CHAPTER 5

CENTOCOR, INC. v. HAMILTON

RIKIN MEHTA,* MADELEINE MCDONOUGH, RUEY JU AND JENNIFER STONECIPHER HILL

I. Why It Made the List

Centocor, Inc. v. Hamilton[1] departs from the majority rule regarding a manufacturer's duty to provide adequate warnings for its prescription drugs. This court becomes the second court to expressly permit a direct-to-consumer (DTC) marketing exception to the learned intermediary doctrine for prescription drugs or devices.[2] These courts have suggested that the doctrine no longer provides full protection for pharmaceutical manufacturers, even if the manufacturer provides accurate information to physicians on the risks and benefits of its drugs. The question then becomes whether these rulings signal radical departures from the long-established rule treating physicians as learned intermediaries, or whether these rulings, reacting to the advent and influence of DTC marketing, mean that manufacturers can no longer rely on physicians to provide risk information to consumers.[3]

II. Facts of Case

Patricia and Thomas Hamilton brought suit against Centocor, Inc., for injuries allegedly caused by the brand named drug Remicade (infliximab), a Food and Drug Administration

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* The views expressed in this chapter are the author's, and do not necessarily reflect those of the Food and Drug Administration.

1 Centocor, Inc. v. Hamilton, 310 S.W.3d 476 (Tex. App. Corpus Christi 2010).

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

3 Victor Schwartz et al., ***Marketing Pharmaceutical Products in the Twenty-First Century: An Analysis of the Continued Viability of Traditional Principles of Law in the Age of Direct-to-Consumer Advertising***, 32 HARV. J. L. & PUB. POL'Y 333, 362 (2009).

(FDA)-approved medication intended to treat her Crohn's disease.[4] Infliximab is a tumor necrosis factor (TNF) blocker that blocks particular substances that cause inflammation and exacerbate a patient's Crohn's disease.[5] Ms. Hamilton had suffered from this disease for most of her life and eventually sought treatment from Dr. Ronald Hauptman.[6] Because of Ms. Hamilton's other medical conditions and allergies, Dr. Hauptman believed that she had two treatment options—steroids or infliximab.[7] Dr. Hauptman prescribed infliximab.[8] According to the prescribing information, infliximab must be administered intravenously under the guidance and supervision of a physician.[9] Ms. Hamilton went to an infusion clinic and received the medication in three doses over a six-week period.[10] The physician overseeing the infusion clinic, Dr. Michael G. Bullen, testified that the decision to take Remicade had already been made when the patient arrived at the clinic.[11] Dr. Bullen further testified that he does not typically warn patients of potential side effects, but only provides information about reactions that may occur during the infusion process.[12]

Ms. Hamilton received her first infusion on December 19, 2001, when she was shown a video produced by Centocor and referred to as a "treatment companion" kit.[13] The video featured several patients who discussed their infliximab experiences.[14] One particular patient described his experiences: "We couldn't control what I had and the doctors really were trying many different medications for me. And basically, things just went from bad to worse. The decision to try infliximab was made with doctors. It was presented to me that this might help."[15] The video shows the patient going into an infusion clinic, and later a doctor appears onscreen to explain the infusion process:[16]

> Physicians should discuss with their patients all potential side effects that may occur during these infusions. There are reports of serious infections, including sepsis and tuberculosis, that may be life threatening. So if you are prone to or have a history of infections, currently have one or develop one while taking Remicade, tell your doctor right away. Also, tell your doctor before beginning treatment if you have had recent close contact with or if you have had past exposure to people with tuberculosis, or if you have any other reason to believe

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4 *Centocor*, 310 S.W.3d at 482. Centocor, Inc., is a subsidiary of Johnson & Johnson, Inc.
5 *Id.* at 482.
6 *Id.* at 485.
7 *Id.*
8 *Id.* at 485-86.
9 *Id.* at 486 n.8.
10 *Id.* at 486.
11 *Id.*
12 *Id.*
13 *Id.*
14 *Id.*
15 *Id.* at 487.
16 *Id.*

