# SUPERIOR COURT OF NEW JERSEY

CHAMBERS OF
JESSICA R. MAYER, J.S.C.
JUDGE

MIDDLESEX COUNTY COURTHOUSE
P.O. BOX 964
NEW BRUNSWICK, NEW JERSEY 08903-964

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**Memorandum of Decision on Plaintiffs' Motion for Partial Summary Judgment and Defendant's Cross-Motion for Partial Summary Judgment**

**In Re: AlloDerm® Litigation, Case Code 295**

**Michael Simineri and Karen Simineri v. LifeCell Corporation**

Docket No. MID-L-5972-11 CM

Decided: May 8, 2015

FILED
MAY 08 2015
JUDGE JESSICA R. MAYER

**Counsel:** For Plaintiffs: Lawrence R. Cohan, Esq., Adrianne W. Webb, Esq., Joseph J. Fantini, Esq., Paola Saneaux, Esq., Sol H. Weiss, Esq., Anapol Schwartz.

For Defendant: David W. Field, Esq., Stephen R. Buckingham, Esq., Joseph A. Fischetti, Esq., Lowenstein Sandler LLP.

Plaintiffs Michael and Karen Simineri ("Plaintiffs") move for partial summary judgment "abrogating the learned intermediary doctrine" in their products liability action against Defendant LifeCell Corporation ("LifeCell" or "Defendant"). (Plaintiffs' Memorandum of Law in Support of Their Motion for Partial Summary Judgment ("Pls.' Br.") at 1). LifeCell opposes Plaintiffs' motion and cross-moves for partial summary judgment "declaring that the learned intermediary doctrine applies in this matter." (Defendant's Brief in Opposition to Plaintiff's Motion for Partial Summary Judgment and in Support of Cross-Motion for Partial Summary Judgment ("Def.'s Opp.") at 1). The court considered the written submissions of counsel regarding the motions. Counsel agreed to

waive oral argument and consented to the court's disposition of the matter based upon the papers submitted. The following memorandum sets forth the court's disposition of the motions.

## I. Statement of Material Facts

Plaintiffs brought this action under the New Jersey Products Liability Act, N.J.S.A. § 2A:58C-1, et seq. ("NJPLA"), to recover damages for injuries Plaintiffs purportedly suffered as a result of LifeCell's alleged "negligence and wrongful conduct in connection with the design, development, processing, manufacturing, testing, packaging, advertising, promoting, marketing, distribution, labeling and/or sale of AlloDerm® for use in hernia repair and/or abdominal reconstruction surgeries." (Pls.' Statement of Undisputed Material Facts ("Pls.' SUF") ¶ 2). Plaintiffs' claims in this case center on LifeCell's alleged failure to adequately warn Plaintiffs of health risks associated with the use of AlloDerm® in ventral hernia repairs. (Id. ¶ 3). By way of consent order dated January 15, 2015, the parties stipulated that this case is governed exclusively by New Jersey law. (Consent Order Stipulating Choice of Law, Jan. 15, 2015)[1].

AlloDerm® is a human tissue product consisting of decellularized human skin harvested from cadavers. (Def.'s Statement of Material Uncontroverted Facts ("Def.'s SUF") ¶ 1). Surgeons and doctors use AlloDerm® for many purposes, including as a skin graft for burn victims, gingival grafts, breast reconstruction, and ventral hernia repair. (Id. ¶ 2). AlloDerm® is not regulated as either a drug or medical device by the federal Food and Drug Administration ("FDA") but rather is regulated by the FDA under policies governing banked human tissue products. (Id. ¶ 4). Although Plaintiffs dispute that AlloDerm® is a "prescription product," Plaintiffs concede that AlloDerm® is marketed and sold exclusively to health care providers and cannot be purchased

[1] Counsel agreed that all pending cases against AlloDerm® in this court are governed by New Jersey law.

directly by individual patients. (Def.'s SUF ¶ 3; Pls.' Response to Def.'s SUF ¶ 3). It is also undisputed that a patient's use of AlloDerm® requires surgical implantation by a licensed physician or medical provider. (Def.'s SUF ¶ 2).

