SUPREME COURT OF NEW JERSEY

IN RE: ACCUTANE® LITIGATION	DOCKET NO.: 079933 ON PETITION FOR CERTIFICATION FROM SUPERIOR COURT OF NEW JERSEY, APPELLATE DIVISION Docket Nos.: A-4760-14T1 A-0164-15T1 Sat Below: Hon. Clarkson S. Fisher, Jr. Hon. Mitchel E. Ostrer Hon. Scott J. Moynihan On Appeal From: Superior Court of New Jersey Law Division, Atlantic County Case No. 271 Sat Below: Hon. Nelson C. Johnson, J.S.C. CIVIL ACTION

AMICUS CURIAE HEALTHCARE INSTITUTE OF NEW JERSEY'S BRIEF IN SUPPORT OF PETITION FOR CERTIFICATION OF DEFENDANTS-PETITIONERS HOFFMANN-LA ROCHE INC. AND ROCHE LABORATORIES INC.

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PRELIMINARY STATEMENT

Amicus curiae HealthCare Institute of New Jersey (HINJ) respectfully submits this brief to emphasize the serious ramifications that New Jersey's life sciences industry would suffer if the Appellate Division's decision remains in place. The life sciences industry impacts New Jersey's economy and welfare like few others. As of 2015, the life sciences industry employed nearly 117,000 people, or 3.6% of all private-sector workers in the State. Those workers earned over $16.9 billion in wages: 8.2% of New Jersey's total wages - good, high-paying jobs. See N.J. Department of Labor & Workforce Development, Quarterly Census of Employment and Wages, 2010-2015 Annual Averages, https://lwd.state.nj.us/labor/lpa/pub/empecon/biopharma.pdf, last visited August 31, 2017.

New Jersey's life sciences companies' strong interest in the fair and reasonable application of the law is at its greatest when erroneous judicial decisions chip away at the very laws put in place to protect and foster the industry's crucial innovations. That is the situation presented in this appeal, because the Appellate Division's decision relegates FDA approval of a drug's warnings to just another fact for the jury to consider in a failure-to-warn case, as opposed to the statutory "super-presumption" of adequacy that the Legislature established and courts have applied.

New Jersey's Product Liability Act (PLA) was enacted in response to excessive exposure to liability that unduly burdened manufacturers and threatened the development of prescription medical devices and drugs. See Dreier, Keefe & Katz, New Jersey Products Liability and Toxic Torts Law at xvi (Gann 2017). Permitting plaintiffs to prosecute claims any time they can present an expert who prefers a warning using slightly different language would result in a sweeping expansion of prescription drug product liability. The issues presented in this appeal go far beyond the FDA-approved label for Accutane. The erroneous decision of the Appellate Division upends and effectively nullifies the clear requirements of the PLA, and deviates from numerous cases that have granted summary judgment to pharmaceutical defendants under the PLA's standards. The Appellate Division's interpretation of the law contravenes explicit statutory requirements and nullifies protections afforded to pharmaceutical and device manufacturers, subjecting life sciences companies to potentially never-ending and scientifically questionable product liability claims.

To this point, approximately 15 multicounty litigations (MCLs) involving prescription drugs or medical devices are currently pending in New Jersey.[1] Those MCLs involve tens of

[1] See http://www.njcourts.gov/attorneys/mcl/index.html, last visited on August 31, 2017.

thousands of plaintiffs, the vast majority of whom are - as in this case - residents of states other than New Jersey. The instant decision potentially affects each and every one of those cases. It also cannot be ignored that, in light of a recent specific-jurisdiction decision by the Supreme Court of the United States, even more out-of-state plaintiffs are likely to flood New Jersey's MCL system with lawsuits with no connection to this state beyond a defendant's corporate presence. See Bristol-Myers Squibb Co. v. Sup. Ct. of Cal., 137 S. Ct. 1773 (2017) (holding that states lack specific jurisdiction over non-resident pharmaceutical companies in cases alleging injuries sustained in other states).

The Appellate Division's decision conflicts with this Court's repeated instruction that "compliance with FDA standards should be virtually dispositive," this Court's recognition that New Jersey has a limited interest in permitting product liability claims against drug manufacturers, and the Legislature's intent to "re-balance the law 'in favor of manufacturers'" and to "reduc[e] the burden placed on them by product liability litigation." Rowe v. Hoffman La-Roche, 189 N.J. 615, 623, 626 (2007).

The PLA expressly presumes that Accutane's warning is adequate because it is FDA-approved - a presumption heretofore subject to rebuttal only by narrow categories of evidence.

Overlooking the PLA's presumption and the absence of the evidence needed to overcome it, the Appellate Division reversed the trial court's sound conclusion and reduced the statutory presumption to nothing more than the general "reasonable inference" standard of Brill v. Guardian Life Insurance Co. of America, 142 N.J. 520 (1995). If the panel's decision stands, the PLA's legislative requirements, and precedent applying them, will lose their significance. As a practical matter, that decision would subordinate the exhaustive scientific work and billions of dollars devoted to obtaining FDA approval of a medicine and its warnings, in favor of a plaintiff's hired expert's opinion on the semantics of the warning.

Plaintiffs therefore cannot be permitted to survive summary judgment merely by criticizing the very language approved by the FDA, and protected by the PLA, when there is no substantial or compelling evidence that a defendant either: (1) deliberately concealed or (2) deliberately manipulated information relevant to the FDA's approval. That is the law of New Jersey, as prescribed by the Legislature and applied by this Court. The Appellate Division's decision not only conflicts with that law, but also risks serious harm to New Jersey's vital life sciences industry.

STATEMENT OF INTEREST

HINJ was granted leave to appear as amicus curiae when this matter was before the Appellate Division, and therefore submits

this amicus curiae brief in support of Defendants-Petitioners Hoffman-La Roche Inc. and Roche Laboratories Inc.'s ("Roche") Petition for Certification pursuant to Rule 1:13-9(d)(3). HINJ respectfully submits this brief to address the harm that would be visited on New Jersey's life sciences industry if the Appellate Division's decision remains in place.

HINJ is a 20-year-old organization comprised of 27 of New Jersey's leading research-based pharmaceutical and medical technology manufacturers.[2] HINJ's purpose is to speak for New Jersey's life sciences industry and to raise awareness of the significant impact that industry has on New Jersey's citizens' economic well-being and quality of life. HINJ also strives to increase public support for New Jersey's research-based pharmaceutical and medical technology industry by increasing awareness and understanding of the industry's importance among New Jersey's elected and appointed officials, media, citizens, and opinion leaders. HINJ also seeks to advance the development and implementation of sound public health and business policies that further the interests of New Jersey, its people, and its research-based life sciences industry. A list of HINJ's 27 member organizations is available at http://hinj.org/about-hinj/hinj-member-companies/.

[2] At the time of the filing of HINJ's Appellate Division amicus curiae brief, HINJ consisted of 24 such companies.

PROCEDURAL HISTORY

HINJ adopts the Procedural History set forth in Roche's Petition for Certification.

ARGUMENT

A. The PLA's Super-Presumption of Adequacy Reflects Sound Public Policy by Appropriately Deferring to the FDA's Expertise and Fostering Innovation in the Life Sciences Community.

The PLA in general, and the super-presumption of adequacy it ascribes to FDA-approved warnings in particular, are a reflection of the Legislature's well-founded deference to the FDA's scientific and safety-related judgments. The Legislature recognized in enacting the PLA that state law failure-to-warn lawsuits present pharmaceutical companies with a myriad of difficulties. See In re: Reglan Litig., 226 N.J. 315, 335 (2016); see also Horn v. Thoratec Corp., 376 F.3d 163, 178 (3d Cir. 2004) (observing that "[s]tate common law tort actions threaten the statutory framework for the regulation of medical devices, particularly with regard to FDA's review and approval of product labeling," and especially because such "actions are not characterized by centralized expert evaluation of device regulatory issues," but rather by encouraging and requiring "lay judges and juries to second-guess the balancing of benefits and risks . . . - the central role of FDA - sometimes on behalf of a single individual or group of individuals"). Absent the application of the PLA's presumption of adequacy for FDA-

approved labeling, pharmaceutical and medical device companies can be subjected to liability based on varying standards, with no benchmark that they should follow, creating the risk of inconsistent results involving the same warning.

Empirical data validate the Legislature's concerns about the impact of product liability lawsuits on prescription drug labeling. For example, a study by Harris Interactive, Inc. found that physicians and pharmacists believe that prescription drug labeling is more complicated than necessary, with product liability litigation viewed as a central factor contributing to the unnecessary complexity. Pharmaceutical Liability Study Report on Findings, Harris Interactive, Inc. (July 15, 2003), available at www.instituteforlegalreform.com/resources/PharmaceuticalLiabilityStudy_report.pdf, last visited August 31, 2017. In particular, 74% of the physicians surveyed and 51% of the pharmacists thought that prescription drug labeling was more complicated than necessary, with 91% of those physicians and 97% of those pharmacists believing that product liability litigation was a primary factor in the complexity. Id. at 20, 31. Those concerns carry particular force in the context of this case, in which the plaintiffs challenge a range of carefully crafted and FDA-approved warning tools that expressly warned about the very condition at issue (as opposed to a simple challenge to the absence of any warning).

The federal authorities mandating the exhaustive FDA approval process address those concerns and justify the PLA's deference to the FDA's judgments concerning the adequacy of warnings. Among the information that must be included with a prescription drug is a description of "serious adverse reactions and potential safety hazards" that reliable scientific evidence indicates are associated with use of the drug. 21 C.F.R. §§ 201.56(a), (c), 201.57(c), (e); 21 C.F.R. § 314.50(d)(5)(viii) (reflecting FDA's direct involvement in balancing the benefits and risks of a drug's labeling); see also Bailey v. Wyeth, 424 N.J. Super. 278, 288-91 (Law Div. 2008) (discussing FDA requirements that manufacturers demonstrate safety, effectiveness, and communication of warnings that adequately disclose risks and benefits), aff'd sub nom., Deboard v. Wyeth, Inc., 422 N.J. Super. 360, 362 (App. Div. 2011) (adopting "well-considered and exhaustive" Law Division reasoning).

Any New Drug Application (NDA) must include "reports of investigation into the safety and effectiveness of the drug, the components and production methods used in the drug's manufacturing, and copies of draft labeling proposed by the manufacturer for the drug." Bailey, 424 N.J. Super. at 288. The labeling must summarize "the essential scientific information needed for safe and effective use of the drug" and disclose "potential safety hazards associated with use of the drug," and

the FDA often determines final language for a label only after "several versions" are exchanged between the FDA and the manufacturer. Id. at 289-90 (citations and internal quotation marks omitted).

In short, extensive and thorough expert review of the science and safety data precedes the FDA's approval of any new medicine. FDA-approved labeling reflects "the preeminent role of federal regulation of drugs and medical devices," Cornett v. Johnson & Johnson, 211 N.J. 362, 387 (2012), and the FDA's expert judgment about what information must be included in a drug's labeling.[3] That approval is by no means automatic or inevitable; rather, the "FDA will not grant approval of a NDA unless the drug is shown to be safe and effective." Id. at 288. Even after approval, the FDA maintains significant control over any proposed

[3] The FDA will not approve a drug if its "labeling is false or misleading in any particular." 21 U.S.C. § 355(d)(7). Even after a drug has been approved, a drug will be deemed misbranded if the "labeling is false or misleading in any particular" and the FDA may withdraw approval of that drug. See id. §§ 331(b) (prohibition on misbranding), 355(e)(3) (withdrawal authority), 352(a), (f), (j) (definition of misbranding), 332 (injunction proceedings), 333(a) (criminal prosecutions), 334 (seizure). Furthermore, the FDA may withdraw approval of a drug if the manufacturer disregards its obligation to submit periodic reports notifying the FDA of adverse drug experiences and other new information that might affect the drug labeling. 21 C.F.R. §§ 314.80(c), (j), 314.81(b)(2)(i), (d). FDA regulations detail the information that must be included in the warnings section of drug labeling and instruct that such "labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug." Id. § 201.57(e) (2003); id. § 201.80(e) (2007).

changes to the label, which, except in rare circumstances, must be "first submitted to the FDA for approval." Id. at 290 (citing 21 C.F.R. 314.70(a)-(d)).

The record in this case provides a striking illustration of the thorough role played by the FDA, with the agency singling out Accutane for "the level of involvement by the [FDA] and [the] sponsor in ensuring [its] safe use." See Sept. 18, 2000 FDA Advisory Comm. Tr. at 15:19-25. It also stands as a striking reminder of the PLA's and this Court's wisdom in deferring to that process to protect innovators in lawsuits challenging the language of FDA-approved warnings. See Perez v. Wyeth Labs. Inc., 161 N.J. 1, 24 (1999) ("FDA regulations serve as compelling evidence that a manufacturer satisfied its duty to warn the physician about potentially harmful side effects of its product.").