> you may be at risk. There are also reports of serious infusion reactions, like hives, difficulty breathing, and low blood pressure. If you have a demyelinating disease such as multiple sclerosis, tell your doctor before you are treated. In rare cases, people with demyelinating disease who were treated with Remicade have seen their symptoms intensify. Up to one in four people experienced the following side effects in clinical studies: upper respiratory infections, headache, nausea, cough, sinusitis, or mild reactions to the infusion, such as rash or itchy skin. But the vast majority of patients, in our experience, have no problems with the infusion.[17]

In general, the patients report that infliximab has helped them feel better.[18] According to testimony at trial, Centocor distributed the videos to the infusion clinic in boxes that also contained the package insert.[19] The nurse at the infusion clinic testified that Ms. Hamilton was given the box with the video to take home after her infusion; however, it was disputed as to whether Ms. Hamilton received any written materials with the video.[20]

Ms. Hamilton received two more infusions of infliximab, one on January 2, 2002, and one on January 30, 2002.[21] Ms. Hamilton initially reported feeling better following her treatment, but later began to experience joint pain.[22] In April 2002, Dr. Adriana Pop-Moody prescribed additional infusions of infliximab.[23] Ms. Hamilton received infusions of infliximab through September 2003 and continued to report joint pain.[24] Her doctors began to suspect that her joint pain was a result of drug-induced lupus, and Dr. Pop-Moody discontinued her infliximab treatments.[25] Plaintiffs sued Centocor for fraud, negligence, gross negligence, and misrepresentation.[26]

At trial, it was undisputed that the video did not list lupus-like syndrome as a potential side effect.[27] In August 2001, however, the Remicade package insert did reference the potential for "lupus-like syndrome":

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17 *Id.*
18 *Id.* at 488.
19 *Id.*
20 *Id.*
21 *Id.*
22 *Id.*
23 *Id.* at 491.
24 *Id.* at 495.
25 *Id.*
26 *Id.* at 498 n.12.
27 *Id.* at 488.

PRECAUTIONS:

Autoimmunity

Treatment with REMICADE may result in the formation of autoantibodies and, rarely, in the development of a lupus-like syndrome. If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with REMICADE, treatment should be discontinued (*see ADVERSE REACTIONS, Autoantibodies/Lupus-like Syndrome*).

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ADVERSE REACTIONS:

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Autoantibodies/Lupus-like Syndrome

In the ATTRACT rheumatoid arthritis study through week 54, 49% of REMICADE-treated patients developed anti-nuclear antibodies (ANA) between screening and last evaluation, compared to 21% of placebo-treated patients. Anti-dsDNA antibodies developed in approximately 10% of REMICADE-treated patients, compared to none of the placebo-treated patients. No association was seen between REMICADE dose/schedule and development of ANA or anti-dsDNA.

Of Crohn's disease patients treated with REMICADE who were evaluated for anti-nuclear antibodies (ANA), 34% developed ANA between screening and last evaluation. Anti-dsDNA antibodies developed in approximately 9% of Crohn's disease patients treated with REMICADE. The development of anti-dsDNA antibodies was not related to either the dose or duration of REMICADE treatment. However, baseline therapy with an immunosuppressant in Crohn's disease patients was associated with the reduced development of anti-dsDNA antibodies (3% compared to 21% in patients not receiving any immunosuppressant). Crohn's disease patients were approximately 2 times more likely to develop anti-dsDNA antibodies if they were ANA positive at study entry.

In clinical studies, three patients developed clinical symptoms consistent with lupus-like syndrome, two with rheumatoid arthritis and one with Crohn's disease. All three patients improved following discontinuation of therapy and appropriate medical treatment. No cases of lupus-like reactions have been observed in up to three years of long-term follow up (*see PRECAUTIONS, Autoimmunity*).[28]

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[28] Id. at 482.

At trial, the court also heard evidence relating to Centocor's marketing of Remicade. Specifically, the court admitted a chart suggesting Centocor's goal was to "'[m]ake the consumer aware the [medical] problem is treatable' and to '[e]ncourage the patient to request a specific drug.'"[29] There was also evidence that Centocor's sales representatives employed strategies to emphasize to doctors the profitability of prescribing Remicade.[30] The court further noted that "Centocor also attempted to minimize negative publicity about the potentially dangerous side effects of Remicade."[31]