The sole question before this court is whether, under New Jersey law, the learned intermediary doctrine ("LID") applies to AlloDerm®, such that LifeCell's duty to warn of any alleged health risks associated with AlloDerm® was owed to Plaintiffs' physicians rather than to Plaintiffs directly. Whether the learned intermediary doctrine is applicable to human tissue products, such as AlloDerm®, that are marketed and made available solely to licensed health care professionals, is an issue of first impression in New Jersey.

## II. Summary Judgment Standard

"A party seeking any affirmative relief may . . . move for a summary judgment or order on all or any part thereof or as to any defense." R. 4:46-1. Summary judgment may be granted as to "any issue in the action . . . although there is a genuine factual dispute as to any other issue . . . ." R. 4:46-2(c).[2] Summary judgment is appropriate if "the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact challenged and that the moving party is entitled to a judgment or order as a matter of law." Ibid. In considering a motion for summary judgment, the court should determine whether "the competent evidential materials presented, when viewed in the light most favorable to the non-moving party, are sufficient to permit a rational factfinder to resolve the alleged disputed issue in favor of the non-moving party." Brill v. Guardian Life Ins. Co. of Am.,

[2] The court recognizes that future dispositive motions are likely to be filed in this case, including motions addressed to the adequacy of the warning provided. Nothing in the court's decision on the pending motions precludes future dispositive motion practice in this case.

142 N.J. 520, 540 (1995). "If there exists a single, unavoidable resolution of the alleged disputed issue of fact, that issue should be considered insufficient to constitute a 'genuine' issue of material fact for purposes of Rule 4:46-2." Ibid.

## III. The New Jersey Products Liability Act and the Learned Intermediary Doctrine

Products liability cases in New Jersey are governed by the New Jersey Products Liability Act, N.J.S.A. § 2A:58C-1 et seq. Under the NJPLA:

> [a] manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.
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> [N.J.S.A. § 2A:58C-2.]

New Jersey law recognizes that some products, such as prescription drugs, may be "unavoidably unsafe" even for their intended use. Feldman v. Lederle Labs., 97 N.J. 429, 446–47 (1984). A manufacturer who knows or should know of the dangerous properties of such a product is required to provide appropriate warnings to the end user of the product. Ibid. An unavoidably unsafe product, accompanied by appropriate warnings, is not defective. Ibid. Thus, under the NJPLA, "[i]n any product liability action the manufacturer or seller shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction . . . ." N.J.S.A. § 2A:58C-4. Normally, the manufacturer of a product owes a duty to warn the ultimate user of the product. See Niemiera v. Schneider, 114 N.J. 550, 559 (1989). However, New Jersey has adopted the learned intermediary doctrine as codified in the NJPLA's definition of an adequate warning:

> An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used, or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician.
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> [N.J.S.A. § 2A:58C-4 (emphasis added).]

Thus, under New Jersey law, "a pharmaceutical manufacturer generally discharges its duty to warn the ultimate user of prescription drugs by supplying physicians with information about the drug's dangerous propensities." Niemiera, supra, 114 N.J. at 559. "To the extent that the pharmaceutical manufacturer is relieved of the duty to warn, the treating physician as the learned intermediary assumes the responsibility to warn the patient of the risks involved" in taking the prescription drug. Id. at 552.

Various rationales have been advanced by courts in New Jersey to explain the learned intermediary doctrine. As the Appellate Division in Bacardi v. Holzman, 182 N.J. Super. 422, 426 (App. Div. 1981) explained:

> The manufacturer has no duty to prepare a warning for the consumer when, under all circumstances, the product only comes into the consumer's hands after it is prescribed by the physician. There is no basis for concluding that the manufacturer should have foreseen that the ultimate consumer would be in the position to make a layman's judgment in terms of whether to continue with the use of the drug or not.
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> [Id. (emphasis added)]

In Bacardi, the court adopted the reasoning of the Ninth Circuit and held that:

> [o]rdinarily in the case of prescription drugs warning to the prescribing physician is sufficient. In such cases the choice involved is essentially a medical one involving an assessment of medical risks in the light of the physician's knowledge of the patient's needs and

> susceptibilities. Further it is difficult under such circumstances for the manufacturer, by label or direct communication, to reach the consumer with a warning. A warning to the medical profession is in such cases the only effective means by which a warning could help the patient.
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> [Id. at 425 (quoting Davis v. Wyeth Laboratories, Inc. 399 F.2d 121, 130 (9th Cir. 1968)).]