B. The Appellate Division's Decision Frustrates the Legislature's Express Intent to Lessen the Burden on New Jersey's Life Sciences Industry.

If left undisturbed, the panel's decision also would contravene legislative policy designed to protect New Jersey's life sciences industry. When the PLA was enacted, "the Legislature carefully balanced the need to protect individuals against the need to protect an industry with a significant relationship to [New Jersey's] economy and public health," i.e., the pharmaceutical industry. See Rowe, 189 N.J. at 626. The

PLA reflects the Legislature's "intent to limit the expansion of products-liability law." Shackil v. Lederle Labs., 16 N.J. 155, 187 (1989). Courts should be "mindful of the Legislature's policy to limit the liability of manufacturers" and "as a matter of sound judicial policy" are to "apply this conservative legislative policy." Roberts v. Rich Foods, Inc., 139 N.J. 365, 374 (1995) (citation and quotation marks omitted).

Therefore, to ensure that FDA-approved warnings fairly insulate pharmaceutical manufacturers from failure-to-warn liability, the PLA specifically states:

> If 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***.

N.J.S.A. 2A:58C-4 (emphasis added). That provision was "intended . . . to limit the liability of manufacturers so as to balance the interests of the public and the individual with a view towards economic reality." Zaza v. Marquess & Nell, Inc., 144 N.J. 34, 47-48 (1996).

This Court has recognized that policy determination, emphasizing that "when prescription drugs are marketed and labeled in accordance with FDA specifications, the pharmaceutical

manufacturers should not have to confront 'state tort liability premised on theories of design defect or warning inadequacy.'" Perez, 161 N.J. at 21-22 (quoting A Question of Competence: The Judicial Role in the Regulation of Pharmaceuticals, 103 Harv. L. Rev. 773, 773 (1990)).

This Court likewise has held that the PLA's statutory presumption means that "compliance with FDA standards should be virtually dispositive" of a failure-to-warn claim. Perez, 161 N.J. at 24. Through the presumption of adequacy, "[t]he Legislature recognized the important role of the federal regulatory system over prescription drugs." In re: Reglan Litig., 226 N.J. at 335. Indeed, this Court described it as a "super-presumption." Kendall v. Hoffman-La Roche, Inc., 209 N.J. 173, 195 (2012).

In other words, the PLA does not merely erect a "vanish[ing]" presumption that is subject to rebuttal by any manner of evidence (or argument) of warning inadequacy; the evidence must be **compelling and substantial**. Bailey, 424 N.J. Super. at 311-12. This Court and the Appellate Division have identified only two bases for rebutting the statutory presumption: "(i) deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects ('Perez/Rowe exception') or (ii) manipulation of the post-market regulatory process ('McDarby exception')." Id. at 312 (citing Rowe, 189

N.J. at 626; Perez, 161 N.J. at 25; and McDarby v. Merck & Co., Inc., 401 N.J. Super. 10, 63 (App. Div. 2008)); accord Cornett, 211 N.J. at 387-88.[4]

If the binding requirements imposed by the Legislature and this Court are to have any practical effect, the Appellate Division's decision must be overturned. Indeed, the Appellate Division ignored the **substantive** evidence required by the PLA and this Court's precedent, and instead wandered into a discussion about the **quantum** of evidence required to rebut the presumption in conjunction with the "reasonable inference" summary judgment standard. By citing Brill, 142 N.J. at 520, and then affording plaintiffs "all reasonable inferences," the Appellate Division essentially applied the N.J.R.E. 301 standard, whereby a plaintiff can rebut the presumption by showing "some" evidence tending to disprove the presumption. That, however, was

[4] See also Baker v. APP Pharmaceuticals LLP et al., No. 3:09-cv-05725, 2012 WL 3598841 (D.N.J. Aug. 21, 2012) (granting summary judgment for pharmaceutical manufacturer where no sufficient evidence to rebut presumption of adequacy); Dobrovic v. Friedman, 2006 WL 2355136 (App. Div. Aug. 16, 2006) (affirming summary judgment under the PLA absent evidence rebutting the presumption of adequacy); Banner v. Hoffmann-LaRoche Inc. & Roche Laboratories Inc., 383 N.J. Super. 364 (App. Div. 2006) (granting defendants' motion to dismiss); Clark v. Hoffman-La Roche, Inc., 2006 WL 1374516 (Law Div. May 2, 2006) (same); Abramowitz v. Cephalon, Inc., 2006 WL 560639, at *3 (App. Div. Mar. 3, 2006) (granting summary judgment under the PLA where there was "no evidence to suggest that the defendants attempted to hide or suppress" information from the FDA.). In accordance with Rule 1:36-3, copies of all unpublished opinions cited herein are appended to this brief as Addendum A.

incorrect. Bailey, 424 N.J. Super. at 312 (recognizing that "the Court in Perez held that in a failure to warn case, the presumption of adequacy afforded to a manufacturer's compliance with FDA requirements is stronger and of greater evidentiary weight than the customary presumption referenced in N.J.R.E. 301").

The panel's ruling cannot be reconciled with this Court's precedents, which have repeatedly held that "**compliance with FDA standards should be virtually dispositive**" of claims brought under the PLA. Rowe, 189 N.J. at 626 (emphasis added); see also Perez, 161 N.J. at 24 ("[A]ny duty to warn physicians about prescription drug dangers is presumptively met by compliance with federal labeling").

The PLA seeks to "reduce the burden on manufacturers of FDA-approved products resulting from products liability litigation," by according deference to the FDA's labeling expertise. Kendall, 209 N.J. at 195. In fact, far from lessening the burden, the Appellate Division's decision means that potentially hundreds of juries would separately determine whether Accutane's FDA-approved IBD warnings are adequate, presenting the risk of divergent outcomes regarding the same warnings. That says nothing of the burden to be placed on potentially hundreds of other juries and life sciences companies in the other pharmaceutical/medical device MCLs currently pending or that may be filed in New Jersey.

The panel's decision contradicts this Court's decree that "only in the 'rare case[]' will damages be assessed against a manufacturer issuing FDA-approved warnings." Ibid. (quoting Perez, 161 N.J. at 25).

SUMMARY

This Court's intervention is needed because the proper application of the PLA is critically important to New Jersey's life sciences industry, which employs more than 100,000 people, develops countless medicines and devices, and includes thirteen of the world's twenty largest research-based pharmaceutical companies. Furthermore, application of the PLA will affect the nearly 20,000 other pharmaceutical cases pending in New Jersey, and the even greater volume likely to flood New Jersey's MCL system soon,[5] confirming the great public importance of this case.

The purpose and intent of the PLA's presumption of adequacy is clear. Following the decisions in Perez and McDarby, the quality and quantum of evidence needed to overcome that

[5] As noted above, the Supreme Court's recent personal-jurisdiction decision, Bristol-Myers Squibb Co., 137 S. Ct. 1773, almost guarantees an increase in consolidated actions filed against New Jersey-based life sciences companies by out-of-state residents. See SCOTUS Decision in Plavix Litigation Could Lead to a Resurgence in New Jersey Mass Tort Filings (June 23, 2017), available at http://www.masstortslawblog.com/2017/06/scotus-decision-nj-mass-tort-filings/, last visited August 31, 2017.

presumption are clear as well. As the court in Bailey summarized:

> The court recognizes that the conduct of [defendants] cited by plaintiff may have been less than exemplary. However, the actions and/or inactions of the defendants have to be viewed in light of plaintiffs' failure to warn claim and the presumption of adequacy established by our legislature. The plaintiffs have not presented compelling or substantial evidence of the type necessary to rebut the presumption of adequacy.

Bailey, 424 N.J. Super. at 324. The recent decision of the Appellate Division has, however, upended that standard and virtually eliminated the presumption altogether. Under that decision, so long as a plaintiff presents a witness who says certain other information should have been provided to the FDA, the presumption disappears. That is a low hurdle to clear, and is certainly not a "super-presumption" that is "virtually dispositive" of all failure-to-warn claims.

By applying the Brill standard and abandoning the need to determine if the evidence presented was "compelling and substantial," the Appellate Division fundamentally undermined the PLA, and its decision is in direct conflict with this Court's, and its own, earlier authority. The panel's ruling is the antithesis of the Legislature's intent in enacting the PLA, which was "'to establish clear rules with respect to specific matters as to which the decisions of the courts in New Jersey have

created uncertainty.'" Rowe, 189 N.J. at 624 (quoting Senate Judiciary Committee, Statement to Senate Committee Substitute for S.B. No. 2805, at 1 (Mar. 23, 1987)).

In short, the Appellate Division allowed the ipse dixit of a party's expert to overcome the PLA's "virtually dispositive" "super-presumption" that FDA-approved warnings are adequate, by applying the far more lenient summary judgment standard. See Dreier, et al., supra, N.J. Products Liab. & Toxic Tort Law, 15:4 at 469 (observing that "[t]he statutory presumption under Perez is . . . much stronger than the typical presumption, which 'disappears' from the case in the face of a sufficient quantum of contrary evidence"). This Court must correct that error and ensure interpretation of the PLA in a manner consistent with the Legislature's goal of fostering innovation and protecting manufacturers who develop and market medicines in accordance with the exhaustive, science-based FDA approval process.

CONCLUSION

For the foregoing reasons, this Court should grant the Petition and reverse the decision of the Appellate Division.

Respectfully submitted,

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ADDENDUM A

(Unpublished opinions)

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NOT FOR PUBLICATION
United States District Court,
D. New Jersey.

Evangeline BAKER et al., Plaintiffs,
v.
APP PHARMACEUTICALS LLP et al., Defendants.

Civil Action No. 09–05725 (JAP).
|
Aug. 21, 2012.

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MEMORANDUM OPINION

PISANO, District Judge.

*1 This matter comes before the Court upon a Motion for Summary Judgment by defendant [1] Baxter Healthcare Corporation ("Baxter" or "Defendant") to dismiss Counts I, II, and VIII of plaintiffs Evangeline Baker ("Mrs.Baker") and Bruce Baker's (collectively "Plaintiffs") First Amended Complaint. (DE 74.) Plaintiffs oppose the Motion. (DE 82.) The Court has considered the parties' submissions and decided the matter without oral argument pursuant to Federal Rule of Civil Procedure 78. For the reasons set forth below, the Court will grant the Motion for Summary Judgment.

I. BACKGROUND

Mrs. Baker visited her primary care doctor complaining of chest pain on September 4, 2007. (Defendant's Statement of Undisputed Material Fact ("Def.SUMF") ¶ 27; DE 74–2.) Mrs. Baker was taken by ambulance to the Hunterdon Medical Center Emergency Room where a cardiac catheterization procedure revealed she had severe coronary artery disease. (*Id.* ¶ 28.) Mrs. Baker was thereafter transferred to Morristown Memorial Hospital, and Dr. James Slater, a cardiac surgeon, performed a triple coronary bypass on Mrs. Baker on September 5, 2007. (*Id.* ¶ 4.)

During her hospital stay, Mrs. Baker was administered the commonly prescribed drug heparin. (*Id.* ¶ 31.) Heparin is an anticoagulant that prevents blood clots. (*Id.* ¶ 4.) But the drug is known to cause heparin induced thrombocytopenia ("HIT"), or low blood platelet count. (*Id.* ¶ 6.) HIT is an allergic reaction, which begins when antibodies attack heparin molecules bound to platelet factor 4 protein. (Plaintiffs' Counter Statement of Material Facts ("Pls.SUMF") ¶ 8; DE 81.) HIT may progress to a more serious adverse reaction called heparin induced thrombocytopenia and thrombosis ("HITT"). (*Id.*) HITT occurs when heparin antibodies activate blood platelets, which in turn cause blood clots. (*Id.*) HITT can lead to, among other things, deep vein thrombosis, stroke, heart attack, gangrene of the extremities, and possibly death. (Def. SUMF ¶ 22.)

Mrs. Baker received heparin during and after her surgery. [2] Dr. Slater administered a heparin drip during Mrs. Baker's coronary artery bypass surgery on September 5, 2007, (Pls. SUMF ¶ 13), and intravenous heparin flushes during the two days after surgery, (Def. SUMF ¶ 32). Mrs. Baker developed atrial fibrillation (a cardiac arrhythmia) on September 7th, and so heparin was reinitiated by Dr. Slater on September 11th and continued through September 14th. [3] (*Id.* ¶¶ 33, 34.) On September 11th, Mrs. Baker's platelet count was measured to be 279,000/mm ^{3}, which is normal. (Pls. SUMF ¶ 14.) However, by September 15th, her platelet count was down to 45,000/mm ^{3}, alerting Mrs. Baker's physicians to the possibility of HIT. (*Id.* ¶¶ 14, 16.) Indeed, an HIT study confirmed that Mrs. Baker was positive for heparin antibodies. (Def. SUMF ¶ 37.) It is not known, however, at what point between September 11th and September 15th that Mrs. Baker's platelet count reached thrombocytopenic levels. (*Id.* ¶ 46; Pls. RSUMF ¶ 46 .) That is because no one measured Mrs. Baker's platelet level during this time period, despite the hospital's stated protocol to monitor a patient's platelet count every three days in order to detect HIT. (Def. SUMF ¶¶ 41, 42, 44.)