The jury found Centocor liable for fraud, negligent misbranding, negligent marketing to Ms. Hamilton's doctors, misrepresentation, and negligent undertaking.[32] The plaintiffs settled claims against Ms. Hamilton's doctors, and the trial court entered a judgment against Centocor for more than $4.8 million.[33] Centocor appealed, arguing that the "learned intermediary" doctrine precludes the claims against Centocor because the company had adequately warned Ms. Hamilton's physicians.[34] Among other points, Centocor also challenged both the sufficiency of the evidence of fraud and causation and the findings of future and punitive damages.[35]

III. Court Ruling

The court held that "when a pharmaceutical company directly markets to a patient, it must do so without fraudulently misrepresenting the risks associated with its products."[36] The court recognized an exception to the learned intermediary doctrine when a pharmaceutical manufacturer engages in direct-to-consumer advertising that fraudulently describes a product's risks and benefits.[37] The court further held that the evidence of causation and fraud was legally and factually sufficient to support the judgment.[38] However, the court held that Patricia Hamilton did not present sufficient evidence of future pain and mental anguish damages.[39] Lastly, the court held that the trial court properly applied the punitive damages.[40] Accordingly, the court reversed the trial court's award of future pain and mental anguish damages, modified the judgment to reflect this change, and affirmed the judgment as modified.[41]

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[29] Id. at 483.
[30] *Id.*
[31] *Id.*
[32] *Id.* at 499 n.13.
[33] *Id.*
[34] *Id.* at 480-81.
[35] *Id.* at 481.
[36] *Id.* at 508.
[37] *Id.* at 499.
[38] *Id.* at 481.
[39] *Id.*
[40] *Id.*
[41] *Id.*

IV. Rationale for Decision

The court described the rationale on which courts have relied when applying the learned intermediary doctrine.[42] First, the court noted that, because prescriptions are required for certain medications, the choice of medication is ultimately made by the physician.[43] Additionally, as medical experts, physicians are in the best position to understand the risks and benefits that medications present.[44] The court also noted the reluctance to interfere with the physician-patient relationship by requiring a pharmaceutical manufacturer to directly warn the patient,[45] for such warnings could contradict the physician's advice.[46] Finally, physicians are better able to effectively communicate information regarding risks to the patients.[47]

The court found that the premises underlying the learned intermediary doctrine were unpersuasive when considered in light of direct marketing to patients.[48] The court cited certain recognized exceptions to the learned intermediary rule for vaccines and oral contraceptives.[49] According to the court, these exceptions are based on "(1) the extent to which the doctor is involved in the decision-making process and the selection of the drug itself; and (2) whether there is a reasonable likelihood that warnings will be adequately conveyed to the patient."[50] In the case of direct marketing to the consumer, the court found this reasoning applicable.[51]

According to the court, pharmaceutical marketing has changed since the learned intermediary doctrine was developed.[52] In particular, direct advertising to consumers has increased dramatically since the 1990s.[53] While prescriptions are still required for many medications, the court found that physicians spend less time with their patients, who, influenced by pharmaceutical advertising, now request medications by name.[54] The court found that pharmaceutical manufacturers that directly advertised to consumers could not consistently argue that physicians are in the best position to understand a medication's propensities.[55] Finally, the court rejected the argument that requiring manufacturers to warn consumers would undermine the physician-patient relationship, when "by its very nature, consumer-directed

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42 *Id.* at 502.
43 *Id.*
44 *Id.* at 502-03.
45 *Id.* at 503.
46 *Id.*
47 *Id.*
48 *Id.* at 508.
49 *Id.* at 503.
50 *Id.* at 504.
51 *Id.* at 508.
52 *Id.* at 506.
53 *Id.*
54 *Id.* at 508.
55 *Id.* at 508.

advertising encroaches on that relationship by encouraging consumers to ask for advertised products by name."[56]

The exception for DTC advertising overlooks the fact that physicians are still obligated to provide their patients with an individualized assessment of the risks and benefits involved in their medical treatments, regardless of how a drug is advertised.[57] Even though physicians may spend less time with individual patients than they had in the past, physicians still have an obligation to determine the appropriate treatment for each patient after considering the patient's individual medical history.[58] While application of the exception suggests that a physician's duty to the individual patient is somehow limited if a pharmaceutical manufacturer engages in DTC advertising,[59] the physician remains nevertheless responsible for the prescription decision. Thus, the learned intermediary doctrine should still apply, despite DTC marketing, as physicians continue to be primarily responsible for communicating risks involving medications to patients.[60]

