy should fall under the direct-to-consumer advertising exception as the extensive advertising campaign by Wyeth that made Premarin and Prempro bestsellers for several years provides more support for the holding in Perez v. Wyeth Laboratories Inc.\textsuperscript{14} Realizing that courts are apprehensive to overrule the learned intermediary doctrine by further expanding the exception for direct-to-consumer advertising, Part V argues that, at a minimum, hormone replacement therapy should fall under the exception that has developed for contraceptives.

I. THE NOT-SO-WONDERFUL WONDER DRUG FOR POST-MENOPAUSAL WOMEN

Women have been wronged by pharmaceutical manufacturers once again. Hormone replacement therapies are not the first prescription drugs or devices to be found harmful to women after being marketed to consumers.\textsuperscript{15} In fact, the Dalkon Shield and the Norplant contraceptive device were not only found to cause harmful adverse effects in the women who used the devices, but both were designed to control female hormones and reproduction.\textsuperscript{16} Additionally, between 1997 and 2001, of the ten drugs that were withdrawn from the market by the FDA, eight were withdrawn because of adverse effects discovered in women, even though the drugs were intended for use by women and men.\textsuperscript{17}

\textsuperscript{14} Id. at 1251 (holding that the learned intermediary doctrine did not apply to drugs (in this case the contraceptive Norplant) directly advertised to consumers).

\textsuperscript{15} See Anna Birenbaum, Shielding the Masses: How Litigation Changed the Face of Birth Control, 10 S. CAL. REV. L. & WOMEN’S STUD. 411 (2001) (discussing the litigation concerning the Dalkon Shield and the Norplant contraceptive device).

\textsuperscript{16} Id. at 411-13.

The announcement by the NIH that it would be stopping the WHI study on the hormone replacement therapy Prempro early because of the high incidence of risks to women taking the drug, was the beginning of a series of published studies releasing data on the risks of hormone replacement therapy. The study, following 16,608 women, was stopped a little after five years, because the risks associated with Prempro exceeded the benefits. Although the study found a 37% reduction in colorectal cancer, 33% less vertebral and hip fractures, and 24% fewer total fractures, the women taking Prempro in the study had 41% more strokes than those taking the placebo, 29% more developed cardiovascular disease, and 26% more women developed breast cancer. Data subsequently released has indicated that long-term use of estrogen-only replacement therapy significantly increases a woman’s chance of developing ovarian cancer, and starting hormone replacement therapy at or after age sixty-five may also significantly increase the risk of developing Alzheimer’s disease. Furthermore, data has shown that hormone replacement therapy may not even relieve the menopausal symptoms for which the drug is intended to be prescribed, such as sleeplessness, lack of vitality, sexual dissatisfaction, or depression.

Many post-menopausal women were shocked by this data as Prempro had been heavily promoted by Wyeth and taken by millions of women for years as a result of such marketing. The plaintiffs in Albertson v. Wyeth Inc., a recent case against Wyeth for its manufacturing of Prempro, cite that immediately prior to the recent studies being released, 38% of post-menopausal women were using either hormone or estrogen replacement therapy, and of those women, six million were taking Prempro, the most popular hormone or estrogen replacement therapy drug in the United States. Wyeth’s Premarin was first patented in 1942 to “cure” the physical

19. Millrood, supra note 1, at 43-44.
20. Id. at 44; see also Rossouw, supra note 18, at 321-22; Writing Group for the Women’s Health Initiative, Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women Principal Results from the Women’s Health Initiative Randomized Controlled Trial, 288 JAMA 321, 321-22 (2002).
21. Lacey, supra note 18, at 334.
22. Millrood, supra note 1, at 44.
23. Id.
24. Id. at 43.
side effects of menopause. In 1966, Robert Wilson, a Brooklyn gynecologist, touted Premarin, a predecessor to Prempro, as the "cure" for the "tragedy of menopause" that "preserves the strength of her bones, the glow of her skin, the gloss of her hair" and "makes women adaptable, even-tempered, and generally easy to live with" in his published best-seller Feminine Forever. Considering that Premarin could only be prescribed for women, it is remarkable that by the mid-1970s, it was the fifth most widely prescribed drug in the country.

Soon thereafter, Wyeth learned that its hormone replacement therapy could also help to prevent osteoporosis, and in 1985, Wyeth launched a campaign to educate women about osteoporosis and assisted in the creation of the National Osteoporosis Foundation. While promoting awareness of osteoporosis, Wyeth simultaneously marketed its hormone replacement therapy, claiming that the therapy could also prevent heart disease without the risk of causing stroke and cancer. This marketing campaign proved enormously successful. Between the years 1990 and 1995, Premarin was the most frequently prescribed drug in the United States. Finally, in 1995, Wyeth's Prempro was approved by the FDA and was the first pill that combined estrogen and progestin. The WHI Study in 2002 ended Wyeth's hopes of reaping greater profits from Prempro, however. Instead, it resulted in a series of lawsuits.

Various women filed suits against Wyeth with claims such as negligence in producing a defective product; failure to provide adequate warnings and labels; misleading women and doctors to believe that menopause was a disease while exaggerating the drugs' benefits; fraud; and breach of warranty. Lawsuits against Wyeth have been filed in Pennsylvania, Ohio, Maryland, Arkansas, and

26. Millrood, supra note 1, at 43.
27. Id. See generally Robert A. Wilson, Feminine Forever (1968).
28. Millrood, supra note 1, at 43.
29. Osteoporosis is a disease in which the bones become extremely porous and subject to fracture. Id.
30. Id.
31. Id.
32. This is all the more remarkable when one considers that only half the population was targeted. Id.
33. Id.
34. Id. at 45.
35. Sharon Coolidge, Hormone Drug Basis for Lawsuit, CINCINNATI ENQUIRER, May 21, 2004, at 1D.
37. Coolidge, supra note 35.
38. RedNova.com, supra note 36 (describing a recent claim by a woman in Maryland against Wyeth).
California, among other states, and there are other lawsuits in the process of being filed. Fortunately for Wyeth, one court recently denied class certification to a group of women who had taken hormone replacement therapy for at least one year prior to 2002.

Thus far, the Pennsylvania Court of Common Pleas is the only court to have reached a decision in a case brought against Wyeth for its advertising, promotion, and sale of Premarin or Prempro. Plaintiffs filed the following claims against Wyeth for its manufacturing and promotion of Prempro: negligence in medical monitoring; unjust enrichment; violation of the UTPCPL; breach of fiduciary duty; and fraud. Plaintiffs argued that the UTPCPL applied to prescription drug manufacturers and that a limited exception should be made to the learned intermediary doctrine for manufacturers who engage in direct-to-consumer advertising. The court rejected this argument and held that the learned intermediary doctrine barred their recovery under the UTPCPL. Otherwise, the court explained, a drug manufacturer would be forced to guarantee that a prescription drug was entirely safe. This, the court held, would be impossible, for “some prescription drugs by their very nature, can never be made safe.”