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*2 Over the next several weeks, Mrs. Baker developed blood clots and gangrene in her left leg, confirming a clinical diagnosis of HITT. (Pls. SUMF ¶¶ 17, 18.) She required a partial amputation of her left foot in November 2007 and amputation of her left leg below the knee in February 2008. (*Id.* ¶ 19.) Plaintiffs thereafter sued several manufacturers of heparin, including Baxter, asserting various product liability claims.[4] Plaintiffs allege that Baxter, the only heparin manufacturer remaining in the action, was aware of but failed to adequately warn of the serious side-effects associated with heparin use.

Defendant's heparin was first approved by the United States Food and Drug Administration ("FDA") forty years ago. (Def. SUMF ¶ 5 .) Before the FDA approves a drug, the manufacturer must show that the drug is safe and effective for its intended use. *See* 21 U.S .C. § 355. To do so, the manufacturer submits a new drug application ("NDA"), which includes, among other things, clinical trial data, a risk-benefit analysis, and proposed labeling. *See* 21 C.F.R. 314.50. Prescription drug labeling must "contain a summary of the essential scientific information needed for the safe and effective use of the drug." 21 C.F.R. 210.56(a)(1). The FDA has the authority to enforce its labeling requirements, and may go so far as to withdraw approval for the drug if the drug's labeling is false, misleading, and/or contains inadequate warnings. *See* 21 U.S.C. § 352(a), (f); 21 U.S.C. § 355(e).

The parties agree that Defendant's heparin has always contained FDA-approved labeling, including risk disclosures and warnings. (Def. SUMF ¶ 5; Pls. RSUMF ¶ 5.) In 2001, the heparin label disclosed the risk of HIT and HITT in the "Precautions" section. (*See* Def. Ex. 3 to Miller Decl.; DE 74–7.) In 2005, Defendant submitted a supplemental NDA via the "changes being effected" process to include additional HIT and HITT information the "Warnings" section of its heparin labeling. *See* 21 C.F.R. 314.70. The FDA suggested several alterations, all of which Defendant incorporated into the labeling, and the FDA found the updated labeling "acceptable" in June 2007. (*See* Def. Ex. 7 to Miller Decl.; DE 74–12.) That labeling, the same labeling found on the heparin administered to Mrs. Baker, stated in the "Warnings" section:

> *Thrombocytopenia*
>
> Thrombocytopenia has been reported to occur in patients receiving heparin with a reported incidence of up to 30%. Platelet counts should be obtained at baseline and periodically during heparin administration ....
>
> *Heparin-induced Thrombocytopenia (HIT) and Heparin-induced Thrombocytopenia Thrombosis (HITT)*
>
> Heparin-induced Thrombocytopenia (HIT) is a serious antibody mediated reaction resulting from irreversible aggregation of platelets. HIT may progress to the development of venous and arterial thromboses, a condition referred to as Heparin-induced Thrombocytopenia and Thrombosis (HITT). Thrombotic events may also be the initial presentation for HITT. These serious thromboembolic events include deep vein thrombosis, pulmonary embolism, cerebral vein thrombosis, limb ischemia, stroke, myocardial infarction, mesenteric thrombosis, renal arterial thrombosis, skin necrosis, gangrene of the extremities that may lead to amputation, and possibly death. Thrombocytopenia of any degree should be monitored closely. If the platelet count falls below 100,000/mm ^{3} or if recurrent thrombosis develops, the heparin product should be promptly discontinued and alternative anticoagulants considered, if patients require continued anticoagulation.

*3 (*See* Def. Ex. 6 to Miller Decl. at 5; DE 74–11.)

Plaintiffs claim that this labeling was inadequate and caused Mrs. Baker's injuries. In particular, Plaintiffs allege that Baxter's heparin product failed to warn of the dangers of heparin administration (Count I) and was defective in design because it did not have an adequate warning label (Count II). (*See* First Am. Compl.; DE 18.) In addition, Plaintiff Bruce Baker alleges loss of consortium resulting from his wife's injuries (Count VIII). (*Id.*) Defendant moved for summary judgment dismissing Counts I, II, and VIII on May 11, 2012. (DE 74.) Plaintiffs filed a brief in opposition on June 19, 2012. (DE 79, 82.) On July 9, 2012, Defendant filed a reply brief in further support of its Motion for Summary Judgment. (DE 86.)

II. STANDARD OF REVIEW

A court shall grant summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter

of law." Fed.R.Civ.P. 56(a). The substantive law identifies which facts are critical or "material." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). A material fact raises a "genuine" issue "if the evidence is such that a reasonable jury could return a verdict" for the non-moving party. *Healy v. N. Y. Life Ins. Co.*, 860 F.2d 1209, 1219 n. 3 (3d Cir.1988).

On a summary judgment motion, the moving party must show, first, that no genuine issue of material fact exists. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). If the moving party makes this showing, the burden shifts to the non-moving party to present evidence that a genuine fact issue compels a trial. *Id.* at 324. The non-moving party must then offer admissible evidence that establishes a genuine issue of material fact, *id.*, not just "some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986). However, "a party who does not have the trial burden of production may rely on a showing that a party who does have the trial burden cannot produce admissible evidence to carry its burden as to the fact." *Celotex Corp.*, 477 U.S. at 323.

The Court must consider all facts and their logical inferences in the light most favorable to the non-moving party. *Pollack v. American Tel. & Tel. Long Lines*, 794 F.2d 860, 864 (3d Cir.1986). The Court shall not "weigh the evidence and determine the truth of the matter," but need determine only whether a genuine issue necessitates a trial. *Anderson*, 477 U.S. at 249. If the non-moving party fails to demonstrate proof beyond a "mere scintilla" of evidence that a genuine issue of material fact exists, then the Court must grant summary judgment. *Big Apple BMW v. BMW of N. Am.*, 974 F.2d 1358, 1363 (3d Cir.1992).

III. LEGAL STANDARD AND ANALYSIS

This is a diversity action, over which the Court has jurisdiction pursuant to 28 U.S.C. § 1332. (*See* First Am. Compl. ¶¶ 1, 2, 4.) It is well established that a federal court sitting in diversity must apply the substantive law of the state whose law governs the action. *Erie R. Co. v. Tompkins*, 304 U.S. 64, 78, 58 S.Ct. 817, 82 L.Ed. 1188 (1938); *Griggs v. Bic Corp.*, 981 F.2d 1429, 1431–32 (3d Cir.1992). Here, the parties agree that the substantive law of New Jersey applies to all claims in this litigation.

***4** In New Jersey, product liability actions are governed by the New Jersey Products Liability Act ("PLA"). N.J. Stat. Ann. § 2A:58C–1, et seq. The New Jersey Legislature enacted the PLA based on an "urgent need for remedial legislation to establish clear rules with respect to certain matters relating to actions for damages for harm caused by products." *Id.* § 2A:58C–1(a). In so doing, "[t]he Legislature intended ... to limit the liability of manufacturers so as to balance [ ] the interests of the public and the individual with a view towards economic reality." *Zaza v. Marquess & Nell, Inc.*, 144 N.J. 34, 675 A.2d 620, 627 (N.J.1996). The New Jersey Supreme Court has observed that "[t]he language chosen by the Legislature in enacting the PLA is both expansive and inclusive, encompassing virtually all possible causes of action relating to harms caused by consumer and other products." *In re Lead Paint Litigation*, 191 N.J. 405, 924 A.2d 484, 503 (N.J.2007).

A. Failure to Warn

In Counts I and II of their First Amended Complaint, Plaintiffs allege one of the causes of action covered by the PLA—failure to warn. The PLA provides that a manufacturer is "not liable for harm caused by a failure to warn if the product contains an adequate warning or instruction ...." N.J. Stat. Ann. 2A:58C–4. An "adequate" warning 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 prescribing physician. *Id.*

1. Presumption of Adequacy for Prescription Drug Labels

In failure to warn cases involving prescription drugs, "[i]f the warning or instruction given in connection with a drug ... has been approved or prescribed by the federal Food and Drug Administration under the 'Federal Food, Drug, and Cosmetic Act,' " there is a rebuttable presumption that the warning is adequate. *Id.* This is no ordinary rebuttable presumption. "Compliance with FDA regulations" gives rise to "what can be denominated as a super-presumption [.]" *Kendall v. Hoffman–La Roche, Inc.*, 209 N.J. 173, 36 A.3d 541, 544 (N.J.2012); *see also Perez v. Wyeth Labs., Inc.*, 161 N.J. 1, 734 A.2d 1245, 1259 (N.J.1999) ("[C]ompliance with FDA standards should be virtually dispositive of such

claims."). Indeed, the PLA's presumption that an FDA-approved prescription drug label is adequate "is stronger and of greater evidentiary weight than the customary presumption referenced in [New Jersey Rule of Evidence] 301." *Bailey v. Wyeth, Inc.*, 424 N.J.Super. 278, 37 A.3d 549, 571 (N.J.Super. Ct. Law Div.2008), aff'd sub nom. *Deboard v. Wyeth,* 422 N.J.Super. 360, 28 A.3d 1245 (N.J.Super.Ct.App.Div.2011).

In this case, there is no dispute that Defendant's heparin labeling was approved by the FDA. (*See* Def. SUMF ¶ 5; Pls. RSUMF ¶ 5.) In 2005, Baxter submitted updated labeling for its heparin products. The FDA suggested several alterations, which Baxter incorporated, and in June 2007, the FDA found the labeling acceptable. Therefore, Defendant is entitled to the statutory presumption that its heparin labeling satisfied its duty to warn.

2. Rebutting the Presumption of Adequacy

***5** Plaintiffs can rebut the "super-presumption" with evidence of "intentional misconduct by the manufacturer." *Bailey,* 424 N.J.Super. 278, 37 A.3d at 569. First, a plaintiff may introduce evidence of "deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects" by the pharmaceutical company, (the "*Perez* exception"). *Perez,* 734 A.2d at 1259. Second, a plaintiff may introduce substantial evidence of "economically-driven manipulation of the post-market regulatory process," (the "*McDarby* exception"). *McDarby v. Merck & Co., Inc.,* 401 N.J.Super. 10, 949 A.2d 223, 256 (N.J.Super.Ct.App.Div.2008).

a. The Perez Exception

Plaintiffs argue that the *Perez* exception applies here to rebut the presumption of adequacy because Defendant failed to disclose relevant information to the FDA when Defendant sought to alter the label in 2005. According to Plaintiffs, had Defendant supplied such information to the FDA, the label would have contained warnings that would have prevented Mrs. Baker's injuries. In particular, Plaintiffs conclude that Defendant failed to disclose the following:

> (1) most HIT cases (approximately 70%) present where heparin is re-administered 4–10 days after initial heparin exposure;
>
> (2) there is an increased risk of HIT between days 4 to 14 of administration;
>
> (3) surgical patients and those in critical care units are much more likely to develop HIT; [5]
>
> (4) platelet counts should be performed prior to initiating heparin therapy; [6]
>
> (5) platelet counts should be monitored at least every other day between 4 and 14 days after initial exposure to heparin in postoperative patients receiving unfractionated [7] heparin; and
>
> (6) low molecular weight heparin has less propensity to cause HIT in comparison to unfractionated heparin.

(Pls. Br. at 16; DE 82.)

The Court finds that Plaintiffs have failed to demonstrate how these six principles raise a genuine fact issue necessitating a trial. First, Plaintiffs present no evidence that Defendant intentionally withheld or concealed this information. Significantly, all of the information Plaintiffs accuse Defendant of withholding was publicly available in published scientific and medical literature. *See Bailey,* 424 N.J.Super. 278, 37 A.3d at 577 (noting the lack of intent to conceal risks where those risks were included in the worldwide medical literature); *see also Chambers v. G.D. Searle & Co.,* 441 F.Supp. 377, 384 (D.Md.1977) (directed verdict granted in favor of the defendant drug manufacturer where "[t]here was no other information available to defendant indicating greater risks or dangers than what was" reviewed by the FDA). Plaintiffs therefore cannot demonstrate intentional concealment or nondisclosure by pointing only to information that was widely available to the scientific and medical community.