V. Impact of Decision

A. Introduction

Under the majority rule, pharmaceutical manufacturers are not required to communicate warnings directly to the patient. Rather, under the learned intermediary doctrine, manufacturers of prescription drugs can satisfy their duty to warn by adequately detailing product risks to prescribing physicians.[61] The principles of the learned intermediary doctrine were explained by the Fifth Circuit in *Reyes v. Wyeth Laboratories*.[62] The court stated that:

> [W]here prescription drugs are concerned, the manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the drug's use. This special standard for prescription drugs is an understandable exception to the Restatement's general rule that one who markets goods must warn foreseeable ultimate users of dangers inherent in his products. Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers.[63]

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[56] *Id.*
[57] *See* Schwartz, *supra* note 3, at 365.
[58] *See* Schwartz, *supra* note 3, at 368.
[59] Schwartz, *supra* note 3, at 368.
[60] *See* Schwartz, *supra* note 3, at 369.
[61] Schwartz, *supra* note 3, at 355.
[62] Reyes v. Wyeth Laboratories, 498 F.2d 1264 (5th Cir. Tex. 1974).
[63] *Reyes*, 498 F.2d at 1276 (internal citations omitted).

Historically, pharmaceutical manufacturers communicated to physicians directly through medical journals or sales representatives. However, as pharmaceutical manufacturers began to advertise directly to consumers, courts have had to consider whether direct advertising compromises the basis of the learned intermediary doctrine, such that an exception to the general rule becomes appropriate. Thus, courts have had to decide whether manufacturers should be required to adequately communicate warnings to the ultimate consumer when they engage in DTC advertising.

Citing the general policy considerations that provide the foundation for the learned intermediary doctrine, many courts have concluded that a manufacturer must adequately warn the prescribing physician. These principles have become widely accepted, and courts have been largely hesitant to find exceptions.[64] When courts have recognized exceptions, they have been narrowly tailored to the specific circumstances of the case.[65]

B. Rationale for the Learned Intermediary Doctrine

The concept of the learned intermediary doctrine was first conceived in ***Markus v. Specific Pharmaceuticals, Inc.***[66] The term "learned intermediary" was first coined by Judge McManus in the Eighth Circuit's 1966 decision in ***Sterling Drug, Inc. v. Cornish***.[67] The majority of jurisdictions subsequently have adopted the doctrine, finding that pharmaceutical manufacturers are not required to directly warn consumers if adequate warnings are given to the prescribing physicians.[68]

Courts have recognized several theories that form the basis of the learned intermediary doctrine.[69] First, courts have recognized the value of the physician-patient relationship and have noted that a requirement for pharmaceutical manufacturers to directly warn consumers could interfere with that relationship by causing patients to distrust the physician's advice.[70] Second, courts have reasoned that physicians are better positioned to advise patients of risks and benefits, especially in light of the physician's need to obtain informed consent from the patient.[71] Finally, manufacturers are not always capable of effectively communicat-

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[64] See Teresa Moran Schwartz, ***Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Doctrine***, 46 Food Drug Cosm. L.J. 829, 831-35 (1991) (describing exceptions to the learned intermediary doctrine for cases involving mass immunization and contraceptive).

[65] See Schwartz, ***supra*** note 64, at 835 (noting "widespread judicial reluctance to recognize new exceptions to the learned intermediary rule").

[66] Markus v. Specific Pharmaceuticals, Inc., 77 N.Y.S.2d 508 (N.Y. App. Div. 1948).

[67] Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir. Mo. 1966) (describing the physician as the "learned intermediary" between the patient and the manufacturer).

[68] See Michael C. Allen, ***Medicine Goes Madison Avenue: An Evaluation of the Effect of Direct-to-Consumer Pharmaceutical Advertising on the Learned Intermediary Doctrine***, 20 Campbell L. Rev. 113, 119-120 (1997).

[69] See Patrick Cohoon, ***An Answer to the Question Why the Time Has Come to Abrogate the Learned Intermediary Rule in the Case of Direct-to-Consumer Advertising of Prescription Drugs***, 42 S. Tex. L. Rev. 1333, 1336 (2001).