The New Jersey Supreme Court has established several rationales favoring application of the LID, including: (1) the desire to avoid intrusion into the doctor-patient relationship; (2) the superior position of doctors to communicate important information about risks to their patients; (3) the inability of drug manufacturers to communicate effectively and directly with patients; and (4) the nearly impossible task of translating complex medical information and risk factors into terms understandable to the average consumer that would be imposed on drug manufacturers. Perez v. Wyeth Labs. Inc., 161 N.J. 1, 17–18 (1999).

Although no New Jersey state court has explicitly addressed the issue, other courts have determined that the learned intermediary doctrine applies to prescription medical devices. See Ellis v. C. R. Bard, 311 F.3d 1272 (11th Cir. 2002) (morphine-drip pump); Porterfield v. Ethicon, Inc., 183 F.3d 464 (5th Cir. 1999) (surgical mesh); Beale v. Biomet, Inc., 492 F. Supp.2d 1360 (S.D. Fla. 2007) (artificial knee); Parkinson v. Guidant Corp., 315 F. Supp.2d 741, 747 (W.D. Pa. 2004) (surgical guidewire); Spychala v. G.D. Searle & Co., 705 F. Supp. 1024 (D.N.J. 1988) (intrauterine device ("IUD")); Hurley v. Heart Physicians, P.C., 898 A.2d 777 (Conn. 2006) (pacemaker); Lacy v. G.D. Searle & Co., 567 A.2d 398 (Del. 1989) (IUD). Additionally, in Perez v. Wyeth Labs. Inc., 161 N.J. 1 (1999),[3] the New Jersey Supreme Court impliedly recognized that the doctrine would

[3] The Perez Court carved out a narrow exception to the LID in the case of direct-to-consumer advertising. 161 N.J. at 21. The Court reasoned that where the manufacturer markets prescription drugs directly to the consumer, the manufacturer interjects itself between the doctor and the patient and thus creates an independent duty to warn the patient. Id. at 17–21. Plaintiffs concede that LifeCell advertised and marketed AlloDerm® only to doctors and healthcare providers. (Pls.' Response to Def. SUF ¶ 3). Thus, the Perez exception to the LID is inapplicable here.

apply to prescription medical devices. Id. at 21 (holding that "the learned intermediary doctrine does not apply to the direct marketing of drugs to consumers," but recognizing that had the manufacturer "simply supplied the physician with information about [the contraceptive device], and not advertised directly to the patients," the LID would bar the plaintiffs' claims).

Several courts have concluded that the LID is particularly appropriate in cases involving medical devices that must be inserted or implanted into the patient by a licensed medical professional. See, e.g. Spychala, supra, 705 F. Supp. at 1032 (applying the LID under New Jersey law and noting that "[t]he insertion of an [intrauterine device], in particular, requires the physician's services, knowledge and skill"); see also Ellis, supra, 311 F.3d at 1280 (noting that it is well settled in Georgia that the LID applies to implantable medical devices); Beale, supra, 492 F. Supp.2d at 1368 ("The rationale behind the doctrine is that patients do not have access to prescription medicines without the intervention of the learned intermediary . . . [and] [g]iven that rationale, it makes even more sense to apply the doctrine in the context of medical devices" that can only be implanted by a doctor); Lacy, supra, 567 A.2d at 401 ("The rationale supporting the learned intermediary doctrine is even stronger when applied to the IUD . . . because not only must the physician order the IUD for his patient, but the physician must also fit the IUD in place.").

A few jurisdictions—albeit with little analysis—have applied the LID to biological medical products.[4] See Christopher v. Cutter Labs., 53 F.3d 1184, 1192–93 (11th Cir. 1995) (blood

[4] The dearth of case law regarding the applicability of the LID to biological medical products is partially explained by the fact that many jurisdictions have exempted blood and tissue based products from certain products liability actions. See 1A-14, Drug Product Liability, § 14.06[4][c][i] & nn.249–52. (Matthew Bender 2015) (citing various state statutes and court decisions excluding blood and tissue products from products liability actions).