The second problem with Plaintiffs' argument is that Defendant did in fact disclose much of what Plaintiffs claim was deliberately concealed or withheld. When submitting its proposed updated label to the FDA in 2005, Baxter included several scientific articles and a number of adverse event reports relating to HIT and HITT. Each article that Defendant submitted discusses HIT/HITT in seriously ill patients and/or patients having undergone surgery, including cardiac surgery. [8] (*See* Def. Ex. 4 pt. 2 to Miller Decl. at 27–31; DE 74–9.) Three of the articles submitted by Baxter to the FDA

discuss thrombocytopenia and/or subsequent thrombosis in patients re-exposed to heparin. (*Id.* at 30–31.)

*6 In fact, in their submission to the FDA, Baxter cited and summarized one of the articles that Plaintiffs accuse Defendant of failing to disclose. (*Cf.* Pls. Ex. L to Poondi Decl., *with* Def. Ex. 4 pt. 2 to Miller Decl. at 27–28.) That article explains that "patients typically develop thrombocytopenia while receiving heparin; the peak onset is 5 to 8 days." (Pls. Ex. L to Poondi Decl. at 502.) The article also states that "[l]ow-molecular weight heparin causes immune thrombocytopenia less often than unfractionated heparin ...." (*Id.* at 505.)

With respect to platelet monitoring, Plaintiffs argue that Defendant failed to disclose the need for platelet measurement every other day. Plaintiffs, in support, point only to two scientific journal articles, the first of which recommends a patient's platelet count be monitored "every other day," and the second of which simply recommends "routine" platelet monitoring. (Pls. Exs. U and V to Poondi Decl.; DE 82–22, 82–23.) Consequently, the available research does not provide a clear-cut rule concerning at what intervals platelet counts should be measured, and Defendant's heparin label takes this into account by instructing that "Platelet counts should be obtained ... periodically during heparin administration" and that "[t]hrombocytopenia of any degree should be monitored closely." (Def. Ex. 6 to Miller Decl. at 5.)

In view of the above, Plaintiffs have failed to present sufficient evidence to prove that Baxter engaged in intentional misconduct. No reasonable fact-finder could conclude that Defendant deliberately concealed or failed to disclose information relating to the serious side-effects of heparin, when, in reality, that information was publicly known in the medical and scientific literature. Further, Plaintiffs cannot preclude summary judgment on the issue of concealment or nondisclosure where the record evidence demonstrates that Defendant did in fact disclose much of the information regarding the risks, diagnosis, and treatment of HIT and HITT that Plaintiffs claim was intentionally kept hidden. The Court therefore finds that, as a matter of law, Plaintiffs have failed to rebut the strong presumption of adequacy with the type of evidence contemplated by the *Perez* exception.

b. The *McDarby* Exception

Plaintiffs next assert that Defendant is not entitled to the statutory presumption of adequacy because Defendant engaged in "economically-driven manipulation of the post-market regulatory process." *See McDarby,* 949 A.2d at 256. The significance of the *McDarby* exception is not immediately obvious until put in context. The case that created the exception, *McDarby v. Merck & Co., Inc.,* was part of the fallout from the widely-prescribed drug, Vioxx. *Id.* at 229. The *McDarby* court found that Merck & Co., the manufacturer of Vioxx, was not entitled to the PLA's presumption of adequacy because, after the drug was approved and on the market, the company downplayed a known cardiovascular risk associated with Vioxx, misrepresented the results of Vioxx clinical studies, resisted a stronger warning label proposed by the FDA, and actively sought to conceal Vioxx's cardiovascular risks from physicians. *Id.* at 259.

*7 Here, Plaintiffs argue that Defendant engaged in economically-driven manipulation of the post-market regulation of heparin. (Pls. Br. at 17–18.) But in support, Plaintiffs do not offer any evidence of the type considered in *McDarby;* in other words, Plaintiffs offer no evidence that Baxter rejected the FDA's proposed changes to heparin labeling, asked pharmaceutical representatives to avoid discussing HIT and HITT when speaking to physicians, or manipulated the conclusions of heparin clinical trials. Instead, Plaintiffs only cite to an August 22, 2008 Power Point presentation prepared by the Baxter Healthcare Pharmacy Advisory Board, which is co-chaired by two non-Baxter employees. (*See* Pls. Ex. CC to Poondi Decl. at 1–2; DE 82–30.) The purpose of the presentation was to get advice and feedback on Baxter's drug, argatroban, an anticoagulant indicated for the treatment of thrombosis in patients with HIT.[9] (*See id.* at 53, 949 A.2d 223.) As such, the presentation contains extensive information on the causes, diagnosis, and treatment of HIT. (*See id.* at 21–50, 949 A.2d 223.) Notwithstanding the educational purpose of providing this information, Plaintiffs call the presentation a "marketing campaign," and they ask the Court to infer that Baxter "hid the truth about the dangers of heparin for purposes of profit, only opting to disclose such information when it could profit from another drug [.]" (Pls. Br. at 6, 18.)

The Court will not consider this presentation as evidence properly supporting application of the *McDarby* exception, or draw an inference of egregious intentional

misconduct from it. To begin, the presentation is dated August 22, 2008, whereas Mrs. Baker's treatment with heparin was almost a year earlier in September 2007. Plaintiffs, however, cannot satisfy the *McDarby* exception with "documents concerning drugs other than [heparin] and instances of conduct by [Defendant] that occurred long after" Mrs. Baker received heparin. *See Bailey,* 424 N.J.Super. 278, 37 A.3d at 577.

Further, the Court cannot accept the conclusion that Plaintiffs have drawn from this presentation. The HIT/HITT-related information contained in the presentation was compiled and communicated not by a Baxter employee, but by a professor of clinical pharmacy at the Philadelphia College of Pharmacy. (*See* Pls. Ex. CC to Poondi Decl. at 21.) Further, the focus of the presentation, argatroban, had not been (and is still not) approved by the FDA such that Baxter could profit from it. It is therefore unreasonable to make the inferential leap that Baxter sought to profit from an unapproved drug with a strategically timed disclosure of the dangers of heparin. *See Lexington Ins. Co. v. W. Pa. Hosp.,* 423 F.3d 318, 333 (3d. Cir.2005) ("Speculation does not create a genuine issue of fact; instead, it creates a false issue, the demolition of which is a primary goal of summary judgment.") (quoting *Hedberg v. Indiana Bell Tel. Co., Inc.,* 47 F.3d 928, 932 (7th Cir.1995). The Court thus finds that Plaintiffs have failed to rebut the presumption of adequacy with substantial evidence of economically-driven manipulation of the post-market regulatory process.

***8** In sum, Plaintiffs have failed to meet their burden of coming forth with sufficient evidence to rebut the "super-presumption" of adequacy afforded to Baxter's FDA-approved heparin labeling. Pursuant to the PLA, Baxter therefore cannot be held liable for a claim of failure to warn, see N.J. Stat. Ann. 2C:58C–4, and summary judgment dismissing Counts I, II, and VIII [10] is appropriate.

B. Causation

Even if a plaintiff is able to demonstrate that a prescription drug's warning is inadequate, that plaintiff still must prove that the inadequate warning proximately caused her injury. *See Campos v. Firestone Tire & Rubber Co.,* 98 N.J. 198, 485 A.2d 305, 311 (N.J.1984). "To satisfy this burden, [a] plaintiff must show that adequate warnings would have altered her doctors' decision to prescribe [the drug]." *Strumph v. Schering Corp.,* 256 N.J.Super. 309, 606 A.2d 1140 (N.J.Super.Ct.App.Div.1992) (Skillman, J., dissenting), rev'd 133 N.J. 33, 626 A.2d 1090 (1993) (adopting Judge Skillman's dissent).

Under many circumstances, "a heeding presumption may be applicable to claims of failure to warn of the dangers of pharmaceuticals ...." *McDarby,* 949 A.2d at 267. A heeding presumption allows one to presume that the plaintiff's physician would not have prescribed the drug to the plaintiff if there had been an adequate warning; in other words, the plaintiff's physician would have heeded the adequate warning. *Id.* The heeding presumption is rebutted, however, if the plaintiff's physician "was aware of the risks of the drug that [he] prescribed, and having conducted a risk-benefit analysis, nonetheless determined its use to be warranted[.]" *Id.* at 268 (citing *Strumph,* 256 N.J.Super. 309, 606 A.2d 1140).

Moreover, "a manufacturer who fails to warn the medical community of a particular risk may nonetheless be relieved of liability under the learned intermediary doctrine [11] if the prescribing physician either did not read the warning at all, ... or if the physician was aware of the risk from other sources and considered the risk in prescribing the product." *Perez,* 734 A.2d at 1261 (citation omitted). In that case, the physician's conduct is the "superseding or intervening cause that breaks the chain of liability between the manufacturer and the [plaintiff]." *Id.*

Here, Plaintiffs suggest that there is a genuine issue of material fact as to whether Mrs. Baker's treating physician, Dr. Slater, would have prescribed heparin had there been a different warning label. (Pls. Br. at 19.) Dr. Slater testified that, hypothetically, he likely would not use a prescription drug beyond the time period indicated on the label. (Slater Dep. 92:12–93:8; Pls. Ex. E to Poondi Decl.; DE 82–6.) Plaintiffs infer that Dr. Slater therefore would have followed a heparin label containing the warnings Plaintiffs argue should have been included. Plaintiffs further suggest that Dr. Slater would have heeded warnings and instructions contained in a black box warning, a "Dear Doctor" letter, [12] or the Physician's Desk Reference.

***9** The Court disagrees that Plaintiffs' evidence raises a genuine issue of material fact as to the element of proximate cause. Dr. Slater stated that he regularly used

heparin in his cardiac surgery practice, was familiar with the risks and benefits of heparin, and was aware of HIT. (*See* Slater Dep. 71:8–72:24; Def. Ex. 10 to Miller Decl.; DE 74–15.) In addition, Dr. Slater stood by his decision to administer heparin to Mrs. Baker. (*See id.* 53:13–54:13, 734 A.2d 1245.) "Evangeline Baker required heparin by standard medical procedure, and well documented clinical knowledge at several different time points during her operation and for several different reasons ... She appropriately received heparin during the course of her cardiac surgery. She appropriately received heparin when she developed atrial fibrillation after her cardiac surgery." (*Id.* 53:13–54:7, 734 A.2d 1245.) Where, as here, a plaintiff's physician testifies that he was "aware of the risks of the drug that [he] prescribed and, having conducted a risk-benefit analysis, nonetheless determined its use to be warranted ... the [heeding] presumption [is] rebutted as a matter of law." *See McDarby,* 949 A.2d at 268 (internal citation omitted).

Further, Dr. Slater testified in his deposition that he does not read the label of drugs he prescribes often, which includes heparin. (Slater Dep. 70:23–71:7, Def. Ex. 10 to Miller Decl.) Moreover, Plaintiffs concede that Dr. Slater never testified that he would have consulted a black box warning or "Dear Doctor" letter, or that he ever reviewed the Physician's Desk Reference when prescribing heparin. Therefore, a different warning would not have made a difference in Mrs. Baker's treatment or outcome because Dr. Slater would not have reviewed it. *See Perez,* 734 A.2d at 1261 (explaining that a manufacturer is not liable under the learned intermediary doctrine where the plaintiff's physician did not rely on any information from the manufacturer in prescribing the drug) (citation omitted).

Finally, it is undisputed that, despite Dr. Slater's order, the staff at Morristown Memorial Hospital failed to follow its own heparin treatment protocol. (Pls. RSUMF ¶ 44; Def. SUMF ¶ 44.) Had the hospital staff followed the treatment protocol, Mrs. Baker's blood platelet levels would have been monitored every three days during heparin administration. And, had that monitoring occurred, Mrs. Baker's physicians would have discovered the onset of HIT sooner. (*See* Shohet Expert Report at 9; Pls. Ex. H to Poondi Decl.; DE 82–9.)

Plaintiffs' expert, Dr. Stephen B. Shohet, attributed Mrs. Baker's injuries to "defects in medical management," including the failure to monitor Mrs. Baker's platelet count between September 11th and September 14th. (*Id.* at 8, 734 A.2d 1245.) While finding the lack of detail in the heparin label regarding HIT in cardiac surgery patients "relevant" to the defects in medical management, Dr. Shohet nevertheless concluded that had the hospital staff measured Mrs. Baker's platelet level consistent with its protocol, "Mrs. Baker's subsequent HIT would probably have been detected substantially earlier [.] Heparin would have been discontinued; HIT progression to HITT would have been averted, and much of the long series of progressive morbidity, including sequential amputations would not have occurred." (*Id.* at 8, 9, 734 A.2d 1245.) Dr. Shohet affirmed this opinion during his deposition, testifying that had the hospital staff monitored on the third day of heparin administration, according to hospital protocol, Mrs. Baker's injuries "would have been substantially mitigated" with a "good chance of avoiding the amputation." (Shohet Dep. 223:21–224:25; Def. Ex. 11 to Miller Decl.; DE 74–16.) Therefore, Plaintiffs have failed to raise a genuine issue of material fact that it was the heparin labeling, as opposed to the failure of the hospital to follow its treatment protocol, that was a "substantial factor in causing or exacerbating" Mrs. Baker's injuries. *James v. Bessemer Processing Co.,* 155 N.J. 279, 714 A.2d 898, 909 (N.J.1998).