II. THE LEARNED INTERMEDIARY DOCTRINE AND ITS EXCEPTIONS

A manufacturer is generally required “to warn consumers of danger[s] associated with the use of its product to the extent the

40. Id. at 1367 n.1 (noting that the Judicial Panel on Multidistrict Litigation was informed of other related actions in the Southern District of Florida, Eastern District of Louisiana, Northern and Southern Districts of Illinois, Eastern District of New York, Northern District of West Virginia, and the District of Puerto Rico).
41. See, e.g., The Williamson Law Firm, Hormone Replacement Therapy or “HRT” Litigation, http://www.eawlaw.com/currentevents.htm (stating the intention of the Edward A. Williamson Law Firm to file “nearly 100 cases for clients who have suffered blood clotting, breast and ovarian cancers or Lupus from the ingestion of the drug manufactured by Wyeth called Prempro”).
44. Id. at *5.
45. Id. at *11.
46. Id. at *9-*10.
47. Id. at *10.
48. Id.
manufacturer knew or should have known of the danger[s]." 49 The learned intermediary doctrine is an exception to a manufacturer's duty to warn for one type of industry: pharmaceutical manufacturers. The learned intermediary doctrine shields them from any liability so long as the manufacturer sufficiently warns the prescribing physicians of the drug's risks and side effects. 50 The doctrine is based on the rationale that the prescribing physician acts as the "learned intermediary" between the drug company and the consumer because he or she assesses the patient's condition along with the drug's risks while taking into account the patient's needs. 51 Although crafted in 1966, 52 the learned intermediary doctrine continues to be followed by the overwhelming majority of courts today, with a few notable exceptions that will be highlighted in detail after a brief discussion of the case law upholding this doctrine.

The learned intermediary doctrine was first pronounced in 1966 by the Eighth Circuit. In the case of Sterling Drug, Inc. v. Cornish the court explained, "If the doctor is properly warned of the possibility of a side effect in some patients, and is advised of the symptoms normally accompanying the side effect, there is an excellent chance that injury to the patient can be avoided." 53 Whereas pharmaceutical companies were, and still are, held to a duty to only inform the doctors, 54 the burden shifted to the doctors to warn patients of the risks and side effects of every drug prescribed. 55 This burden was in addition to the physician's traditional role of advising patients about how and when to take the drug. It thus became the duty of the doctor prescribing the medication to be fully aware of the characteristics of the drug, the proper amount of the drug to be administered, and the different medications the patient was taking. 56

Recognizing changes in the physician-patient relationship and how prescription drugs are marketed to consumers, a few jurisdictions

50. Ausness, supra note 10, at 103-04.
51. Edwards, 933 P.2d at 300 (citing Cunningham v. Pfizer & Co., Inc., 532 P.2d 1377, 1381 (Okla. 1975)).
52. Sterling Drug, Inc. v. Cornish, 370 F.2d 82 (8th Cir. 1966).
53. Id. at 85.
55. Ausness, supra note 10, at 107-08.
56. See William M. Brown, Déjà Vu All Over Again: The Exodus from Contraceptive Research and How to Reverse It, 40 BRANDEIS L.J. 1, 21 (2001).
have found exceptions to the learned intermediary doctrine.\textsuperscript{57} First, several jurisdictions have ruled that patients are not precluded from holding the manufacturers of mass immunizations liable for the failure to warn consumers of the risks and side effects.\textsuperscript{58} In \textit{Davis v. Wyeth Laboratories Inc.}, the court based its reasoning on the fact that mass immunizations, such as the polio vaccine, are often given without a physician present.\textsuperscript{59} Thus, there is often no physician to act as an intermediary.\textsuperscript{60}

Another category of prescription drugs for which courts have held manufacturers liable for their failure to warn consumers are drugs for which the FDA has mandated manufacturers to provide warnings directly to consumers.\textsuperscript{61} Several states have recognized this exception. Most cases have involved contraceptives and contraceptive devices, while Oklahoma has adopted the exception for nicotine patches.\textsuperscript{62} Before discussing this category, it should be noted that courts are split as to whether merely complying with FDA regulations precludes consumers from holding manufacturers of drugs liable.\textsuperscript{63} With respect to the learned intermediary doctrine, several courts have held that merely complying with FDA minimum standards is not necessarily sufficient to relieve drug manufacturers of liability.\textsuperscript{64}

In \textit{Stephens v. G.D. Searle & Co.} in 1985, a court held for the first time that Michigan law requires pharmaceutical drug manufacturers of oral contraceptives to warn patients who are taking the drugs for contraceptive purposes directly of the risks and side effects

\begin{itemize}
\item \textsuperscript{57} See Casey, \textit{supra} note 54, at 939-47 (discussing case law supporting the vaccine, oral contraceptives, and intrauterine device exceptions).
\item \textsuperscript{58} See, \textit{e.g.}, Edwards v. Basel Pharm., 933 P.2d 298, 301 (Okla. 1997) (discussing the vaccination exception and its rationale as well as Oklahoma and Nevada case law); Allison v. Merck & Co., Inc., 878 P.2d 448 (Nev. 1994).
\item \textsuperscript{59} Davis v. Wyeth Labs., Inc., 399 F.2d 121 (9th Cir. 1968); see also Samuels v. American Cyanamid Co., 495 N.Y.S.2d 1006 (N.Y. Sup. Ct. 1985) (holding that a pharmaceutical company had a duty to warn "travel" vaccine recipients of adverse side effects).
\item \textsuperscript{60} Davis, 399 F.2d at 131.
\item \textsuperscript{61} Ausness, \textit{supra} note 10, at 112-13; see also McKee v. Moore, 648 P.2d 21, 24 (Okla. 1982) (holding that a physician has the duty to warn patients of drug side effects instead of the manufacturer unless FDA regulations require the manufacturer to warn the consumers directly through drug labeling).
\item \textsuperscript{62} Edwards, 933 P.2d at 301 (discussing cases involving contraceptives that support an exception to the learned intermediary doctrine if the FDA requires the manufacturers to directly warn consumers, and concluding that the same rationale should be extended beyond contraceptives and include nicotine patches).
\item \textsuperscript{63} Ausness, \textit{supra} note 10, at 113.
\end{itemize}
of the contraceptives.\textsuperscript{65} It found that the learned intermediary doctrine should not apply to cases involving oral contraceptives because contraceptives are not like therapeutic, diagnostic, and curative drugs.\textsuperscript{66} The court laid out several reasons for its watershed decision. It noted that because there is no assessment of medical need for a patient seeking contraceptives, there is not complete reliance on the physician's selection of an appropriate method of contraception as would be the case were a doctor prescribing and treating an illness.\textsuperscript{67} Moreover, the focus with oral contraceptives is on patient choice rather than the doctor's advice.\textsuperscript{68} Generally, before a patient goes to the doctor the patient has already decided that she wants to take oral contraceptives.\textsuperscript{69} The court concluded that a direct warning to the patient was required due to the primary role the patient's choice plays in the prescription.\textsuperscript{70}