> Drugs and medical devices clearly fall within the definition of "product," but in most jurisdictions, either by statute or case law, blood, blood-related products, and human tissues are not considered products. Section 402A of the Restatement (Second) does not define the term "product." Section 19(a) of the Third Restatement provides that "[a] product is tangible personal property distributed

product); Erickson v. Baxter Healthcare, Inc., 151 F. Supp.2d 952, 962 (N.D. Ill. 2001) (same); Doe v. Alpha Therapeutic Corp., 3 S.W.3d 404, 419–20 (Mo. Ct. App. 1999) (same); Tortorelli v. Mercy Health Ctr., Inc., 242 P.3d 549 (Okla. Civ. App. 2010) (allograph bone putty).

## IV. Analysis

Preliminarily, the court notes that the LID, standing alone, is not a defense to a failure-to-warn claim. Rather, the doctrine merely governs to whom a warning is owed. If the doctrine applies, the manufacturer may satisfy its obligation by providing the appropriate warnings to the physician. If the doctrine does not apply, the manufacturer must provide appropriate warnings directly to the end user of the product. Although the LID governs to whom a warning is owed, it does not answer the ultimate question whether the warnings provided in a particular case are adequate as a matter of law.[5]

Plaintiffs argue that the LID is inapplicable to AlloDerm® because AlloDerm® is not regulated by the FDA as a prescription drug or medical device and it is "well-established" that the LID only applies to FDA-approved drugs and devices. (Pls.' Br. at 17). Plaintiffs primarily rely on

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> commercially for use or consumption,["] and comment c to § 19 specifically excludes human blood, blood-related products, and tissues from products liability claims. Several states' products liability statutes likewise exclude blood, blood-related products, and tissues from their scope. In addition, almost every state has a "blood shield law," which insulates blood, plasma, blood derivative and blood product manufacturers and providers from certain types of tort liability . . . . [Ibid.]

[5] Both parties have submitted factual and legal arguments that are irrelevant to the single question addressed by these motions—the applicability of the LID to AlloDerm®. For example, the parties vehemently dispute the quality and quantity of clinical testing required by the FDA and conducted by LifeCell. (Pls.' Br. at 18–24; Def.'s Opp. at 29–34). To the extent that the factual and legal arguments made by the parties relate to issues separate and apart from the LID—such as the adequacy of the warnings provided or what LifeCell knew or should have known regarding the risks of using AlloDerm® in hernia repairs—the parties will have an opportunity to address those questions to the court at the appropriate time. The court declines to make any determinations as to any issues other than the applicability of the LID at this time.

two lines of reasoning as bases for their argument: (1) the applicability of the LID is dependent on the FDA's classification of a product as either a prescription drug or device; and (2) although courts have applied the LID to FDA-approved drugs and devices, no court has applied the LID to human tissue products, such that a decision by this court applying the LID to AlloDerm® would be an unwarranted expansion of New Jersey law.

### A. The FDA's Classification of a Medical Product as a Drug, Device, or Human Tissue Product Has No Bearing on the Applicability of the Learned Intermediary Doctrine.

Plaintiffs first argue that because human tissue products are subject to less stringent pre- and post-market approval requirements than FDA-approved drugs and medical devices, LifeCell should not be entitled to the protections of the LID. (Pls.' Br. at 14–18). Contrary to Plaintiffs' contention that AlloDerm® is "not subject to FDA regulations," (Pls.' Br. at 18), or that "LifeCell knowingly circumvented the FDA and avoided any compliance with FDA regulations," (Pls.' Br. at 11), AlloDerm® is regulated by the FDA pursuant to regulations pertaining to banked human tissue. See 21 C.F.R. § 1270 et seq. The FDA regulations for banked human tissue primarily focus on donor screening and testing for communicable diseases. Ibid.

Plaintiffs cite a number of cases from other jurisdictions applying the LID to medical devices and argue that "[t]he reasoning behind these rulings make it abundantly clear that the LID is intended to apply solely to pharmaceutical drugs and medical devices which are approved and regulated by the FDA." (Pls.' Br. at 18). None of the cases relied on by Plaintiffs base application of the LID on the FDA's classification of medical products as either drugs or devices. (Def.'s Opp. at 17). Rather, the cases cited by Plaintiffs focus on the traditional rationales underpinning the LID; namely that where a medical product is available only through the intervention of a licensed physician, any duty to warn is owed to the physician and not the patient.