***10** Ultimately, Plaintiffs cannot demonstrate that the alleged inadequacy of Defendant's heparin labeling resulted in Mrs. Baker's injuries. Because Dr. Slater was aware of and understood the risks of heparin, and did not choose to read heparin's warning label or any additional information from Defendant, no reasonable jury could conclude that a different label would have altered Dr. Slater's decision to administer heparin. Lastly, Mrs. Baker cannot demonstrate that it was the heparin label, rather than the hospital's failure to monitor her platelet levels, that was the substantial factor in causing her blood clots, gangrene, and eventual amputations. As such, summary judgment dismissing Counts I, II, and VIII is also appropriate because Plaintiffs have failed to demonstrate sufficient evidence to raise a genuine issue of material fact as to the element of proximate cause.

IV. CONCLUSION

For the reasons above, the Court grants Defendant's Motion for Summary Judgment and dismisses Counts I, II, and VIII of Plaintiffs' First Amended Complaint. An appropriate order is filed herewith.

All Citations

Not Reported in F.Supp.2d, 2012 WL 3598841

Footnotes

1 Defendants App Pharmaceuticals, LLC and Hospira World Wide Inc., doing business as Hospira Inc., are no longer parties to this action. (*See* DE 20, 64.)

2 Mrs. Baker also received heparin during her cardiac catheterization at Hunterdon Medical Center, but that heparin was not manufactured by Baxter. (Def. SUMF ¶ 29.)

3 In their opposition to Defendant's Statement of Undisputed Material Facts, Plaintiffs dispute that there is any evidence that heparin was reinitiated because of Mrs. Baker's atrial fibrillation. (Plaintiffs' Response to Defendant's Statement of Undisputed Material Facts ("Pls.RSUMF") ¶ 34; DE 81.) But Plaintiffs' expert, Dr. Stephen B. Shohet, inferred that heparin was reinstated due to the atrial arrhythmia. (Expert Report of Stephen Shohet, M.D. at 5, Pls. Ex. H to Poondi Decl.; DE 82–9.)

4 Counts III, IV, V, VI, and VII of the First Amended Complaint as well as Plaintiffs' claim for punitive damages were dismissed on November 30, 2011. (DE 46.) Only Counts I, II, and VIII remain.

5 It is not clear to whom Plaintiffs are comparing surgical and critically ill patients. Heparin is used in patients with serious conditions such as deep vein thrombosis, pulmonary embolism, disseminated intravascular coagulation and in patients undergoing abdominothoracic or cardiac surgery. (*See* Def. Ex. 6 to Miller Decl. at 4 ("Indications and Usage").) Thus, it makes sense that the patient population in which heparin is indicated would be the patient population more likely to develop an adverse reaction to HIT as compared to any other patient population.

6 The heparin label provides, "Platelet counts should be obtained at baseline ...." (*See* Def. Ex. 6 to Miller Decl. at 5.) Therefore, Plaintiffs cannot seriously contend that Defendant failed to disclose that platelet counts should be performed before initiating heparin, as this is plainly stated on the heparin label.

7 There are two forms of heparin: unfractionated heparin and low molecular weight type heparin. (*See* Francis Expert Report at 1–2; Pls. Ex. B to Poondi Decl.; DE 82–3.)

8 The articles disclose, for example, patients who underwent coronary artery bypass surgeries, aortic valve replacement, mitral valve repair, and an angiographic procedure for uterine artery embolization. (*See* Def. Ex. 4 pt. 2 to Miller Decl. at 27–31.)

9 Baxter submitted an NDA to manufacture, market, and sell argatroban in 2008, but the FDA has not yet approved that NDA. (*See* Def. Exs. 1 and 2 to Miller Supp. Decl.; DE 86–2, 86–3.)

10 Count VIII, Plaintiff Bruce Baker's loss of consortium claim, is derivative of and dependent on the survival of Counts I and II. Therefore, since the Court will grant summary judgment dismissing Counts I and II, it will also grant summary judgment dismissing Count VIII.

11 The "learned intermediary" doctrine holds that "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 v. Schneider,* 114 N.J. 550, 555 A.2d 1112, 1117 (N.J.1989). The New Jersey Supreme Court recognized that when a drug manufacturer markets their prescription drug directly to the consumer, there is a corresponding duty to warn the consumer, *Perez,* 734 A.2d at 1263. But that corresponding duty is not at issue in this case.

12 "Dear Doctor" letters may be sent by drug manufacturers to physicians to inform them of important new information about a drug. *See* 21 C.F.R. 200.5.

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KeyCite Yellow Flag - Negative Treatment
Distinguished by Knipe v. SmithKline Beecham, E.D.Pa., September 30, 2008

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UNPUBLISHED OPINION. CHECK COURT RULES BEFORE CITING.

Superior Court of New Jersey, Appellate Division.

Slavo DOBROVIC, M.D. and Bojana Dobrovic, Plaintiffs-Appellants/Cross-Respondents,
v.
Stanley M. FRIEDMAN, M.D., Defendant-Respondent/Cross-Appellant,
and
Eli Lilly and Company, Defendant-Respondent,
and
Sharad Wagle, M.D., Javad Iqbal, M.D., Kenneth A. Citak, M.D., Morteza Shahamat, M.D., and Valley Hospital, Defendants.

Argued March 8, 2006.
Decided Aug. 16, 2006.

Synopsis

Background: Patient brought action against psychiatrist for medical malpractice and against drug manufacturer based on failure to warn of risks of anti-depressant. The Superior Court, Law Division, Bergen County, granted defendants' motions for summary judgment, and patient appealed.

Holdings: The Superior Court, Appellate Division, held that:

[1] evidence supported jury's finding that psychiatrist did not breach applicable standard of care, and

[2] patient failed to rebut statutory presumption that drug manufacturer's warning label for anti-depressant was adequate.

Affirmed.

West Headnotes (2)

[1] Health
Psychiatric Treatment in General

Evidence supported jury's finding that psychiatrist's course of treatment of patient with rapidly increased dosages of anti-depressant and by refusing to allow patient's wife to participate in patient's therapy sessions did not fall below standard of care, in medical malpractice action; anti-depressant was approved remedy for patient's depression, despite risk of developing mania, pace of dosage escalation was appropriate given nature of patient's depression, slow improvement, and physical attributes, and there was no standard of care applicable to issue whether to allow spouses to participate in therapy.

Cases that cite this headnote

[2] Products Liability
Drugs in General

Products Liability
Warnings or Instructions

Psychiatric patient failed to rebut presumption that statutory warning on effects of anti-depressant was adequate, and thus failed to establish that drug manufacturer did not adequately warn him of risk of mania from anti-depressant, in products liability action; manufacturer's label contained warning of risk of developing mania, which was very disorder that patient suffered from. N.J.S.A. 2A:58C-4.

1 Cases that cite this headnote

On appeal from Superior Court of New Jersey, Law Division, Bergen County, L-1222-01.

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Attorneys and Law Firms

Appellant/cross-respondent Slavo Dobrovic argued the cause pro se.

Lauren E. Handler argued the cause for respondent Stanley Friedman, M.D. (Porzio, Bromberg & Newman, attorneys; Ms. Handler, of counsel; Ms. Handler, Borden R. Gillis, and Darren T. DiBiasi, on the brief).

John Brenner argued the cause for respondent Eli Lilly and Company (McCarter & English, attorneys; John C. Garde and Debra M. Perry, of counsel; Mr. Garde, Ms. Perry, and James H. Knight, on the brief).

Before Judges WEFING, WECKER and GRAVES.

Opinion

PER CURIAM.

*1 Plaintiff Slavo Dobrovic, M.D.[1] and Bojana Dobrovic, his wife, appeal from a summary judgment order dismissing their products liability action against defendant Eli Lilly and Company (Lilly), and an order dismissing their medical malpractice action based on a jury verdict in favor of defendant Stanley Friedman, M.D. Plaintiff alleged in his complaint that Friedman negligently prescribed the antidepressant medication Prozac, manufactured by Lilly, and that Lilly failed to adequately warn of the alleged side effects of Prozac.[2] We affirm.

Plaintiff, who was seventy-two years old at the time of trial, was born in Croatia, then part of the former Yugoslavia. While a seventeen-year-old student, plaintiff was arrested and imprisoned for approximately one year for writing "Free Croatia" on a city wall. After his release, plaintiff attended medical school. In 1970, plaintiff, his wife, and their children emigrated to the United States. Plaintiff completed his medical education in the United States, and in 1978, he opened a private practice with offices in Jersey City and Englewood. By 1982, plaintiff had become a board-certified orthopedic surgeon, and he was on staff at several hospitals, including Englewood Hospital.

On November 9, 1994, plaintiff admitted a patient to Englewood Hospital, but failed to attend to her for three days, explaining, "I just forgot her." Plaintiff also failed to "respond to multiple calls from nurses." On November 13, 1994, plaintiff examined the patient and backdated his progress notes, falsely indicating that he had treated the patient soon after her admission to the hospital. Nurses at the hospital reported plaintiff's conduct, and on December 13, 1994, Englewood suspended plaintiff's hospital privileges and instituted disciplinary proceedings against him. Plaintiff still had staff privileges at Meadowlands and Christ Hospitals, however, and he continued to see patients at his offices in Jersey City and Englewood.

In January 1995, plaintiff appeared before the Credentials Committee of Englewood Hospital for a hearing regarding the November 1994 incident. In a written report the committee expressed "considerable concern" that plaintiff's answers to their questions were "rambling and often inappropriate." The committee noted the possibility that "a neuropsychiatric problem may have caused or contributed to this situation." The committee therefore suspended plaintiff's hospital privileges and required that prior to reinstatement he undergo psychiatric, neurological, neuropsychological, and medical evaluations. The committee recommended that the hospital revoke plaintiff's staff privileges if he failed to comply. The Englewood Hospital Medical Executive Committee accepted the recommendations of the Credentials Committee, and plaintiff saw defendant Friedman, a board-certified psychiatrist, for psychiatric evaluation and treatment.

On February 1, 1995, plaintiff met with Friedman for the first time. During that session, plaintiff discussed his financial difficulties, revealing that his office properties were in foreclosure. He also discussed his family difficulties, explaining that his daughter had married a man he did not approve of, and that he feared for the safety of his daughter and son because they were both residing in Croatia. Plaintiff also indicated that he had recently lost approximately twenty-five pounds, had insomnia, had difficulty concentrating, was distracted, and felt compelled to wash his feet in cold water every evening, a routine he had to follow while imprisoned in Croatia.

*2 Friedman diagnosed plaintiff as suffering from a major depression, known as double depression superimposed on a chronic dysthymia, and obsessive compulsive disorder. He also determined that plaintiff was

chronically angry and unhappy, but did not suffer from bipolar disorder, a psychiatric condition characterized by alternating periods of depression and mania. Friedman concluded that plaintiff "was not psychologically oriented and ... would not benefit from psychotherapy alone." Thus, in addition to weekly therapy sessions, Friedman decided to treat plaintiff with antidepressant medication and prescribed a "basic dose" of 20 mg of Prozac per day. Friedman acknowledged during his deposition that he did not discuss with plaintiff the potential side effects of taking Prozac during the initial session on February 1, 1995.

On February 5, 1995, plaintiff's wife, Bojana, who handled the couple's finances, returned to Croatia to resolve several developing financial problems, including problems concerning their purchase of shares in a hotel from the Croatian government. Bojana had made a similar trip in November and December 1994, and when plaintiff opened the mail in her absence, he was surprised to discover that their monthly expenses were $20,000 to $30,000. When Bojana returned home on February 19, 1995, she discovered that plaintiff was unusually anxious, very talkative, and sweaty, and plaintiff experienced sexual dysfunction during their marital relations. Bojana said she called Friedman to discuss these symptoms, but he refused to talk to her.

During a session with Friedman on February 22, 1995, plaintiff discussed an incident at a hospital, alleging that hospital personnel "run after you like wolves to tear you apart." Defendant concluded that plaintiff continued to exhibit chronic anger and depression, and he increased plaintiff's dosage of Prozac to 40 mg per day because plaintiff was not "improving rapidly enough if at all at this point." Friedman admitted that this increase in dosage within a relatively short time was contrary to the manufacturer's recommendations as set forth in the *Physician's Desk Reference* ("PDR"), and he acknowledged that he had still not discussed potential side effects with plaintiff. Friedman also conceded that it takes several weeks for the maximum effect of Prozac to be realized.