The court also noted that the nature of the physician-patient relationship is different in the case of oral contraceptives because a woman can continually get refills without consulting her physician; thus, she is taking the prescription without any assessment of its side effects.\textsuperscript{71} Finally, the court observed that pharmaceutical manufacturers aggressively advertise oral contraceptives to women.\textsuperscript{72} As a result of such advertising, women believe that oral contraceptives are the most effective form of birth control and use this information to request them from their physicians.\textsuperscript{73} The court further observed that doctors acquiesce to the women's demands by prescribing the oral contraceptives for such women.\textsuperscript{74}

Decided two weeks after Stephens v. G.D. Searle & Co., the Supreme Judicial Court in Massachusetts, the state's highest court, echoed the "peculiar characteristics" of oral contraceptives, to include the doctor's passive role and minimal oversight of side effects to justify a manufacturer's duty to warn in MacDonald v. Ortho


\textsuperscript{66} Id.
\textsuperscript{67} Id.
\textsuperscript{68} Id.
\textsuperscript{69} Id.
\textsuperscript{70} Id. at 381.
\textsuperscript{71} Id.
\textsuperscript{72} Id. at 380.
\textsuperscript{73} Id.
\textsuperscript{74} Id. at 380-81.
Pharmaceuticals Corp. It also reasoned that oral contraceptives are subject to such extensive federal regulation by the FDA that a woman who takes such drugs does so with a level of informed consent. Odgers v. Ortho Pharmaceuticals Corp., also decided in 1985, held that the learned intermediary doctrine does not apply for oral contraceptives as well. In addition to the reasons cited in MacDonald and Stephens, the court noted that one of the policies behind the learned intermediary doctrine was to prevent patients from refusing to take prescription drugs by becoming unnecessarily afraid of the drugs after reading the warnings. It therefore concluded that this problem does not exist with oral contraceptives as it is better for a woman to be informed since there are so many birth control options.

With respect to intrauterine devices for women, the courts are split. The Fourth and Sixth Circuits upheld the learned intermediary doctrine as applied to intrauterine devices in 1987 and 1992 respectively. In 1989, however, the Eighth Circuit held that the learned intermediary doctrine should not apply to intrauterine devices. The court reasoned that they are unlike other prescription drugs and more like oral contraceptives because the prescribing doctor does not “make an intervening, individualized medical judgment in the birth control decision.”

The final exception that has been carved from the learned intermediary doctrine is for prescription drugs that undergo direct-to-consumer advertising. Over twenty-five years before the New

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76. Id. at 69-70.
78. Id. at 878.
79. Id.
Jersey Supreme Court decision in 1999, the California Supreme Court held pharmaceutical companies liable for over-promotion of their prescription drugs by representatives. The court concluded that the pharmaceutical company had "so water[ed] down" its drug warnings to doctors through its promotion of the drugs, by a vigorous sales program, that doctors effectively disregarded the warning. In Perez v. Wyeth Laboratories Inc., the New Jersey Supreme Court held that the learned intermediary doctrine is inapplicable when prescription drugs are directly marketed to the consumer. A rebuttable presumption exists that when the manufacturer complies with FDA advertising, labeling, and warning requirements, the manufacturer has satisfied its duty to warn the consumer about the potentially harmful side effects of its product. The court further held, however, that when the manufacturer has advertised its drug directly to consumers, the role of the physician in prescribing the drugs does not break the chain of causation for a manufacturer's failure to warn the patient of harmful side effects.

The Perez court noted that legal jurisprudence about medicine is based on outdated notions that no longer exist of physicians who make house calls, neighborhood pharmacies, and drug companies who advertise only to physicians. Its first reason for rejecting the learned intermediary doctrine as applied to prescription drugs that are directly marketed to consumers was that the decision to take the prescription drug is no longer only one of medical judgment. Second, physicians spend less time per patient because of managed care, so they do not have the time to detail to each patient all of the adverse side effects of each medication. Third, manufacturer advertising to consumers is very effective and undermines each of the underlying premises of the learned intermediary doctrine. The fact that such advertising is so effective showed that consumers are "active in their health care decisions" and that prescription drugs are not too complex for lay consumers to understand.

84. Id.
86. Id. at 1259.
87. Id. at 1257-59.
88. Id. at 1247.
89. Id. at 1255.
90. Id.
91. Id. at 1255-56.
92. Id. at 1256.
The court further stated that the argument that getting rid of the learned intermediary doctrine would undermine the physician-patient relationship is moot because that is already taking place as a result of the direct-to-consumer advertising. 93 With regard to direct-to-consumer advertising by pharmaceutical companies, the court stated, “It is one thing not to inform a patient about the potential side effects of a product; it is another thing to misinform the patient by deliberately withholding potential side effects while marketing the product as an efficacious solution to a serious health problem.” 94 The court noted that consumer protection is especially important for “life-style” drugs which are heavily advertised, elective, and can cause serious side effects. 95

Just three months before the case was decided, the Fifth Circuit refused to find such an exception, 96 and since Perez, no court has yet to follow its lead. 97 Two courts have thus far addressed the direct-to-consumer advertising exception to the learned intermediary doctrine, declining to adopt Perez. 98 One federal district court upheld the learned intermediary doctrine and rejected the Perez rationale, but after making choice-of-law determinations under Illinois and New York law, the court did not grant summary judgment to defendant manufacturer for those ten plaintiff consumers who had the device implanted in New Jersey. 99 Although another federal district court may have found the Perez decision “well-reasoned,” the court declined to follow Perez because the court was forced to predict Ohio state law. 100 The court believed that the Ohio Supreme Court would not have followed Perez because no other court had done so in the five years since Perez had been decided. 101

All other courts since Perez that have addressed the learned intermediary doctrine without respect to direct-to-consumer advertising have also upheld the learned intermediary doctrine. In 2001, the Connecticut Supreme Court answered a certified question from