For example, in Craft v. Peebles, 893 P.2d 138 (Haw. 1995), the court applied the LID to saline breast implants explaining that "[b]ecause the manufacturer has little or no contact with the ultimate consumer and the treating physician makes the purchasing decisions and judgments concerning medical products, the warnings are better conveyed to the physician . . . ." Id. at 155. In applying the LID, the court noted that in the case of medical devices, as with prescription drugs, the physician is in the best position to assess the risks and convey that information to the patient. Ibid. The Craft court made no reference to FDA regulations or product classifications in its decision to apply the LID.

Similarly, in Haffner v. Stryker Corp., No. 14-cv-00186-RBJ, 2014 U.S. Dist. LEXIS 137214, at *9–10 (D. Colo. Sept. 29, 2014), the court did not reference FDA regulations in applying the LID to a metal knee implant. The parties in Haffner did not dispute that the doctrine applied to the device in question. Rather, the plaintiff in Haffner argued that the manufacturer failed to provide adequate warnings to the medical provider. Ibid. The Haffner court noted that Colorado adopted the LID and any warnings or instructions were owed to the plaintiff's healthcare provider. Ibid. Plaintiffs in this case concede that the Haffner court provided little analysis regarding application of the LID but argue that the decision relied on by the Haffner court "makes clear that the court gave significant credence and consideration to the fact that the product involved" was an FDA-regulated medical device. (Plaintiffs' Reply to Defendant LifeCell Corporation's Opp. to Motion for Summary Judgment ("Pls.' Reply") at 10) (discussing O'Connell v. Biomet, Inc., 250 P.3d 1278 (Colo. Ct. App. 2010)). Contrary to Plaintiffs' assertion, the court's decision in O'Connell v. Biomet, Inc., 250 P.3d 1278 (Colo. Ct. App. 2010) demonstrates that the FDA's regulation of the product as a medical device had no bearing on the court's decision to apply the LID. Other than noting that the product was an FDA-approved medical device, the court

did not make a single reference to FDA regulations in determining that the LID applied. See O'Connell, supra, 250 P.3d at 1279, 1281–82. The court in O'Connell relied on traditional rationales favoring application of the LID:

> [W]e are persuaded that the learned intermediary doctrine should apply to failure to warn claims in the context of a medical device installed operatively when it is available only to physicians and obtained by prescription, and the doctor is in a position to reduce the risks of harm in accordance with the instructions or warnings.
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> Here, the fixator is only available to a patient through a qualified physician's prescription. . . . Because it was the responsibility of Dr. Brian as a learned intermediary to assess the risks and benefits of surgically applying the fixator to O'Connell's arm, defendants' duty was to warn and provide adequate instructions to Dr. Brian
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> [Id. at 1281–82 (emphases added)].

According to the O'Connell court, the primary consideration for application of the LID is whether the medical product in question is available only through a physician.

In Hurley v. Heart Physicians, P.C., 898 A.2d 777 (Conn. 2006), the Supreme Court of Connecticut reversed the trial court's dismissal of the plaintiff's products liability claim, not because the LID did not apply to the device, but because a genuine factual dispute existed whether the manufacturer's oral communications to the plaintiff's doctor worked to nullify the FDA-approved warnings accompanying the pacemaker. Id. at 788. The court's discussion of the LID was utterly devoid of any reference to FDA regulations. Id. at 783–86. Rather, the Hurley court explained that the LID is "based on the principle that prescribing physicians act as learned intermediaries between a manufacturer and consumer and, therefore, stand in the best position to evaluate a patient's needs and assess [the] risks and benefits of a particular course of treatment." Id. at 783 (quoting Guevara v. Dorsey Laboratories, Division of Sandoz, Inc., 845 F.2d 364, 367 (1st Cir. 1988)) (alteration in original).