On March 1, 1995, Friedman increased plaintiff's prescription of Prozac to 60 mg per day. He told plaintiff that "he wasn't getting better fast enough and that he was not a small person and that [the increased dosage] was indicated." According to Friedman, during the session on March 8, 1995, plaintiff revealed that he was angry that Bojana "was staying in Croatia longer than he had anticipated." On March 20, 1995, after Bojana had returned home, she telephoned Friedman and informed him that plaintiff "had gone berserk," had been violent, had been "breaking furniture," and was on his way to the airport to get a flight to Croatia "to kill all these people," presumably referring to the Croatian government officials involved in the unsuccessful hotel investment transaction.

*3 Two days later, plaintiff, who had not flown to Croatia, attended his regularly scheduled session with Friedman, and Friedman observed that plaintiff seemed "more depressed." According to Friedman, plaintiff explained that Bojana had lost $85,000 in the hotel shares purchase, one of a series of bad investments. Plaintiff blamed the financial loss on the Croatian government, and he was enraged at government officials for referring to him as a "Serb," a term he considered a gross insult. Although Friedman admitted he had considered the possibility that plaintiff had experienced an episode of mania, a potential side effect of Prozac, he ultimately determined that this was an episode of rage brought on not by taking Prozac, but by plaintiff's financial problems and anger at his wife. Friedman explained that manic behavior is generally associated with an "an elevated mood, hyperactivity, lack of sleep without any side effects, loss of real[ity] ... [and] buying sprees," none of which plaintiff exhibited.

Friedman acknowledged that Bojana called several times and asked to participate in plaintiff's therapy sessions. He denied her request, however, explaining that plaintiff was not psychotic and so "we have to respect his privacy." Moreover, according to Friedman, plaintiff never asked to have his wife included in the therapy sessions, and plaintiff was indifferent to the decision not to include her.

On March 29, 1995, Friedman observed that plaintiff appeared "remarkably better," but nevertheless noted that plaintiff's "anger" was "easily triggered by inadvertent [and] innocent comment[s] by others." Friedman admitted that during this session plaintiff expressed concern about the potential side effects of Prozac, but plaintiff did not report suffering any side effects, other than dry mouth and sexual dysfunction. Plaintiff testified to the contrary, that he had been experiencing many of the PDR-listed side effects, including sexual dysfunction, insomnia, feelings of anger, and increased irritability. Plaintiff claimed that defendant simply characterized the PDR as "baloney," explaining that the "company has to write something."

In April 1995, Midlantic Bank filed foreclosure actions against plaintiffs, seeking possession of their commercial buildings in Englewood and Jersey City. On May 17, 1995, Friedman observed that plaintiff appeared to be progressively more angry and he increased plaintiff's dosage of Prozac to 70 mg per day. Friedman also conceded that he was familiar with "the literature" which said that use of Prozac can increase anger.

On May 24, 1995, defendant increased plaintiff's dosage of Prozac to 80 mg per day, the maximum recommended amount. Nonetheless, on June 7, 1995, based in part on Friedman's favorable evaluation, Englewood Hospital reinstated plaintiff's staff privileges, albeit on a gradual and supervised basis. Friedman testified that he recommended plaintiff's reinstatement because plaintiff was "better than he was a year ago when he was perfectly acceptable to the staff of Englewood Hospital," even though he had not recovered "from his depression."

***4** On June 12, 1995, plaintiff was arrested for causing a disturbance at a local car dealership with which he had a longstanding dispute. Plaintiff was jailed and released later that night. When Friedman saw plaintiff for the last time on June 14, 1995, he said plaintiff was "mad at the Ford dealership who had rooked him and he was mad at the police for arresting him," and "he was mad at me" for being "rude" to Bojana. When Friedman was asked if he considered the incident at the Ford dealership to be consistent with mania, he answered: "No. I regarded him as a volcano that was simmering along and every once in a while it would have an explosion."

On June 15, 1995, plaintiff saw Sharad Wagle, a psychiatrist, who diagnosed plaintiff as manic and arranged for admission to Valley Hospital, where plaintiff remained for five days. During his hospitalization, plaintiff was treated by another psychiatrist, who diagnosed him as suffering from bipolar disorder, a diagnosis subsequently disputed by both parties' psychiatric experts. When plaintiff returned home, Bojana described his condition as unresponsive, and said this condition lasted for several days.

Plaintiff did not subsequently return to the practice of medicine. Bojana closed plaintiff's offices and wrote to each of the hospitals at which he maintained staff privileges, advising them that he was taking a leave of absence. In October 1995 plaintiff began treatment with Dr. Nicholas Marchese, a psychiatrist, who diagnosed plaintiff as suffering from post-traumatic stress disorder. Marchese explained that post-traumatic stress disorder "produces a variety of symptomatologies such as agitation, apprehension, [and] depression...." Marchese opined that plaintiff had developed this disorder as a result of "the increased amounts of Prozac" prescribed by Friedman, and concluded that as a result plaintiff was "psychologically dysfunctional." Marchese admitted that he had both treated and evaluated plaintiff, but said he did so only after receiving plaintiff's permission to submit an evaluation to the Board of Medical Examiners (BME).

In May 1996, plaintiff entered into a letter agreement with the BME under which he agreed not to practice medicine pending a demonstration of his fitness and competence. At the time of trial, plaintiff testified that he was still unable to practice because he had no confidence in his abilities. He also stated that he continued to suffer from sexual dysfunction.

Dr. Harold Bursztajn, plaintiff's expert in the field of forensic psychiatry, testified that Friedman deviated from the accepted standards of care in acting as both an evaluator and treating physician. Bursztajn explained that the Academy of Psychiatry and Law provides in its ethics code that "whenever possible" a psychiatrist should not function in such a dual role because it inevitably violates confidentiality and creates a relationship of "power dependency," not trust.

***5** Bursztajn also concluded that Friedman deviated from the accepted standards of care by increasing plaintiff's dosage of Prozac too quickly. Bursztajn explained that Prozac has an unusually slow rate of elimination half-life and thus steady states of the drug in the body are only achieved after about four to five weeks of use. Therefore, psychiatrists should only increase a patient's dosage of Prozac after six weeks of use.

Bursztajn maintained that a rapid increase in dosage is more likely to produce adverse side effects, including the most dangerous side effect, mania. Bursztajn described mania as a "very dangerous delirious state where the person begins to have pressured speech, they lose their judgment, [and] they begin to take unnecessary risks ." Bursztajn concluded that plaintiff had developed mania as a side effect of taking "toxic dosages" of Prozac,

finding that the June 12, 1995, car dealership incident was "clearly a manic episode." Bursztajn testified that Friedman should have immediately discontinued the use of Prozac once plaintiff began to suffer side effects and should have monitored plaintiff for signs of mania. And Bursztajn concluded that defendant deviated from accepted standards in failing to warn plaintiff about all of the potential side effects of Prozac, including mania, anxiety, nervousness, violent behavior, abnormal dreams, insomnia, and sweating.

According to Bursztajn, Friedman also deviated from the accepted standards of care by: (1) prescribing Prozac without first "creating a therapeutic alliance" with plaintiff; (2) failing to include Bojana in plaintiff's therapy sessions; and (3) failing to consider plaintiff's history, including his imprisonment in Croatia, an experience that, according to Bursztajn, had caused plaintiff to develop post-traumatic stress disorder. Bursztajn found that that condition had remained in remission until 1994, when plaintiff developed complex post-traumatic stress disorder. Bursztajn explained that:

> Complex post-traumatic stress disorder refers to the complications which can occur when people are especially not just traumatized, but are subsequently re-traumatized.... You ... giv[e] up. You get a sense of loss of hope, there's no future; a loss of identity, a loss of who you are and what life means to you.

Bursztajn concluded that plaintiff was "so demoralized that he will not have the energy or the stamina to be able to concentrate, to be able to make the kind of fine-grain decisions that you need to be able to [make to] be a practicing physician."

In contrast, Dr. Alexander Glassman, defendant's expert psychiatrist testified that Friedman did not deviate from accepted standards of care. Glassman alleged that the ethics code published by the American Academy of Psychiatry constitutes merely "guidelines" and does not establish a standard of care. Moreover, from his review of the record, Glassman found that plaintiff had suffered from depression, and he had been properly treated by Friedman, even though Friedman also acted as an evaluator.

***6** Similarly, Glassman testified that Friedman had not deviated from accepted standards of care in failing to include Bojana in plaintiff's therapy sessions because "there is no accepted standard of care about whether you see a spouse or a relative." Glassman explained that generally family members are only included in therapy sessions when a patient is psychotic or suicidal, which plaintiff was not. In fact, he noted that

> many people with an analytical background would frown on seeing the family because they feel it contaminates the relationship, that you want as clean a relationship with the patient where the patient can absolutely trust you and there's no question about you talking to anybody else about anything they say to you. There are other people that wouldn't feel that that's such a religious issue, that you can be flexible about it and there's no standard of care, people do different things. Part of it depends on the relationship between the patient and the spouse. Those are all issues that go into making a decision.

With regard to treatment, Glassman noted that Prozac is a "very traditional" drug used to treat depression, and concluded that such a prescription was entirely appropriate here. He also opined that defendant had not deviated from accepted standards in escalating plaintiff's dosage at the pace he did. Glassman explained that the PDR does not "set the standard of care." Instead, he described the PDR as a compilation of drug "packag[ing] inserts," representing guidelines, not standards for the administration of medication. He explained that to "some extent" the information is not entirely accurate because "drug[ ] companies often add stuff to the PDR to sort of protect themselves." Thus, he noted that physicians often appropriately prescribe medication in excess of PDR recommended dosages. He opined that the pace of dosage escalation was appropriate in this case given the nature of defendant's depression, his slow improvement, and his physical attributes.

Glassman admitted that mania is a potential side effect of using Prozac, but he maintained that patients generally develop mania very early in their treatment and defendant

did not exhibit any signs of mania until the car dealership incident on June 12, 1995. Moreover, Glassman claimed that it is very rare for a patient who does not have an individual or family history of bipolar disease, such as plaintiff, to suffer mania as a result of Prozac use. He testified that Friedman did not deviate from the standard of care in prescribing Prozac, even though plaintiff may have developed mania, because it was "an appropriate drug to use for depression" and it was "very unlikely" to cause mania.

Moreover, Glassman concluded plaintiff's alleged inability to return to the practice of medicine was not a consequence of taking Prozac or allegedly developing mania. He explained that generally as soon as you stop taking Prozac "the mania goes away." And Glassman noted that he had never treated anyone who developed "residual symptom[s]" as a result of Prozac use, nor was there any "real description in the literature of cases where someone has ... residual damage from these episodes." Instead, Glassman opined that plaintiff was suffering from long-standing depression-related and personality-related psychiatric difficulties.

*7 **[1]** The jury resolved the conflicting expert testimony in favor of defendant, and we perceive no legitimate basis to intervene. Based on our review of the record, we have concluded there is ample evidence to support the jury verdict, and the verdict did not constitute a miscarriage of justice under the law warranting a new trial. *Dolson v. Anastasia,* 55 *N.J.* 2, 6-7, 258 A.2d 706 (1969); *Baxter v. Fairmont Food Co.,* 74 *N.J.* 588, 599, 379 A.2d 225 (1977); *Law v. Newark Bd. of Educ.,* 175 *N.J.Super.* 26, 37, 417 A.2d 560 (App.Div.1980); *see also R.* 2:10-1. Plaintiff's contentions to the contrary are without sufficient merit to warrant extended discussion. *R.* 2:11-3(e)(1)(B) & (C).

[2] With respect to the summary judgment in favor of Lilly, the trial court reasoned as follows:

> Plaintiff has the burden of proving that defendant[']s alleged inadequate warning was a proximate cause of injuries. Plaintiff must show that adequate warnings would have altered the doctor's decisions to prescribe Prozac. Dr. Friedman's uncontroverted testimony shows that the decision to prescribe Prozac would not have been altered by his subsequent knowledge of events or because of any alleged inadequacies in the Prozac warning label. Plaintiffs have failed to present any supportive evidence in order to defeat defendant's motion for summary judgment specifically with regard to the issue of proximate causation.
>
> Plaintiffs have failed to show that Lilly's warning label for Prozac was inadequate. Dr. Friedman's uncontroverted testimony that Lilly produced a warning with Prozac regard[ing][the] potential risk of mania, the very injury from which plaintiff, Dobrovic allegedly suffered. Dr. Friedman was aware of the warning and evaluated plaintiff for mania. In his medical opinion, plaintiff did not suffer from mania. The warning was thus adequate and discharg [ed] defendant Lilly's duty under the learned intermediary doctrine. Defendant Lilly's motion for reconsideration from the Court's 12/20/02 order is granted....