93. Id.
94. Id. at 1257.
95. Id.
96. In re Norplant Contraceptive Prods. Litig., 165 F.3d 374 (5th Cir. 1999).
97. In re Meridia Prods. Liab. Litig., 328 F. Supp. 2d 791, 811-12 n.19 (N.D. Ohio 2004) (specifically rejecting plaintiff's argument to adopt the Perez court's direct-to-consumer advertising because the federal court must apply state law under diversity jurisdiction and no other state has adopted New Jersey's rationale).
98. See In re Norplant Contraceptive Prods. Liab. Litig., 215 F. Supp. 2d 795 (Tex. 2002);
   In re Meridia, 328 F. Supp. 2d at 791.
100. In re Meridia, 328 F. Supp. 2d at 811-12 n.19 (involving a plaintiff's claim that Wyeth failed to warn about the side effects of a diet drug which it had advertised to consumers).
101. Id.
the Second Circuit Court of Appeals as to whether the learned intermediary doctrine was controlling Connecticut law. The state supreme court held that the learned intermediary doctrine does apply, but limited its holding to the facts of the case. The facts did not implicate any of the recognized exceptions. The Supreme Court of Kentucky answered a certified question from the Sixth Circuit as to whether the doctrine applies in Kentucky by adopting the Restatement (Third) of Torts. In so doing, the court decided that the learned intermediary doctrine should still apply in Kentucky, but subject to exceptions that the court declined to address because the facts of the case did not warrant discussion of the exceptions. In 2004, the Eighth Circuit Court of Appeals held that, under North Dakota law, the learned intermediary doctrine barred plaintiff's action for damages against the pharmaceutical company for failure to warn of a drug's side effects.

With respect to the pharmaceutical manufacturer's liability to warn consumers of drugs' adverse side effects and risks, the drafters of the Restatement (Third) of Torts chose to straddle the fence as to whether the learned intermediary doctrine or its exceptions should apply. Section 8(d) states that a prescription drug manufacturer must warn prescribing and other health care providers of the foreseeable risks of harm associated with the drug or "the patient when the manufacturer knew or had reason to know that no health care provider would be in a position to reduce the risks of harm in accordance with the instructions or warnings." The drafters noted that the Restatement left developing case law to resolve the question of whether other exceptions to the learned intermediary doctrine should be recognized.

103. Id.
104. Id. at 846-47 (implicating none of the exceptions because the drug was not heavily marketed to consumers, was not a contraceptive, was not a mass immunization, and the FDA did not require additional warnings directly to consumers).
106. Id. at 765-70 (noting that the Restatement (Third) of Torts, Products Liability, provides for some recognized exceptions to the doctrine and discusses the exceptions but declines to apply those exceptions to Kentucky law, thus preserving the applicability of exceptions to future Kentucky case law).
109. Id. § 8(d).
110. Edwards v. Basel Pharm., 933 P.2d 306, 306 (Okla. 1997) ("The Restatement has left to developing case law to resolve whether other exceptions to the learned intermediary rule should be recognized.").
III. WHY DO WE STILL HAVE THE LEARNED INTERMEDIARY DOCTRINE ANYWAY?

Although there are many reasons why scholars and courts continue to uphold the learned intermediary doctrine, those reasons are outweighed by the arguments for overturning the doctrine and holding manufacturers directly liable to consumers for failing to provide direct warnings. Those who support the learned intermediary doctrine continue to do so for several reasons. First, they believe that the physician-patient relationship has remained unchanged despite the advent of direct-to-consumer advertising. This belief, however, ignores evidence to the contrary. For better or for worse, physicians are prescribing the drugs that patients are requesting. As one study showed, eighty-six percent of patients who requested Claritin received the drug from their physicians. Additionally, while doctors ultimately have control to write the prescriptions, they must now spend time talking their patients out of drugs they have seen advertised. Learned intermediary doctrine supporters further argue that requiring manufacturers to warn patients undermines the physician-patient relationship. Yet the evidence shows the opposite. Pharmaceutical advertisements are undermining the physician-patient relationship because patients are not going to doctors with symptoms but with drug names.

Second, those in favor of the learned intermediary doctrine claim that patients cannot sufficiently understand drug warnings and that it is too difficult for pharmaceutical companies to explain the risks of drugs on a level that consumers are able to understand. Nonetheless, patients are specifically asking their doctors for drugs and are increasingly researching drugs on their own. Thus, it seems that if pharmaceutical companies took the

114. Castagnera & Gerner, supra note 7, at 121; see also Perez v. Wyeth Labs. Inc., 734 A.2d 1245, 1255 (N.J. 1999); Casey, supra note 54, at 956.
115. Perez, 734 A.2d at 1256 (citing Casey, supra note 54, at 956) (footnotes omitted); see also Castagnera & Gerner, supra note 7, at 120.
116. Ausness, supra note 10, at 137.
117. See Casey, supra note 54, at 956 (stating that consumers are more active in their health care decisions today); Powell-Bullock, supra note 112, at 42 (providing an example that patients were requesting Claritin from their physicians).
time to make the warnings and contraindications easier for lay persons to understand, patients would actually benefit.

Third, some scholars fear that if patients are exposed directly to too many warnings by a manufacturer, the patients will not want to use the drugs and will not seek medical help. There does not seem to be any proof for this assertion as scholars who state this argument use language that demonstrates mere speculation, such as “might . . . scare off.” In fact, the evidence shows that even though patients have been warned of drugs’ side effects and warnings, whether generally in direct-to-consumer advertisements or specifically by their physicians, they are still requesting the drugs from their physicians.

Supporters of the learned intermediary doctrine also claim that it is too difficult for manufacturers to adequately convey the warnings and side effects to consumers. They support this claim by stating that radio or TV advertisements do not allot enough time to satisfy all of the requirements for sufficient warnings according to the FDA guidelines. Furthermore, one claim is that it is difficult to adequately convey the risks to consumers in print advertisements because the warnings and contraindications are in small print on the back. Despite this claim, a 2001 study in a British medical journal reported that ninety-eight percent of direct-to-consumer print advertisements satisfy the FDA advertising guidelines and fifty-one percent of direct-to-consumer advertisements provide even more information than is required. Also, “direct-to-consumer warnings are no more burdensome than direct-to-consumer advertising.” It also logically follows that drug companies could design the print advertisements so that the warnings and contraindications are larger and not on the back.