[70] *Id.*

[71] *Id.*

ing complex medical information to individual patients, who necessarily rely on the information provided by their physicians.[72] Prescribing physicians are therefore in the best position to evaluate the risks and benefits of a particular treatment for an individual patient.

Under the learned intermediary doctrine, the pharmaceutical manufacturer's duty to warn extends to the physician—not the ultimate consumer.[73] Thus, the manufacturer is not liable for failing to warn when it provides adequate warnings to the physician, who acts as a "learned intermediary" between the manufacturer and the patient.[74] As the Eighth Circuit explained in ***Ehlis v. Shire Richwood, Inc.,*** "a warning to the physician is deemed a warning to the patient; the manufacturer need not communicate directly with all ultimate users of prescription drugs."[75]

C. Exceptions to the Learned Intermediary Doctrine

1. Mass Immunizations

The first exception to the learned intermediary doctrine was recognized just two years after the Eighth Circuit originally coined that term. In ***Davis v. Wyeth Laboratories, Inc.,*** the Ninth Circuit found an exception to the learned intermediary doctrine in the context of mass immunizations.[76] In *Davis*, the court found that the doctrine did not apply to claims involving mass immunizations because the vaccines were administered with little or no physician intervention.[77] However, this exception was later limited to childhood vaccines; under the National Childhood Vaccination Act of 1986, manufacturers are not required to directly warn consumers of risks relating to the administration of childhood vaccines.[78]

2. Contraceptives

Following the recognition of an exception for mass immunizations, some courts also adopted a narrow exception to the learned intermediary doctrine for oral contraceptives.[79] These courts have found that prescriptions for oral contraceptives present circumstances distinguishable from those of other prescriptions. For example, in ***MacDonald v. Ortho Pharmaceutical Corp.,*** the Massachusetts Supreme Court refused to apply the learned intermediary

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[72] *Id.*

[73] *See* Richard B. Goetz et al., ***A Defense of the Learned Intermediary Doctrine***, 63 Food & Drug L.J. 421 (2008).

[74] *See id.* at 422.

[75] Ehlis v. Shire Richwood, Inc., 367 F.3d 1013, 1016 (8th Cir. 2004).

[76] Davis v. Wyeth Laboratories, Inc., 399 F.2d 121, 131 (9th Cir. Idaho 1968).

[77] *Id.*

[78] *See* 42 U.S.C. § 300aa-22(c) ("No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, solely due to the manufacturer's failure to provide direct warnings to the injured party … of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.").

[79] *See, e.g.,* Odgers v. Ortho Pharm. Corp., 609 F. Supp. 867, 873-75 (E.D. Mich. 1985); Stephens v. G.D. Searle & Co., 602 F. Supp. 379, 380-81 (E.D. Mich. 1985); Lukaszewicz v. Ortho Pharm. Corp., 510 F. Supp. 961, 964-65 (E.D. Wis. 1981), *amended on other grounds,* 532 F. Supp. 211 (E.D. Wis. 1981); MacDonald v. Ortho Pharm. Corp., 475 N.E.2d 65, 69-70 (Mass. 1985).

doctrine to a case involving oral contraceptives.[80] The court reasoned that the doctrine was not applicable because patients were typically more involved in the decision to use oral contraceptives, and, therefore, physicians played a more passive role in the decision-making process.[81] Further, physicians may not be able to adequately convey all of the risks and information regarding the use of oral contraceptives given the limited interaction between the physician and patient.[82] Thus, the court found that the manufacturer of oral contraceptives "is not justified in relying on warnings to the medical profession to satisfy its common law duty to warn, and that the manufacturer's obligation encompasses a duty to warn the ultimate user."[83]

Some jurisdictions have similarly found that the learned intermediary doctrine does not apply to cases involving contraceptive intrauterine devices (IUDs).[84] However, other courts have rejected further exceptions to the doctrine under similar circumstances.[85]

D. Direct-to-Consumer Advertising of Prescription Pharmaceuticals

1. Regulation of Direct-to-Consumer Advertising

FDA began regulating the marketing of prescription drugs following the 1962 Kefauver-Harris Amendments to the Federal Food, Drug, and Cosmetic Act.[86] There were two significant requirements for prescription drug marketing following the Kefauver-Harris Amendments.[87] First, regulations require advertisements to contain a "brief summary" that provides information regarding the drug's side effects, contraindications and effectiveness.[88] Additionally, advertisements cannot be false or misleading and must present a "fair balance" between information regarding the drug's safety and its efficacy.[89]

During the 1980s, pharmaceutical manufacturers began to advertise directly to consumers on television and in periodicals.[90] In 1983, FDA requested that pharmaceutical

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[80] MacDonald v. Ortho Pharm. Corp., 475 N.E.2d 65 (Mass. 1985).