N.J.S.A. 2A:58C-2(b) subjects a seller to liability for a product which "fail[s] to contain adequate warnings or instructions...." In a failure-to-warn case the plaintiff has the burden of proving by a preponderance of the evidence that the manufacturer did not warn of the risks attendant to the product, and that the failure to warn was a proximate cause of the plaintiff's injuries. *Sharpe v. Bestop, Inc.,* 314 *N.J.Super.* 54, 62-63, 713 A.2d 1079 (App.Div.1998), *aff'd o.b.,* 158 *N.J.* 329, 730 A.2d 285 (1999). And *N.J.S.A.* 2A:58C-4 provides that

> [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.... 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, ... in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician. If the warning or instruction given in connection with a drug ... has been approved or prescribed by the federal Food and Drug Administration ... a rebuttable

> presumption shall arise that the warning or instruction is adequate.

***8** Lilly's warning accompanying Prozac was approved by the United States Food and Drug Administration (FDA), and the trial court concluded that plaintiff failed to rebut the statutory presumption under *N.J.S.A.* 2A:58C-4, that Lilly's FDA-approved warning was adequate. *See Perez v. Wyeth Lab., Inc.*, 161 *N.J.* 1, 24, 734 A.2d 1245 (1999) ("FDA regulations serve as compelling evidence that a manufacturer satisfied its duty to warn the physician about potentially harmful side effects of its product."). In this case, it is undisputed that Lilly warned of the very side effect that plaintiff allegedly experienced-a series of manic reactions while on Prozac. Accordingly, the record fully supports the trial court's determination that plaintiff failed to rebut the statutory presumption that Lilly's warning was adequate.

Affirmed.

All Citations

Not Reported in A.2d, 2006 WL 2355136

Footnotes

1 Because the claims of Bojana Dobrovic are derivative, we refer to Slavo Dobrovic, M.D. as plaintiff.

2 Prozac (fluoxetine), an antidepressant, is a registered trademark of Eli Lilly and Company.

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UNPUBLISHED OPINION. CHECK COURT RULES BEFORE CITING.

Superior Court of New Jersey,
Atlantic and Cape May Counties.

CLARK
v.
HOFFMAN-LA ROCHE, INC., et al.

Decided May 2, 2006.

Defendant's Motion to Dismiss the Complaint with Prejudice.

Attorneys and Law Firms

Diane E. Lifton for Defendants.

Christopher A. Seeger for Plaintiffs.

HIGBEE, J.

MEMORANDUM OF DECISION ON MOTION

Pursuant to Rule 1:6-2(f)

***1** Having carefully reviewed the papers submitted and oral arguments presented, I have ruled on the above Motion as follows:

Defendants Hoffmann-La Roche, Inc. and Roche Laboratories, Inc. (collectively "domestic defendants") bring this motion to dismiss plaintiffs Codie & James Clark and Sarah Clark's complaint with prejudice for failure to state a claim upon which relief can be granted pursuant to *R.* 4:6-2(e). Plaintiffs oppose this motion.

BACKGROUND

On December 22, 2004, Plaintiffs filed a complaint with the Superior Court of New Jersey-Atlantic County-Law Division seeking to recover for birth defect related injuries allegedly caused to Sarah Clark by Codie Clark's ingestion of the prescription drug Accutane. Plaintiffs' complaint consists of five counts: (1) defective design under the New Jersey Products Liability Act ("NJPLA"); (2) failure to warn under the NJPLA; (3) breach of implied warranty under the NJPLA; (4) punitive damages under the common law and NJPLA; and (5) violations of the New Jersey Consumer Fraud Act ("NJCFA").

Defendants have filed this motion asserting that all of these claims are premised on a theory of failure to warn and thus, they are barred as a matter of law by the "learned intermediary doctrine ." Domestic defendants also argue that neither Utah law nor New Jersey law allows for causes of action against United States Food and Drug Administration ("FDA")-approved prescription drugs. Additionally, defendants assert that Plaintiff's claims are barred by the statute of limitations for personal injuries. Domestic defendants believe that Utah law properly governs these claims.

Plaintiffs oppose this motion arguing that the learned intermediary doctrine does not bar their claims. Plaintiffs assert that they have properly pleaded a claim for design defect and that domestic defendants' motion is otherwise inappropriate as the complaint adequately states a claim. Plaintiffs believe that New Jersey law applies to this matter.

On May 2, 2005 the New Jersey Supreme Court designated all pending and future litigation in New Jersey involving the drug Accutane as a mass tort to be handled on a coordinated basis before this court. This case represents one of the matters in the Accutane mass tort.

ANALYSIS

R. 4:6-2(e) allows a party to bring a motion to dismiss a complaint for failure to state a claim upon which relief can be granted. *R.* 4:5-7 provides that "[e]ach allegation of a pleading shall be simple, concise and direct, and no technical forms of pleading are required. Additionally, all pleadings shall be liberally construed in the interests of justice.

On a motion under *R.* 4:6-2(e), the complaint is to be thoroughly and liberally searched in order to determine if a cause of action can be garnered from the document, even if it is contained in an obscure statement, and an opportunity to amend should be given if necessary.

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Printing Mart v. Sharp Electronics, 116 *N.J.* 739, 746 (1989). This is especially so if the litigation is in its early stages with further discovery yet to be taken. *Id.* On a motion to dismiss, the plaintiff is accorded every reasonable inference and the motion "should be granted only in rare instances and ordinarily without prejudice. As such, 'if a generous reading of the allegations merely suggests a cause of action, the complaint will withstand the motion." ' *Smith v. SBC Communications Inc.,* 178 *N.J.* 265, 282 (2004) (*quoting F.G. v. MacDonell,* 150 *N.J.* 550, 556 (1997).

***2** In the case at hand, defendants claim that plaintiffs have failed to state a claim upon which relief can be granted and refer to the warnings that were provided in association with the drug Accutane as well as to the matters alleged in the pleadings. The parties do not dispute that the warnings that accompanied the drug are integral to the decision in this motion. *See e.g. Pension Benefit Guaranty Corp. v. White Consol. Indus., Inc.,* 998 *F.2d* 1192, 1196 (3d Cir.1993); *Syncsort, Inc. v. Sequential Software, Inc.,* 50 *F.Supp.2d* 318, 325 (D.N.J.1999) (finding that "undisputably authentic documents expressly relied upon or integral to the pleadings" may be considered without turning a motion to dismiss into one for summary judgment). Plaintiffs attached a number of exhibits to their opposition to this motion, defendants object to all but one and have filed a separate motion to exclude same from consideration. The exhibit that was not objected to was the Patient Information/Consent form signed by Ms. Clark. This form is part of the "Pregnancy Prevention Program for Women on Accutane" and is integral to the allegations set forth in the pleadings. The remaining seven exhibits attached to the opposition are evidentiary documents that plaintiffs could use to support their allegations. Defendants want the court to view only the exhibit helpful to their position. These items are all helpful to the court in deciding whether to dismiss the complaint and are all integral to an understanding of the allegations. This court will therefore deny the defendant's motion to exclude these documents and consider them in making the decision in this case.

Plaintiffs claim that defendants Hoffmann-LaRoche Inc., and F. Hoffmann-La Roche, Ltd. ("Swiss defendant") are part of a unified conglomerate known as "the Roche Group." Domestic defendants are New Jersey corporations with their principal place of business located in Nutley, New Jersey. Accutane is a drug manufactured and distributed in New Jersey by the defendants. Accutane is a prescription drug intended to treat people suffering from severe cystic acne. There is no dispute that Accutane is a teratogen, a drug that can cause severe physical and cognitive birth defects and malformations in children exposed to the drug during gestation. Accutane was first developed in 1971. In 1982, the FDA approved Accutane for treatment of cases of severe cystic acne not responding to other treatments.

Plaintiffs Codie and James Clark allege that their daughter Sarah was born with significant birth deformities because Codie Clark ingested Accutane while pregnant. Plaintiff was prescribed Accutane by her dermatologist and began taking the drug on or about March 1, 2001. At this time Ms. Clark was unaware that she had recently become pregnant with Sarah Clark. Ms. Clark resided in Utah at the time she was prescribed Accutane and during the time she ingested Accutane. Her prescribing physician was located in Utah. Plaintiffs allege Sarah was conceived, was born and resides in Utah.

***3** Plaintiffs claim that the defendants, as a whole, had a duty to both advise of the danger of birth defects and to provide adequate instructions, information and safety procedures essential to ensure that the use of Accutane was as safe as possible. Plaintiffs assert that Accutane is so dangerous that in order to ensure its safe use, special requirements and limitations must be provided as well as advice and monitoring to avoid prescribing the drug to pregnant women.

The plaintiffs allege in their complaint that defendants knew from 1971 when Accutane was developed that it was a powerful teratogen. They further allege specifically that in order to get the drug approved by the FDA for use in the United States the defendants intentionally deceived the FDA and, in fact, concealed foreign studies and results of United States clinical trials that would have disclosed to the FDA the extent of the danger of birth defects.

The contention of the plaintiffs is that the defendants for years took steps to over promote the drug in the United States because abortion was legal here and defendants viewed abortion as the answer to the birth defect problem. The plaintiffs allege that despite growing concern by the FDA over the failure of the warnings which were made stronger and stronger over time, the defendants resisted

any attempt to create a national pharmacy registry which they knew or should have known would have prevented the drug from being taken by pregnant women. Such a registry is now required.

Plaintiffs also allege that the risk of children being born with tragic birth defects far outweighed the benefits of Accutane which treats acne.

The complaint specifically alleges:

> "56. In 1988, the FDA became alarmed at the growing number of children being born with Accutane related birth defects. At that time, the FDA had received confirmation of 66 known cases of deformed children being born to mothers ingesting Accutane since 1982. In response, the FDA's Director of the Division of Birth Defects and Developmental Disabilities at the Center for Disease Control concluded:
>
> > In closing, let me note that I feel a great urgency to prevent infants and children from having the serious birth defects and birth defects and developmental disabilities associated with the Accutane embryopathy. As you know, the problems are as serious as the Thalidomide embryopathy.... It is not often that we know how to prevent all cases of a particular serious birth defects or developmental disabilities. In this instance, however, we know how to prevent further cases. We simply need to remove the drug from the market.
> >
> > I know that because the product is effective against cystic acne that removing the drug from the market will no be popular. On the other hand, I know that 40 infants born alive after first trimester exposure to Accutane have died as infants or children because of developmental errors that Accutane caused. I believe that if 40 teenagers or young adults with acne had died as a result of therapy caused by this drug that the drug would have been viewed as too dangerous, even though effective, to be on the market. I do not believe that the benefits outweigh the risk and that the drug should be removed from the market as soon as possible.
>
> *4 57. Accordingly, the FDA requested that Roche conduct a study to test the effectiveness of its efforts to prevent pregnancies. In response, Roche proposed a study that the FDA *rejected* because the FDA concluded the study was not scientifically valid and contained a bias resulting in a falsely inflated success rate for pregnancy prevention.
>
> 58. Meanwhile, the number of patients using Accutane more than doubled between 1992 and 1999. Out of these patients being treated with Accutane, Roche knew that 50 percent were females, of whom 85 to 90 percent were of childbearing age and potential. By 2000, Roche received reports of almost 2,000 cases of Accutane-exposed pregnancies since the drug's approval, with 70% of the exposures occurring *after* the implementation of Roche's defective pregnancy prevention program."

Plaintiffs allege that the defendants have attempted to avoid using safeguards to prevent birth defects resulting from Accutane throughout the history of the drug in order to maximize the profits received from the drug.

The written information that accompanies a prescription of Accutane is replete with warnings to avoid pregnancy while taking the drug. Indeed, the drug contains a black box warning, the strongest warning the FDA requires, that begins by stating, "Accutane must not be used by females who are pregnant or who may become pregnant while undergoing treatment." The black box warning provides that Accutane is contraindicated in females of childbearing potential unless a patient meets all of eight listed requirements. These requirements include that the patient undergo two pregnancy tests with negative results prior to being prescribed Accutane. Further, the requirements repeatedly assert the need for the patient to communicate with and understand instructions from the prescribing physician.

On February 23, 2001, Ms. Clark (at the time she was still Codie Stark), signed the one-page Patient Information/ Consent form that was part of the Pregnancy Prevention Program for Women on Accutane. The form instructs patients in bold, capital letters to not sign the form or take Accutane if there is anything that the patient does not understand. The form contains fifteen paragraphs of information regarding the hazards of taking Accutane and the patient is supposed to sign their initials after each paragraph to indicate that they understand the various warnings and instructions associated with the drug. Ms. Clark initialed each of the fifteen paragraphs on the form and signed the form at the bottom of the page.