Another reason against requiring manufacturers to directly warn consumers is because it will subject manufacturers to greater liability,

118. Ausness, supra note 10, at 137.
119. Id.
120. See, e.g., Powell-Bullock, supra note 112, at 41-42 (explaining how those drugs that are the most heavily advertised to consumers are prescribed the most frequently by physicians and using Claritin as an example).
121. Ausness, supra note 10, at 137.
123. Id.
125. Castagnera & Gerner, supra note 7, at 143.
thus increasing the number of lawsuits and, in turn, the manufacturers' costs. This phenomenon could then drive manufacturers away from making the type of drugs for which an exception to the learned intermediary doctrine has been created. First, while it may be true that discarding the learned intermediary doctrine for those drugs which are directly advertised to consumers would potentially subject pharmaceutical manufacturers to greater liability, this does not necessarily mean that they would be subjected to greater lawsuits or that their costs would increase. As the New Jersey Supreme Court held in Perez, a manufacturer is entitled to a rebuttable presumption that it complied with all of the FDA advertising regulations that are required to warn a patient. Thus, “FDA regulations serve as compelling evidence that a manufacturer satisfied its duty” to warn the consumers directly, just as the same presumption exists for manufacturers who warn physicians. As noted, a 2001 study found that ninety-eight percent of direct-to-consumer advertisements comply with FDA regulations and fifty-one percent provide more information than required, including “quantitative data” about the frequency of the side effects listed. Thus, barring the learned intermediary doctrine when there is direct-to-consumer advertising may not subject companies to liability. Expanded liability is therefore not an unreasonable burden to place on manufacturers as they currently have the ability to communicate easily with consumers and are already forced to comply with FDA regulations. It simply provides a recourse for harmed consumers that does not currently exist when manufacturers fail to comply with FDA regulations.

One scholar commented that when the exception to the doctrine for oral contraceptives was created, there was an exodus by companies from the manufacturing of contraceptives. Thus, the same could be possible once again if the doctrine were lifted for direct-to-consumer advertisements. Since so many companies engage in direct-to-consumer advertising, it is intuitively more difficult to believe that companies would stop manufacturing drugs for which they engage in such advertising, especially because those are the drugs that make the

126. Ausness, supra note 10, at 139.
127. See Brown, supra note 56, at 39-45.
129. Id.
130. Woloshin et al., supra note 124, at 1144.
131. Perez, 734 A.2d at 1255-56; see also Castagnera & Gerner, supra note 7, at 120.
132. Perez, 734 A.2d at 1257-59.
133. Brown, supra note 56, at 29-34.
most profit. Because they do not want to forfeit the profits they are making through advertising, it is possible that drug companies would rather be more careful about what their advertisements conveyed to consumers because of the possible liability.

The final argument in support of expanding the exceptions to the learned intermediary doctrine, particularly in the context of direct-to-consumer advertisements, is that the FDA already regulates the promotion and labeling of prescription drugs. This ignores the reality that FDA regulations provide no recourse for consumers who are harmed by inadequate warnings. Not only do they provide no recourse for harmed consumers, but data suggests that the FDA is not sufficiently regulating prescription drug advertising as it has instead been "captured by the industry it regulates." Additional liability for manufacturers may help make manufacturers more conscious about messages that advertisements send to consumers for fear of potential liability.

There are also several strong arguments in support of overturning the learned intermediary doctrine. Patients now play a much more active role in their health care because of direct-to-consumer advertising. Patients no longer go to the doctor solely with symptoms of an illness and rely on the doctor to prescribe the appropriate

134. See, e.g., Powell-Bullock, supra note 112 (stating that between 1997 and 1999, physicians prescribed most frequently those drugs that were advertised the most); Why Drugs Cost So Much, NEWSWEEK, Sept. 25, 2000, at 22, 29-30 ("[O]ne study notes that the 10 most heavily advertised drugs accounted for 22 percent of the increase in drug spending between 1997 and 1998.").

135. Harrison & Jefferson, supra note 82, at 630-34 (providing a brief history of FDA regulation of prescription drugs and summarizing its current regulatory scheme).


137. Hall, supra note 82, at 469-70. The full quote reads:

Once an agency is captured by the industry it regulates, agency policy makers and adjudicators have incentives to defer to the interests of the industry rather than protecting the interests of consumers. While this article does not charge the FDA with capture by the pharmaceutical industry, judicial review of companies' actions independent of and supplemental to agency action guards against capture by lessening the unilateral power of the agency, making capture less attractive to the industry.

138. Fushman, supra note 82, at 1171 (discussing how patients go to doctors' offices with names of prescription drugs and demanding prescriptions); see also THE HENRY J. KAISER FAMILY FOUNDATION, IMPACT OF DIRECT-TO-CONSUMER ADVERTISING ON PRESCRIPTION DRUG SPENDING 5 (2003), available at http://www.kff.org/rxdrugs/20011129a-index.cfm ("Nearly a third (30%) of adults say they have talked to their doctor about a drug they saw advertised, and 44% of those who talked to their doctor received a prescription for the medication they asked about.").
medications. Instead, patients increasingly go to the doctor asking for specific drugs and stating that they have the particular symptoms that fit that drug.\(^{139}\) Thus, manufacturers can no longer claim that they are unable to communicate with patients directly, for their advertisements to consumers have proven quite successful.\(^{140}\)

Further, as more and more drugs are created with pages of side effects and contraindications, it is unreasonable to rely on physicians to relay all of the information to patients.\(^{141}\) It is especially unreasonable within managed care because a physician's time with an individual patient is decreased.\(^{142}\) Thus, as the health care industry and prescription drug industry change with the times and technology, the law needs to follow the changes appropriately. The law needs to reflect the fact that pharmaceutical manufacturers are now communicating directly with consumers.\(^{143}\) Additionally, pharmacists provide an additional link in the chain from manufacturer to patient, and present another opportunity by which pharmaceutical manufacturers can reach consumers to appropriately warn them of drugs' side effects and contraindications.\(^{144}\)

If Wyeth had known that it would be held liable for any failure to warn women of the risks and side effects of hormone replacement therapy, it might have been more cautious in its clinical research on the drug as well as in its promotion to physicians and consumers. It is therefore possible that lives could have been saved. Instead, the result is that women have been wronged for decades by the lack of knowledge about hormone replacement therapy and its heavy promotion by Wyeth.

The following sections demonstrate that if women can sufficiently prove their cases, they should be able to hold Wyeth liable for failure to warn them directly because hormone replacement therapy actually fits into both the direct-to-consumer advertising exception and the exception for contraceptives and contraceptive devices. Hormone replacement therapy as a direct-to-consumer advertising exception will be discussed first as expanding this

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\(^{139}\) Fushman, \textit{supra} note 82, at 1171 (describing also the phenomenon of "doctor shopping" in which a patient goes to another doctor if the first does not give him the desired prescription that he requested, and explaining that this is the reason that the European Economic Community completely banned direct-to-consumer advertising of prescription drugs).