In Humes v. Clinton, 792 P.2d 1032 (Kan. 1990), the court recognized that the plaintiffs' claim involved an FDA-approved intrauterine device; however, the FDA's approval had no bearing on the court's application of the LID. Id. at 1034, 39–40. In applying the LID, the court explained that "[s]ince prescription drugs are available only to a physician, it is the physician's duty to inform himself or herself of the characteristics of the drugs prescribed and to exercise his or her judgment of which drug to administer in light of the drug's propensities and the patient's susceptibilities." Id. at 1039 (emphasis added). The Humes court rejected an argument by the plaintiffs that federal regulations governing oral contraceptives and intrauterine devices created a duty on the part of the manufacturer defendant to provide warnings directly to the patient. Id. at 1042–43 (analyzing 21 C.F.R. §§ 310.501–.502). According to the Humes court, although the regulations were intended to "inform patients of the benefits and risks involved in the drug's usage," the regulations mandated that the information be provided to the physician to aid the physician in communicating with the patient and therefore did not create any duty on the part of the manufacturer to warn the patient directly. Ibid.

Having reviewed Plaintiffs' "supporting" case law, this court finds none of the cited cases make it "abundantly clear" or "well-established" that "the LID is intended to apply solely to pharmaceutical drugs and medical devices which are approved and regulated by the FDA." (Pls.' Br. at 17–18) (emphasis added). In fact, in each of the cases relied on by Plaintiffs, the courts concluded that the focus of the LID is whether a patient can only obtain the medical product in question—be it a drug, device, or any other form of medical product—from a licensed medical professional. In such cases, the patient necessarily relies on the skills and expertise of the physician to weigh the risks and benefits of the medical product in light of the physician's knowledge of the patient. The patient seeks information and advice from the physician regarding the medical product

and thus, the manufacturer satisfies its duty to warn by providing the relevant risk information to the physician. It is then the physician's duty to convey that information to the patient.[6]

Plaintiffs agree with Defendant that "the essence of the LID is that when a doctor is responsible for determining that a product should be used, it is the doctor, and not the manufacturer, who is best situated to convey all appropriate information to the patient, and therefore, the manufacturer's duty to warn is to the doctor, and not the patient." (Pls.' Reply at 10; Def.'s Opp. at 18–19). However, Plaintiffs argue "that requires regulatory oversight." (Pls.' Reply at 10). Plaintiffs ignore the fact that AlloDerm® is regulated by the FDA. Plaintiffs are unable to explain how the FDA's determination that AlloDerm® is classified and regulated as a human tissue product rather than a device has any bearing on the application of the LID. Plaintiffs simply argue that the LID only applies to FDA-regulated drugs and devices without providing any settled legal support for their argument. The court finds that AlloDerm® is an FDA-regulated medical product

[6] Equally unavailing is Plaintiffs' argument that the NJPLA itself demonstrates that the LID only applies to drugs and devices. (Pls.' Br. at 17–18). Plaintiffs argue that the "connection" between the LID and the FDA's regulation of drugs and devices is evidenced by the NJPLA's presumption of adequacy for FDA-approved warnings and the NJPLA's adoption of the FDA's definitions of "drug" and "medical device." (Ibid.). Under the NJPLA:

> [i]f the warning or instruction given in connection with a drug or device or food or food additive has been approved or prescribed by the federal Food and Drug Administration under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. 301 et seq. or the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. § 201 et seq., a rebuttable presumption shall arise that the warning or instruction is adequate. For purposes of this section, the terms "drug", "device", "food", and "food additive" have the meanings defined in the "Federal Food, Drug, and Cosmetic Act."
> [N.J.S.A. § 2A:58C-4.]

A plain reading of the statute demonstrates that the applicability of the LID is not dependent on the NJPLA's rebuttable presumption of adequacy. Indeed, many of Plaintiffs' arguments are addressed to the adequacy of the AlloDerm® warnings, rather than to the applicability of the LID. The flaw in Plaintiffs' argument is highlighted when the court considers the fact that the NJPLA's rebuttable presumption encompasses warnings on food and food additives in addition to drugs and medical devices. See N.J.S.A. § 2A:58C-4. Clearly, the NJPLA's rebuttable presumption of adequacy would not include food and food additives within the framework of the LID.

made available to patients only through licensed healthcare providers and that Plaintiffs failed to provide any cogent explanation as to why the rationales underlying the LID are inapplicable here.