[81] ***MacDonald***, 475 N.E.2d at 69.

[82] *Id.* at 70.

[83] *Id.*

[84] ***See, e.g.***, Hill v. Searle Labs., Inc., 884 F.2d 1064, 1070 (8th Cir. 1989) (finding that IUDs were similar to other types of birth control because the physician does not necessarily make an individualized medical assessment in making the prescription decision).

[85] Lacy v. G.D. Searle & Co., 567 A.2d 398, 400 (Del. 1989) (refusing to apply an exception to the learned intermediary doctrine in a case involving injuries resulting from the use of an IUD).

[86] 1962 Kefauver-Harris Drug Amendments, Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified as amended at 21 U.S.C. § 352(n) (2000)); ***see also*** 21 U.S.C. § 393(b)(1) (2000) (requiring FDA to "promote the public health by … taking appropriate action on the marketing of regulated products in a timely manner.").

[87] See Schwartz, ***supra*** note 3, at 341.

[88] 21 C.F.R. § 202.1(e).

[89] 21 C.F.R. § 202.1(e)(5).

[90] See Schwartz, ***supra*** note 3, at 344-345.

manufacturers voluntarily suspend DTC advertisements.[91] FDA withdrew the moratorium in 1985 and stated that "current regulations governing prescription drug advertising provide sufficient safeguards to protect consumers."[92] Thus, DTC advertising was subject to the "brief summary" and "fair balance" requirements.[93] A pharmaceutical manufacturer could satisfy the "brief summary" requirement by including the approved labeling in a print advertisement; however, manufacturers faced unique challenges with respect to broadcast advertisements.[94] In response, FDA issued a draft guidance document in August 1997 to clarify its position on DTC advertisement, which became final in 1999.[95]

The guidance described a manufacturer's obligation to disclose only the drug's "major risks" in the audio or visual component of a broadcast advertisement; thus, the manufacturer need not disclose ***all*** potential side effects.[96] As broadcast advertisers needed to make "adequate provision … for dissemination of the approved or permitted package labeling,"[97] manufacturers began to provide means for customers to request additional product information, such as toll-free telephone numbers, website addresses or patient referrals.[98]

Since then, DTC advertising has represented an increasing percentage of total pharmaceutical sales. According to a study published by the ***New England Journal of Medicine***, annual spending on DTC advertising increased by 330 percent between 1996 and 2005.[99] Additionally, during this time, total spending on pharmaceutical promotion increased from $11.4 billion to $29.9 billion.[100]

2. Exceptions to the Learned Intermediary Doctrine for DTC Marketing

Before ***Centocor***, few cases suggested that an exception to the learned intermediary doctrine would exist for DTC marketing. One court, however, specifically adopted the exception. In ***Garside v. Osco Drugs***, the plaintiff alleged that the manufacturer of phenobarbital failed to adequately warn her of the risks associated with the drug.[101] The district court for the

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[91] Statement of Nancy M. Ostrove, Ph.D., Deputy Director, Division of Drug Marketing, Advertising, and Communications, before the Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism, Senate Committee on Commerce, Science, and Transportation (July 24, 2001), ***available at*** http://www.fda.gov/NewsEvents/Testimony/ucm115206.htm.

[92] Direct-to-Consumer Advertising of Prescription Drugs; Withdrawal of Moratorium, 50 Fed. Reg. 36,677 (Sept. 9, 1985).

[93] ***See*** Schwartz, ***supra*** note 3, at 345.

[94] ***Id.***; ***see also supra*** note 91.

[95] ***See supra*** note 91.

[96] See Guidance for Industry on Consumer-Directed Broadcast Advertisements, 64 Fed. Reg. 43,197 (Aug. 9, 1999).

[97] 21 C.F.R. § 202.1(e)(1).

[98] ***See supra*** note 96.