\(^{140}\) Perez v. Wyeth Labs. Inc., 734 A.2d 1245, 1255 (N.J. 1999). (remarking that prescription drug "advertising campaigns can pay off in close to billions in dividends").

\(^{141}\) See Perez, 734 A.2d at 1255-56.

\(^{142}\) \textit{Id. at} 1245-57 (basing its decision on this underlying rationale).

\(^{143}\) See Castagnera & Gerner, \textit{supra} note 7, at 123-24 (arguing that the burden to adequately warn the patient of the drug's side effects and contraindications should rest on the pharmacist).
exception would have broader implications for holding future drug manufacturers liable, as well as others engaged in extensive direct-to-consumer advertising.

IV. HORMONE REPLACEMENT THERAPY AND DIRECT-TO-CONSUMER ADVERTISING

Wyeth's Premarin and Prempro are exactly the type of drugs for which the court in *Perez v. Wyeth Laboratories Inc.* did not intend for the learned intermediary doctrine to still apply because of the excessive direct-to-consumer advertising by the manufacturer. As pointed out in *Perez*, when the learned intermediary doctrine was devised to shield drug manufacturers from liability, they were not directly advertising to consumers. Today's marketplace has changed as pharmaceutical companies inundate consumers with advertisements for prescription drugs, and Wyeth's promotion of Prempro and Premarin is more the rule than the exception. Advertising was an essential part of Wyeth's business strategy for Prempro and Premarin. It reached consumers through two advertising methods: direct advertising to consumers and forming partnerships with patient groups. In 2001, Wyeth spent $40 million on consumer advertising alone for its two hormone replacement therapy drugs. One direct-to-consumer sixty second television advertisement depicted a woman stating, 'Menopause is complicated. Talking to my doctor helped. For me, she prescribed Prempro. It's relieving my uncomfortable symptoms and, along with calcium and exercise, helping prevent osteoporosis.' Just as the *Perez* court found that Wyeth had engaged in direct-to-consumer advertising through ads in women's magazines, the same is true of advertisements for hormone replacement therapy as Wyeth spent $30 million between 1997 and 1998 solely on direct-to-consumer magazine advertisements for Premarin. One study found that in a one-year study of prescription drug advertisements in consumer magazines between

146. Id. at 1251-53.
1998 and 1999, sixty-three percent of all advertisements were drugs that only treated symptoms. Of that category of drugs, hormone replacement therapy and allergy medications were the most frequent advertisements. The study also concluded that prescription drug advertisements in magazines were most common in women's magazines. This is a marketing strategy in response to women's preference to read about medical information in magazines so that they can then take the advertisement with them when they see their physician.

A magazine headline for Premarin that stated, “Everyday they are learning more about estrogen loss. That's why I'm glad I take my Premarin,” and a headline for Prempro that stated, “Making Sense Out of the Complexities of Menopause. Prempro Can Help,” are precise examples of the vague statements that the Perez court was concerned about being conveyed to consumers. Furthermore, even though hormone replacement therapy was only approved to treat the side effects of menopause and prevent osteoporosis, many physicians believed that the therapy actually increased a woman's life span at least in part because of Wyeth's marketing to physicians.

Wyeth also employed the marketing tactic of forming patient-industry partnerships in which it would fund “disease awareness” campaigns and make huge profits. After studies revealed in 1988 that hormone replacement therapy helped to prevent osteoporosis, Wyeth initiated a massive campaign to increase public awareness of osteoporosis and to instruct women to discuss treatment with their physicians. Wyeth also provided financial support to the Society for Women's Health Research (SWHR) for which it even funded an elegant evening at the Ritz Carlton, but not without turning the event from a campaign for women's health and research into an advertisement for Wyeth.

151. Woloshin et al., supra note 124, at 1141.
152. Id. at 1142.
153. Id. at 1143.
154. Zoeller, supra note 150, at 41.
155. Woloshin et al., supra note 124, at 1141.
156. Levy, supra note 149, at 120.
159. Waldholz, supra note 148.
161. Zoeller, supra note 150, at 41.
162. Alicia Mundy, Hot Flash, Cold Cash: How a Once-Respected Women's Group Went Through the Change — With the Help of Drug Industry Money, WASH. MONTHLY, Jan./Feb. 2003, at 35; see also BURTON & ROWELL, CTR. FOR MEDIA & DEMOCRACY, supra note 160, at 5.
Wyeth's direct-to-consumer advertisements and disease partnership campaigns certainly paid off, as it reaped huge profits from its two drugs, Prempro and Premarin. Between 1990 and 1995, Premarin was the prescription drug most frequently given in the U.S.\textsuperscript{163} By 2001, Prempro sales alone reached approximately $900 million,\textsuperscript{164} with 22.3 million prescriptions written per year.\textsuperscript{165} One study found that 92\% of gynecologists routinely offered hormone replacement therapy to their menopausal patients.\textsuperscript{166} A study comparing prescribing patterns of hormone replacement therapy in the United States with Europe found that the former was the greater user.\textsuperscript{167} This could at least be due in part to Wyeth's heavy advertising to physicians and consumers of hormone replacement therapy in the United States.\textsuperscript{168} Wyeth bombarded physicians and, more importantly, consumers, with advertisements for Premarin and Prempro, just as the \textit{Perez} court found that Wyeth had inundated consumers with advertisements for the Norplant System.\textsuperscript{169}

Thus, the analysis in \textit{Perez}, dismissing the premises for the learned intermediary doctrine when the manufacturer engages heavily in direct-to-consumer advertising, applies to hormone replacement therapy as well. The \textit{Perez} court stated that the fear of undermining the doctor-patient relationship, an original reason for the learned intermediary doctrine, no longer exists with direct-to-consumer advertising for two reasons.\textsuperscript{170} The advertisements themselves are already undermining the relationship, and the success of the advertisements demonstrates that patients are taking an active role in their health care decisions.\textsuperscript{171} Just as this analysis was particularly true with the