### B. The Rationales Underlying the Learned Intermediary Doctrine Warrant Application of the Doctrine in This Matter.

Plaintiffs further argue that because no New Jersey court has held that the learned intermediary doctrine applies to human tissue products, this court should decline to do so. (Pls.' Reply at 2). Plaintiffs contend that such a ruling would "change the landscape of New Jersey products liability litigation by declaring that the LID applies to **all** manufacturers of **any medical product** whenever that product is chosen by a healthcare provider." Ibid. Plaintiffs note the lack of case law in any American jurisdiction applying the LID to human tissue products. (Pls.' Reply at 2). Conversely, Plaintiffs found no cases wherein a court considered the issue and declined to apply the doctrine to human tissue products. Few courts have addressed the application of the LID to human tissue products.[7] Thus, Plaintiffs argue that the lack of case law militates against the application of the doctrine in this case.

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[7] The court located a single case applying the LID to a human tissue-based allograph product. In Tortorelli v. Mercy Health Ctr., Inc., 242 P.3d 549 (Okla. Civ. App. 2010), the product in question was an allograph bone putty made from cadaver paste. Id. at 556 & n.5. The plaintiff had a bone tumor removed from her tibia and the putty was placed in the plaintiff's leg to promote bone growth. Id. at 556. The plaintiff brought a products liability claim against the manufacturer alleging the putty caused an allergic reaction. Id. at 557. In affirming the trial court's entry of summary judgment in favor of defendant manufacturer, the court noted that "[c]ertain products, including prescription drugs and other items requiring a prescription or physician's order are inherently dangerous or incapable of being made safe, but serve a public benefit." Id. at 558 (emphasis added). The court explained that "[i]t is the physician's duty to inform himself of the qualities and characteristics of those products which he administers or prescribes for use of his patients, and to exercise his judgment, based on his knowledge of the patient as well as the product." Ibid. (quoting McKee v. Moore, 648 P.2d 21, 24 (Okla. 1982)).

Defendant cited three cases applying the LID to biologic blood products intended for hemophiliacs. (Def.'s Opp. at 16 (citing Christopher v. Cutter Labs., 53 F.3d 1184 (11th Cir. 1995); Erickson v. Baxter Healthcare, Inc., 151 F. Supp.2d 952 (N.D. Ill. 2001); Doe v. Alpha Therapeutic Corp., 3 S.W.3d 404 (Mo. Ct. App. 1999))). Plaintiffs dispute the relevance of these cases because "blood products are licensed by the FDA and require written warnings that must be approved by the FDA" and "[s]uch is not the case with AlloDerm." (Pls.' Reply at 8). The court notes that although blood products are governed by different regulations than those governing human tissue products, both sets of regulations are administered by the FDA pursuant to the Public Health and Services Act. See 42 U.S.C. §§ 262, 264;

The court disagrees that applying the LID to AlloDerm® would be an unwarranted expansion of New Jersey's learned intermediary doctrine. The NJPLA "is not intended to codify all issues related to product liability, but only to deal with matters that require clarification." N.J.S.A. 2A:58-1(a). The NJPLA "does not legislate the boundaries of the learned intermediary doctrine." Perez, supra, 161 N.J. at 15. The pending motions in this case require the court to consider the well-established rationales underlying the LID and apply them to AlloDerm®. As the Perez court noted, such determinations are "well within the competence of the judiciary. Defining the scope of tort liability has traditionally been accepted as the responsibility of the courts." Id. at 16 (quoting Kelly v. Gwinnell, 96 N.J. 538, 555–56 (1984)).

Plaintiffs contend the Perez decision demonstrates that "New Jersey courts do not favor expanding the LID." (Pls.' Reply at 3). In Perez, the Court created an exception to the LID in cases where a drug manufacturer advertises directly to the consumer, thus interfering with the traditional doctor-patient relationship. Perez, supra, 161 N.J. at 21. The Court observed, however, that "[o]bviously, the learned intermediary doctrine applies when its predicates are present" and "[h]ad Wyeth . . . simply supplied the physician with information about the product, and not advertised directly to the patients, plaintiffs would have no claim against Wyeth based on an independent duty to warn patients." Ibid. Plaintiffs concede that LifeCell did not advertise or market AlloDerm® directly to patients and that AlloDerm® is only made available to healthcare professionals. (Pls.' Response to Def.'s SUF ¶ 3). This court finds that the court-developed

21 C.F.R. 600 et seq.; 21 C.F.R. 1270 et seq. Furthermore, those regulations pertaining to human tissue products also include labeling, warning, and recording requirements. See e.g., C.F.R. §§ 1271.350, 1271.370.