[99] Julie M. Donohue et al., ***A Decade of Direct-to-Consumer Advertising of Prescription Drugs***, 357 New Eng. J. Med. 673 (2007).

[100] ***Id.***

[101] Garside v. Osco Drugs, 764 F. Supp. 208, 210 (D. Mass. 1991).

District of Massachusetts indicated that an exception to the learned intermediary doctrine could exist in the context of DTC marketing.[102] The court stated in a footnote that "advertising of a prescription drug to the consuming public may constitute a third exception to the learned intermediary doctrine."[103] However, the court concluded that this exception would not apply in that situation because the manufacturer did not advertise the product to the consuming public.[104]

In *Edwards v. Basel Pharmaceuticals*, the Oklahoma Supreme Court addressed the application of the learned intermediary doctrine to a case involving injuries allegedly caused by prescription nicotine patches.[105] Citing the exception that generally had been applied to oral contraceptive cases, the court found that the same reasoning would apply to cases involving prescription nicotine cases.[106] The court held that "[w]hen direct warnings to the user of a prescription drug have been mandated by a safety regulation promulgated for the protection of the user, an exception to the learned intermediary doctrine exists, and failure on the part of the manufacturer to warn the consumer can render the drug unreasonably dangerous."[107] The decision suggests that the exception would only apply when FDA requires manufacturers to provide direct warnings.

The New Jersey Supreme Court recognized an exception to the learned intermediary doctrine for DTC marketing in 1999 in *Perez v. Wyeth Labs., Inc.*[108] The case involved injuries allegedly caused by Wyeth's product, Norplant, an FDA-approved contraceptive implanted under the skin.[109] Plaintiffs alleged that Wyeth engaged in a "massive advertising campaign … directed at women rather than at their doctors."[110] The campaign included advertisements on television and in women's magazines.[111] Plaintiffs alleged that the advertisements failed to warn of Norplant's side effects and only described the simplicity and convenience of using the product.[112]

The trial court granted summary judgment in favor of Wyeth by applying the learned intermediary doctrine, a judgment the appellate court affirmed.[113] The New Jersey Supreme Court considered whether an exception would apply in light of the alleged DTC advertising. While the court recognized that the "learned intermediary doctrine applies when its

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[102] Garside, 764 F. Supp. at 211.
[103] *Id.* at 211 n.4.
[104] *Id.*
[105] Edwards v. Basel Pharmaceuticals, 933 P.2d 298 (Okla. 1997).
[106] *Edwards*, 933 P.2d at 301.
[107] *Edwards*, 933 P.2d at 301.
[108] Perez v. Wyeth Labs., Inc., 734 A.2d 1245 (N.J. 1999).
[109] *Perez*, 764 A.2d at 1247.
[110] *Id.*
[111] *Id.*
[112] *Id.*
[113] *Id.* at 1249.

predicates are present,"[114] the court nevertheless concluded that "[t]he direct marketing of drugs to consumers generates a corresponding duty requiring manufacturers to warn of defects in the product."[115] The court explained that pharmaceutical manufacturers should be entitled to a rebuttable presumption that they have satisfied their duty to warn when the warnings given comply with FDA regulations.[116] Thus, while the manufacturer does not have an independent duty to warn patients, the manufacturer must provide adequate warnings if it engages in DTC advertising,

The New Jersey decision has not been widely adopted by other jurisdictions, however. In fact, other courts to consider the issue have refused to adopt an exception to the learned intermediary doctrine for DTC advertising.[117] In 2007, the West Virginia Supreme Court went against the majority of jurisdictions and refused to adopt the doctrine.[118] Citing the exception for DTC advertising announced in *Perez*, the West Virginia court found that there would be "no benefit in adopting a doctrine that would require simultaneous adoption of numerous exceptions in order to be justly utilized."[119]

E. Impact of Centocor

The language used by the Court of Appeals of Texas in *Centocor* suggests that the exception is limited to DTC marketing that "fraudulently misrepresent[s]" risks associated with the product.[120] Under this construction, the rule described in *Centocor* could be viewed as a narrow exception to the learned intermediary doctrine. Although the full impact of *Centocor* is still unknown, the decision parts from the long-standing principles of the learned intermediary doctrine.[121] The reasoning in *Centocor* calls into question the physician's role in fully advising the patient of the risks and benefits of a prescription drug, even though numerous courts have recognized that physicians can best evaluate a patient's medical history, co-morbidities, and most advantageous treatment options. Therefore, one view is that exceptions to the learned intermediary doctrine may not take the importance of the physician's judgment, experience and expertise into account.