\textsuperscript{163} Coolidge, \textit{supra} note 35.
\textsuperscript{164} Melody Petersen, \textit{Survey Halted, Drug Makers Seek to Protect Hormone Sales}, N.Y. TIMES, July 17, 2002, at C1.
\textsuperscript{166} Boris Kaplan et al., \textit{Gynecologists' Trends and Attitudes Toward Prescribing Hormone Replacement Therapy During Menopause}, 9 MENOPAUSE 354, 355-59 (2002).
\textsuperscript{167} Jacqueline V. Jolleys \& Frede Olesen, \textit{A Comparative Study of Prescribing of Hormone Replacement Therapy in USA and Europe}, 23 MATURITAS 47 (1996) ("Sales of HRT as a proxy for both prescribing and consumption fall into three groupings: the USA being the highest; the UK and Scandinavian countries are in the middle group; continental Europe has low sales in terms of women treatment years of HRT, although France is approaching the middle group.").
\textsuperscript{168} \textit{See HUANG \& VAN AELSTYN, ARTHUR W. PAGE SOCY, supra} note 165, at 5-6 (describing the extensive advertising of Wyeth's hormone replacement therapy); Waldholz, \textit{supra} note 148 (discussing Wyeth's successful advertising of Premarin and Prempro).
\textsuperscript{169} \textit{See Perez v. Wyeth Labs. Inc.}, 734 A.2d 1245, 1248 (N.J. 1999) (referring to Wyeth's advertising campaign as "massive").
\textsuperscript{170} \textit{Id.} at 1256.
\textsuperscript{171} \textit{Id.}
Norplant devices in Perez, it is true with hormone replacement therapy because of the patient's active role in the decision to use the drugs. Wyeth certainly can not be said to "lack effective means" to communicate with the public as it has spent so much money on television and magazine advertisements for Premarin and Prempro. Perez further concluded that direct-to-consumer advertisements should not preclude patients from holding pharmaceutical companies liable, particularly with respect to a lifestyle drug, such as the Norplant device. This is because consumers should receive more protection from drugs that are not medically necessary. This analysis also extends to hormone replacement therapy, as it simply improves a woman's quality of life by lessening the side effects of a natural stage in a woman's life. After the WHI Study, doctors recommended that women adopt healthier lifestyles by eating and drinking more healthfully, particularly foods with more calcium and vitamin D, having bone density scans, exercising, and stopping smoking. These recommendations provide further evidence that hormone replacement therapy is a lifestyle drug because a woman can alleviate menopausal symptoms by changing her lifestyle.

Finally, as will be discussed below, one of the reasons that courts developed the exception to the learned intermediary doctrine for oral contraceptives was because they were heavily marketed to women. Thus, the impact of direct-to-consumer advertising on women's usage was a factor in the oral contraceptives analysis.

V. HORMONE REPLACEMENT THERAPY WITHIN THE ORAL CONTRACEPTIVES EXCEPTION

Although the direct-to-consumer advertising exception to the learned intermediary doctrine should apply because of heavy advertising and promotion by Wyeth, the reality is that only the Supreme Court of New Jersey Court has adopted the exception in Perez v. Wyeth Laboratories Inc. There may, however, be a greater possibility of getting around the learned intermediary doctrine by expanding the exception for oral contraceptives to include hormone replacement

172. Id. at 1255 (quoting Lars Noah, Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues, 32 GA. L. REV. 141, 158 (1997)).
174. Perez, 734 A.2d at 1257.
175. Id. at 1256.
therapy, as several courts have recognized the oral contraceptives exception and some states even include intrauterine devices (IUDs).

Much of the court's rationale in Stephens v. G.D. Searle & Co. about oral contraceptives also applies to hormone therapy drugs. First, as with oral contraceptives, the decision to take hormone replacement therapy is made by the female patient after consultation with her doctor rather than being based upon a doctor's diagnosis. Menopause is not a disease for which a woman goes to her physician seeking a cure; menopause is a natural phase in a woman's reproductive life cycle. As a natural stage, there are natural symptoms that are manifested in the woman's body. A woman may decide which method is best for her to alleviate the uncomfortable symptoms. Nonetheless, there are alternatives to hormone replacement therapy for coping with menopause, just as there are means to prevent pregnancy other than oral contraceptives. A woman may decide to take natural soy and herbs in place of a prescription, or a woman may decide to stay active, live a healthy lifestyle, and eat low-fat, healthy foods. There are other alternatives for treating osteoporosis as well. A woman may take calcium supplements or even the prescription drug Fosamax instead of hormone replacement therapy. If a woman chooses to take hormone replacement therapy over the other options, she must still decide among the various brand names, including alternatives to Wyeth's Prempro, such as Eli Lilly's Evista. While a physician may inform a patient's decision, the choice between hormone replacement therapy and the alternatives is one which the woman must ultimately make. The woman herself must balance the pros of hormone replacement therapy, such as the prevention of osteoporosis and the alleviation of symptoms including tissue dryness, mood swings, and night sweats, with the treatment's cons, such as possible increased risk of breast cancer. Just as a woman's decision to take oral contraceptives alters conception and child-bearing (natural

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179. Id.
181. Harvard Medical School, supra note 178, at 1.
182. Petersen, supra note 164.
183. Id.
184. Harvard Medical School, supra note 178, at 3.
185. Id. Only the possible risk of breast cancer is listed because at the time the plaintiffs who filed lawsuits against Wyeth decided to take Wyeth's prescription hormone replacement, this was the major concern as the results of the WHI Study sponsored by the NIH had not yet been released. As a result of the study, a woman opting for hormone replacement therapy today must weigh the pros against a longer list of cons.
processes of the female reproductive system), the decision to use hormone replacement therapy is a decision to alleviate the side effects of the natural process of menopause (a later phase of the female reproductive cycle). Both hormone replacement therapy and oral contraceptives are taken by women as quality of life drugs, and patient choice plays a large role in the prescription of both.186

Courts upholding the oral contraceptives exception to the learned intermediary doctrine have also based their decision on the drug's marketing. Heavy advertising to consumers by pharmaceutical companies has induced many women to believe that oral contraceptives are the best form of contraception, so they request them from their physicians.187 As a result of such "zealous marketing practices,"188 as of 2002, 11.6 million women were using oral contraceptives.189 That is the equivalent of just less than twenty percent of women of child-bearing age in the United States.190 If twenty percent of women is the result of "zealous" advertising, then the marketing of hormone replacement therapy has been incredibly "zealous." As of 1995, thirty-eight percent of postmenopausal women between the ages of fifty and seventy-four were using hormone replacement therapy.191 As of the summer of 2002, fifteen million women were receiving prescriptions for hormone replacement therapy a year.192 Furthermore, when one considers that the recent WHI studies revealed unexpected risks associated with hormone replacement therapy, the marketing strategies must have been quite extraordinary. As this note has discussed, for years Wyeth inundated women with advertisements that both Premarin and Prempro alleviated the symptoms of menopause and prevented osteoporosis.193 Just as the pharmaceutical advertisements for oral contraceptives were successful, Wyeth's advertising campaign was equally successful in recruiting physicians to prescribe hormone replacement therapy.