rationale favoring the LID in cases involving implantable devices is met in this case and favors application of LID to the human tissue product, AlloDerm®.[8]

As previously discussed, AlloDerm® is not marketed or sold directly to patients. AlloDerm® can only be obtained through a licensed healthcare professional. Obtaining a medical product directly from a healthcare professional is a basic principle of the LID. As other courts have concluded in the context of medical devices, application of the LID is particularly appropriate where the medical product in question not only must be acquired through the intervention of a licensed physician, but also must be implanted into the patient by the physician. In such cases, the patient relies heavily upon the "physician's services, knowledge and skill" in considering the needs and characteristics of the patient and weighing the risks, benefits, and appropriateness of the implantation of the medical product in question. See Spychala, supra, 705 F. Supp. at 1032 (interpreting New Jersey law and applying the LID to intrauterine device).

To require LifeCell to communicate directly with the patient would unnecessarily intrude on the doctor-patient relationship. In a surgical context, as compared to prescription drugs, the doctor has an even more prominent role in evaluating and selecting the most appropriate course of treatment—including the selection of the particular products to be used in the surgery. Furthermore, the surgeon, rather than the manufacturer, is best positioned to convey appropriate information to the patient regarding the benefits and risks of products such as AlloDerm®. Given the nature of AlloDerm® and its uses, it is unlikely that a patient would ever inspect the product

[8] The court rejects Plaintiffs' argument that the Perez Court's reliance on the Restatement (Third) of Torts: Products Liability (1997) regarding the LID compels a finding by this court that the LID does not apply to human tissue products. (Pls.' Reply at 7–8). Section 19(c) of the Restatement (Third) of Torts: Products Liability does not merely exclude human tissue products from application of the LID, but excludes human tissue products from products liability actions entirely. Restatement (Third) of Torts: Products Liability § 19(c) (1997). This court presumes that Plaintiffs are not advocating adoption of section 19(c) which would abrogate Plaintiffs' cause of action entirely.

or review its labeling or literature. Under such circumstances, LifeCell's duty extends only to providing the necessary information and warnings to the doctor. The doctor must then determine what information should be conveyed to the patient regarding the product.

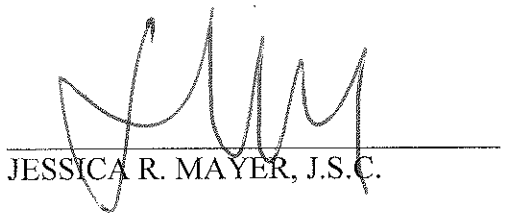
Finally, the complexity inherent in surgical procedures favors application of the LID to AlloDerm®. It is well settled in New Jersey that "[b]ecause prescription drugs are often complex in formula and effect, the physician is in the best position to take into account the propensities of the drug and the susceptibilities of the patient, and to give a highly individualized warning to the ultimate user based on the physician's specialized knowledge." Spychala, supra, 705 F. Supp. 1031–32; see also Perez, supra, 161 N.J. at 35 ("Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of [the] patient. . . . The choice [the physician] makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative." (quoting Reyes v. Wyeth Labs., Inc., 498 F.2d 1264, 1276 (5th Cir.), cert. denied, 419 U.S. 1096 (1974) (alteration in original))).

This legal reasoning is applicable to AlloDerm®. According to the deposition testimony of Plaintiffs' treating doctor in this case, a physician choosing to implant AlloDerm® must consider a number of factors such as the patient's medical history and comorbidities, the type of procedure undertaken, and the specific surgical techniques employed. (Field Cert., Ex. A, Deposition of Dr. Gerardo M. Garcia, at 48:17-49:24, 101:9-110:9). Thus, the court finds in this case that "the physician is in the best position to take into account the propensities" of AlloDerm® and "the susceptibilities of the patient, and to give a highly individualized warning to the ultimate user based on the physician's specialized knowledge." Spychala, supra, 705 F. Supp.1031–32.

In sum, the court finds that the rationales favoring application of the LID are present in this case and apply to AlloDerm®.

## V. Conclusion

For the foregoing reasons, Plaintiffs' motion for partial summary judgment is DENIED. Defendant's motion for partial summary judgment applying that the learned intermediary doctrine is GRANTED.



JESSICA R. MAYER, J.S.C.

Dated: May 8, 2015