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[114] *Id.* at 1257.

[115] *Id.* at 1263.

[116] *Id.* at 1259.

[117] See, e.g., In re Norplant Contraceptive Prods. Liab. Litig., 215 F. Supp. 2d 795, 827 (E.D. Tex. 2002) (noting that "apart from New Jersey, direct-to-consumer advertising does not negate the applicability of the learned intermediary doctrine"); In re Meridia Prods. Liab. Litig., 328 F. Supp. 2d 791, 812 n.19 (N.D. Ohio 2004) (declining to apply Perez).

[118] State ex rel. Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899 (W. Va. 2007).

[119] *Johnson & Johnson*, 647 S.E.2d at 477.

[120] *Centocor*, 310 S.W.3d at 508.

[121] Centocor has petitioned the Texas Supreme Court for review.

In 1998, the American Law Institute recognized the potential for exceptions to the learned intermediary doctrine, but declined to incorporate those exceptions when it described the doctrine in the Restatement (Third) of Torts: Products Liability § 6(d).[122] Comment e to Section 6 notes, "The Institute leaves to developing case law whether exceptions to the learned intermediary rule in these or other situations should be recognized."[123]

In the age of mass media and DTC advertising, some have questioned the continued viability of this long-standing doctrine.[124] However, other recent decisions suggest that the doctrine continues to be applicable despite changes in how pharmaceutical products may be advertised. For example, in ***Schilf v. Eli Lilly & Co.,*** the United States District Court for the District of South Dakota recently concluded that the South Dakota Supreme Court, which had never directly addressed the applicability of the learned intermediary doctrine, would now adopt it.[125] In rejecting the claim that the manufacturer of a prescription antidepressant had a duty to warn the consumer, the court found the "overwhelming" precedent from other jurisdictions and the policy justifications persuasive in finding that the doctrine would apply under South Dakota law.[126] Similarly, in ***O'Connell v. Biomet, Inc.,*** the Colorado Court of Appeals joined the list of courts that have expressly adopted the doctrine.[127] ***O'Connell***, which involved the manufacturer of a medical device, highlights the underlying rationale for the learned intermediary doctrine.

As described above, courts' decisions related to DTC marketing have been largely reluctant to recognize an exception to the learned intermediary doctrine, which recognizes the historically important role physicians have played in prescription decisions. Even in the age of DTC marketing, many courts continue to find these justifications persuasive. While a minority of jurisdictions may permit an exception to the learned intermediary doctrine for DTC marketing, it is likely that the exception will be narrowly construed to encompass only fraudulent or deceptive marketing. So long as the physician-patient relationship remains an integral part of healthcare decision-making, the learned intermediary doctrine must have continued application in evaluating a pharmaceutical manufacturer's duty to warn.

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[122] Restatement (Third) of Torts: Products Liability § 6(d) (1997).
[123] Restatement (Third) of Torts: Products Liability § 6(d) cmt. e.
[124] See Perez v. Wyeth Labs, Inc., 734 A.2d 1245 (N.J. 1999).
[125] Schilf v. Eli Lilly & Co., No. CIV 07-4015, 2010 WL 4024922 (D.S.D. Oct. 13, 2010).
[126] *Schilf*, 2010 WL 4024922 at *2.
[127] O'Connell v. Biomet, Inc., No. 09CA0224, 2010 WL 963234 (Colo. App. Mar. 18, 2010).

VI. Conclusion

The decision in *Centocor* represents a departure from the traditional application of the learned intermediary doctrine. The scope of the exception to the doctrine described in *Centocor* may ultimately depend on the specific circumstances of the individual prescription decision and the nature of the advertisements at issue. In general, the doctrine's well-established foundation and policy justifications may dissuade future courts from adopting the DTC exception. On October 1, 2010, the Texas Supreme Court requested a full briefing on the merits. If the decision is allowed to stand, it could become binding in Texas, and other jurisdictions may choose to adopt similar exceptions. So long as the physician has the ultimate responsibility for the prescription decision, the learned intermediary doctrine continues to be relevant and applicable in law.