187. Id.
188. Id.
193. HUANG & VAN AELSTYN, ARTHUR W. PAGE SOC'Y, supra note 165, at 5-6.
As is the case with oral contraceptives, hormone replacement therapy drugs have been taken by women for extended periods of time similar to oral contraceptives. An exception to the learned intermediary doctrine for oral contraceptives was justified at least in part due to this extended usage. Doctors have prescribed hormone replacement therapies for various lengths of time, from only five or ten years to indefinite amounts of time. One study showed that seventy percent of American gynecologists prescribe hormone replacement therapy for indefinite periods of time while sixteen percent stop prescribing it after ten years. This is despite the fact that hot flashes, a common symptom of menopause for which hormone replacement therapy is taken, usually subside after five years.

Extended use of oral contraceptives created a different doctor-patient relationship because a woman could refill her prescription without seeing her physician for long periods of time. Physicians commonly prescribe oral contraceptives after seeing the patient once and then only annually. As a result, physicians only minimally monitor side effects of oral contraceptives. In some cases, the relationship is even more attenuated because manufacturers send the birth control in bulk shipments directly to birth control clinics where they are given without prescriptions. The concern that physicians are not able to monitor the drugs’ side effects as a result of only annual visits is not a serious concern with hormone replacement therapy. Nor is there a concern with hormone replacement therapy being sent in bulk to clinics to be given without a physician.

Although one of the reasons the court in Stephens v. G.D. Searle & Co. abandoned the learned intermediary doctrine for oral contraceptives was the minimal nature of the physician-patient relationship, this requirement has become arguably less important since the Eighth Circuit expanded the oral contraceptives exception to include intrauterine devices (IUDs). Instead of focusing on the minimal nature of the physician-patient relationship, the Eighth Circuit focused on the role of the physician in a patient’s decision-making process to

194. Kaplan et al., supra note 166, at 356.
195. Id.
undergo contraception with an intrauterine device.\textsuperscript{203} Even though a device must be implanted and monitored by a physician, the patient rather than the physician decides to implant the device.\textsuperscript{204} Similarly, although a patient must see a physician regularly when taking hormone replacement therapy,\textsuperscript{205} the decision to use hormone replacement therapy to alleviate the symptoms of menopause is a personal decision made by the woman after evaluating the alternatives.\textsuperscript{206}

Additionally, for both oral contraceptives and hormone replacement therapy, there exists a public policy interest in preventing patients from refusing to take prescription drugs after reading the warnings, but patients should be informed of the range of options.\textsuperscript{207} A woman should be informed about the drug's risks and side effects so she is better able to weigh the therapy against the alternatives.\textsuperscript{208} If knowing all of the risks of hormone replacement therapy leads a woman to decide not to use the drugs, then she is not harmed by that decision.

Finally, some courts have recognized an exception to the learned intermediary doctrine for oral contraceptives since the FDA already mandates that manufacturers include patient package inserts with the distribution of all oral contraceptives.\textsuperscript{209} The FDA similarly mandates that manufacturers directly warn consumers of estrogens, using patient package inserts.\textsuperscript{210} The underlying rationale for this is that the learned intermediary doctrine is meaningless if the FDA requires direct communication from the manufacturer to the patient.\textsuperscript{211} The requirements for patient inserts for oral contraceptives were promulgated because oral contraceptives are taken by large numbers of women, who are generally healthy, for long periods of time because they choose to prevent pregnancy.\textsuperscript{212} Similarly, the FDA promulgated a regulation in 1990 requiring patient package inserts to be distributed

\textsuperscript{203} Id. at 1071.
\textsuperscript{204} Id.
\textsuperscript{205} McNagny, supra note 196, at 605.
\textsuperscript{206} Harvard Medical School, supra note 178, at 1.
\textsuperscript{208} See Harvard Medical School, supra note 178, at 1.
\textsuperscript{209} Although this note considers the FDA regulation of patient package inserts as one factor as to why oral contraceptives are excluded in some jurisdictions from the learned intermediary doctrine, some scholars consider the exception for oral contraceptives separate from the exception for drugs which have FDA-mandated patient warnings. See, e.g., Ausness, supra note 10, at 111-12; Andrea M. Greene, \textit{Pharmaceutical Manufacturers' Liability for Direct Marketing and Over-Promotion of Prescription Drugs to Product Users}, 26 \textit{AM. J. TRIAL ADVOC.} 661, 670-71 (2003).
\textsuperscript{210} 21 C.F.R. § 310.515 (2005).
\textsuperscript{211} Ausness, supra note 10, at 113.
to all patients with each package of hormone replacement therapy.\textsuperscript{213} In 1999, the FDA even issued a draft guidance for the labeling of estrogens for the pharmaceutical industry.\textsuperscript{214}

The FDA's recent changes to its labeling requirements for hormone replacement therapy drugs further demonstrate that because hormone replacement therapy is already heavily regulated by the FDA, it should also be excluded from the learned intermediary doctrine. As a result of the WHI Study, the FDA is requiring new safety changes to the labels of all products that contain either estrogen alone or a combination of estrogen and progestin.\textsuperscript{215} The new labeling requirements include new physician prescribing information, new leaflets with updated information for patients, and new warning labels on the outside of the prescription boxes.\textsuperscript{216} The boxed warning is the highest level of FDA warning for prescription drugs.\textsuperscript{217} It includes results of the WHI Study, a statement that estrogens and progestins should not be used to prevent cardiovascular disease, and a statement that physicians should only prescribe estrogens and progestins at the lowest effective doses for the shortest possible durations.\textsuperscript{218}

**CONCLUSION**

The class actions against Wyeth for failure to warn patients of the risks of its hormone replacement therapy drugs present ripe opportunities for courts to chip away at the out-dated learned intermediary doctrine, either by recognizing the New Jersey Supreme Court's direct-to-consumer advertising exception or by expanding the oral contraceptives exception. Although recognition of the direct-to-consumer advertising exception would be more beneficial for consumers, it is the less likely of the two due to the plethora of drugs

\textsuperscript{213} 21 C.F.R. § 310.515 (2005).
\textsuperscript{217} Stephenson, *supra* note 215, at 537-38.
\textsuperscript{218} Id. at 537-38.
now marketed to consumers which would be affected. Thus, expanding the oral contraceptives exception to include hormone replacement therapy presents reluctant courts with the most palatable means of chiseling away at the learned intermediary doctrine.

How many more hormone replacement therapy-like incidences will it take before society has had enough and finally decides to hold pharmaceutical companies accountable for their products just as it holds accountable manufacturers of other products?

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