The parties vigorously dispute which state's laws should apply to this litigation. As is obvious from plaintiffs' complaint, plaintiffs feel that New Jersey law should apply based upon the defendants' contacts with the forum state. Thus, plaintiffs seek remedies under the NJPLA and the NJCFA. By contrast, the defendants assert that Utah law should apply based upon the plaintiffs' contacts with Utah. While the complaint solely refers to the application of New Jersey law, plaintiffs' opposition to this motion asserts that even if Utah law were determined to apply, this matter should not be dismissed for failure to state a claim, but rather, plaintiffs should be afforded an opportunity to amend the complaint and plead under Utah law.

***5** As noted above, all New Jersey state litigation pertaining to alleged injuries stemming from Accutane have recently been consolidated as a mass tort before this court. At present there are over two-hundred cases pending, although only a few involve birth defects. Discovery is proceeding as agreed to by the parties.

Both New Jersey and Utah afford defenses to drug manufacturers that comply with certain FDA requirements in obtaining approval for public consumption of their products. *See Perez v. Wyeth Laboratories, Inc.*, 161 *N.J.* 1, 24 (1999) (stating that "FDA regulations serve as compelling evidence that a manufacturer satisfied its duty to warn the physician about potentially harmful side effects of its product"); *Grundberg v. Upjohn Co.*, 813 *P .2d* 89, 99 (Utah 1991) (holding "that a broad grant of immunity from strict liability claims based on design defects should be extended to FDA-approved prescription drugs in Utah").

Under the learned intermediary doctrine, because a physician functions as an intermediary between manufacturer and consumer, "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 by Niewmiera v. Schneider*, 114 *N.J.* 550, 559 (1989). Both New Jersey and Utah recognize the learned intermediary doctrine. *See Id.; Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 79 *P.3d* 922, 929 (Utah 2003) (finding that the learned intermediary doctrine applied to pharmacists as well as drug manufacturers).

The instant matter is not governed solely by the learned intermediary doctrine because despite whatever information was given to the physician, and despite whatever direct-to-consumer advertising, if any, had been conducted, warnings about Accutane were provided directly to the patients, including Ms. Clark. *Perez, supra*, 161 *N.J.* at 19 ("When all of its premises are absent, as when direct warnings to consumers are mandatory, the learned intermediary doctrine ... simply drops out of the calculus, leaving the duty of the manufacturer to be determined in accordance with general principles of tort law.") (*quoting Edwards v. Basel Pharms.*, 116 *F.3d* 1341, 1343 (10th Cir.1997)). Normally, the adequacy of a warning is a question of fact for a jury to determine. *Feldman v. Lederle Laboratories, a Div. of American Cyanamid Co.*, 125, *N.J.* 117, 140 (1991) (*discussing Abbot by Abbot v. American Cyanamid Co.*, 844 *F.2d* 1108, 1115 (4th Cir.1988)); *see also House v. Armour of America, Inc .*, 886 *P.2d* 542, 551 (Utah App.1994) ("Whether the warning provided by the label was adequate presents a question of fact, to be resolved by the trier of fact."). However, "where the warning is accurate, clear, and unambiguous," it can be deemed adequate as a matter of law. *Felix v. Hoffmann-LaRoche, Inc.*, 540 *So.2d* 102, 105 (Fla.1989) (finding that the warnings to avoid pregnancy on Accutane were adequate as a matter of law); *see also, Hammock v. Hoffmann-LaRoche, Inc.*, 269 *N.J. Super*, 289, 293 (App.Div.1993) *rev'd on other grounds* 142 *N.J.* 356 (1995). "Adequacy, of course, must be gauged in terms of probable efficacy in sparing the consumer the hazard of a risk not reasonably appreciated by him in his use of the product." *Torsiello v. Whitehall Laboratories, Division of Home Products Corp.*, 165 *N.J. Super*, 311, 321 (App.Div.) *certif. denied*, 81 *N.J.* 50 (1979).

***6** The NJPLA, specifically, *N.J.S.A.* 2A:58C-4 provides:

> In 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 or, in the case of dangers a manufacturer or seller discovers or reasonably should discover after the product leaves its control, if the manufacturer or seller provides an adequate warning or instruction. 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

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> 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. If 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."

The New Jersey Supreme Court noted with regard to prescription drugs, "a manufacturer who knows or should know of the danger or side effects of a product is not relieved of its duty to warn. Rather, as the comment expressly states, it is only the unavoidably unsafe product *'accompanied by proper warning'* that is not defective." *Feldman v. Lederle Laboratories,* 97 *N.J.* 429, 447 (1984) (internal citations omitted) (emphasis in the original).

In the matter at hand, the court finds that the warning provided to plaintiffs was adequate as a matter of law. The warnings/instructions communicate 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. One does not need to be a physician to understand the language in the black box warning on Accutane that states in part:

> Accutane must not be used by females who are pregnant or who may become pregnant while undergoing treatment. Although not every fetus exposed to Accutane has resulted in a deformed child, there is an extremely high risk that a deformed infant can result if pregnancy occurs while taking Accutane in any amount even for short periods of time. Potentially any fetus exposed during pregnancy can be affected. Presently, there are no accurate means of determining after Accutane exposure which fetus has been affected and which fetus has not been affected.

*7 Consequently, defendants have satisfied their burden under either New Jersey or Utah law to provide an adequate warning with respect to the risks associated with pregnancy while taking Accutane to the patients who use this drug. As to the New Jersey law, the decision on the Accutane failure to warn claim as it relates to birth defects has been made by the Appellate Division in the case of *Banner v. Hoffmann-LaRoche Inc. & Roche Laboratories Inc.*, 383 *N.J.Super.* 364 (App.Div.2006). The court in that case found that the warnings were adequate. *Id.* at 377. This court is bound by that decision. The parents Codie Clark and James Clark's claims for failure to warn are dismissed.

The failure to warn counts are stricken for all parties. All claims for personal injury of James and Codie Clark are stricken based on the statute of limitations under either New Jersey or Utah law. The plaintiff parents were advised that Accutane could cause substantial birth defects. They knew when their daughter was born that she had severe birth defects. Both Utah and New Jersey have two year statutes of limitations. *Utah Code Ann.* § 78-15-3; *N.J.S.A.* 2A:14-2. Although both states have discovery rules, they would not be applicable under these facts. The complaint was filed three years after Sarah's birth and both parents' claims are barred.

The Supreme Court of New Jersey in the *Banner* decision further stated that the court could not conclude that Roche had a duty to withhold the drug from a woman unless she agreed to use a contraceptive technique that may have violated her religious principles. *Banner, supra,* 383 *N.J.Super,* at 384. In *Banner,* the patient was a 24 year old married woman who was prescribed Accutane and elected not to use birth control because of religious reasons. *Id.* at 372. Plaintiff intended to abstain from sex while using Accutane. *Id.* However, while on Accutane she and her husband did engage in sexual relations and the tragic result was a profoundly disabled child. *Id.*

The facts before this court are similar but also different from those in the *Banner* case. The difference is that in *Banner* the claim was for wrongful birth and for wrongful life, that is, that better control of the mother's methods of contraception would have prevented the *Banner* child from being conceived. This is the claim that is dismissed by the Appellate Division in the *Banner* decision.

Here, the allegation is that the child Sarah Clark was a living entity already conceived and growing in her mother's womb when she was exposed to Accutane sold to her mother to cure her mother's acne. The child does not have a failure to warn claim because adequate warnings were given to the mother. The question that is posed in this case is does Sarah Clark have her own strict liability claim based on design defect against defendants.

The law on whether a living child can make a claim for damages it suffered in utero independent of its parents is well settled. The Supreme Court of New Jersey held for the first time in 1960 in the case of *Smith v. Brennan,* 31 *N.J.* 353 (1960) that a surviving child has a right in tort for prenatal injuries whether inflicted when the child was viable or not:

> ***8** We are not aware of a single case since *Stemmer v. Kline* was decided in 1942 in which a court of last resort, considering the question for the first time, denied the right of a child born alive to maintain a common law action for prenatal injuries. And as we have mentioned above at least four states have overruled prior decisions denying liability. Today it certainly cannot be said that there is any lack of precedent permitting such an action. Indeed, Dean Prosser has said the trend toward allowing recovery "is so definite and marked as to leave no doubt that this will be the law of the future in the United States." *Prosser, supra,* at *p.* 175.
>
> *Id.* at 361.

The New Jersey Supreme Court then held:

> We conclude that the reasons advanced for the decisions denying recovery to a child who survives a prenatal injury are inadequate. They deny basic medical knowledge; they ignore the protection afforded unborn children by other branches of the law, and are founded upon fears which should not weigh with the courts. We believe that a surviving child should have a right of action in tort for prenatal injuries for the plain reason that it would be unjust to deny it. Therefore, the rule of *Stemmer v. Kline* is no longer the law of this State.
>
> *Id.* at 366.

As to the requirement that the fetus be "viable" at the time of injury, the Supreme Court held:

> Whether viable or not at the time of the injury, the child sustains the same harm after birth, and therefore should be given the same opportunity for redress.
>
> *Id.* at 367.

All states except Alabama have allowed such claims. 40 *A.L.R.3d* 1222 (2005). In the Utah case of *Barson v. E.R. Squibb & Sons. Inc.,* 682 *P.2d* 832 (1984), the Supreme Court of Utah upheld a verdict for a minor plaintiff brought on her behalf by her parents as her guardians ad litem. The minor plaintiff had suffered severe birth defects after her mother was treated during her pregnancy with a hormone injection of a drug manufactured by E.R. Squibb. *Id.* at 834.

Sarah Clark, therefore, can have an action for design defect brought on her behalf if the law allows an action based on the facts of her claim. The Utah Products Liability Act ("UPLA") and the case law interpreting the UPLA generally provides immunity to a drug manufacturer for claims of design defect when the drug was approved by the FDA. *Grundberg, supra,* 813 *P.2d* at 91.

The Supreme Court of Utah in *Grundberg* states:

> We hold that a drug approved by the United States Food and Drug Administration ("FDA"), properly prepared, compounded, packaged, and distributed, cannot as a matter of law be "defective" in the absence of proof of inaccurate, incomplete, misleading, or fraudulent information furnished by the manufacturer in connection with FDA approval. We acknowledge that by characterizing all FDA-approved prescription medications as "unavoidably unsafe," we are expanding the literal interpretation of comment k.
>
> ***9** *Id.* at 90.

The complaint in this case at hand specifically alleges the FDA was provided inaccurate, incomplete and misleading information. Thus, the holding in *Grundberg* would not preclude a claim. The Utah statute substantially limits common law design defect claims in other ways. In the case of *Brown v. Sears. Roebuck & Co.,* 328 *F.3d* 1274, 1279 (2003), the United States Court of Appeals for the Tenth Circuit stated that Utah imposes additional "barriers" as they describe them to a cause of action. The Tenth Circuit

also found that the Utah statute does not allow a risk/utility test. *Id*. at 1281.

The *Brown* case specifically holds that the UPLA requires an objective consumers expectations test as the first barrier to a cause of action. *Id.* at 1282. The test is whether an objective consumer would anticipate the danger, and if so, then the product is not unreasonably dangerous. *Id.* In the *Brown* case, the court held the fact the victim was a child, not a purchaser or user of the product, did not change the requirement of the objective consumer expectation test. *Id.* Since the objective consumer given the warnings that accompanied Accutane would be aware of the danger, a cause of action for design defect under Utah law does not exist.

Pursuant to the NJPLA, there are three causes of action for a defective product. *N.J.S.A.* 2A:58C-2. In all cases, the plaintiff must prove "by a preponderance of the evidence that product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it" fits one of three criteria. *Id.* The first cause of action is a manufacturing defect, which is not alleged here. *Id.* The second cause of action is based on inadequate warnings, which has already been excluded. *Id.* The third is that the product was designed in a defective manner. *Id.*

Under the NJPLA, if "at the time the product leaves the manufacturer or seller, there is no feasible alternative design that would have prevented the harm without substantially impairing the reasonably anticipated use or intended function of the product," then the manufacturer is not liable. *N.J.S.A.* 2A:58c-3(1). This would seem to dispose of plaintiff's claim as no feasible alternative product is proposed by plaintiff. The statute goes on to state that the provisions above do not apply if the court finds by clear and convincing evidence:

(1) The product is egregiously unsafe or ultrahazardous

(2) The ordinary user or consumer of the product cannot reasonably be expected to have knowledge of the product's risk, *or* the product poses a risk of serious injury to persons other than the user or consumer; and

(3) The product has little or no usefulness."

N.J.S.A. 2A:58c-3b(1)-(3).

This court certainly could find that Accutane was egregiously unsafe under *N.J.S.A.* 2A:58c-3b(1) based on the allegations of the complaint. This court could also find that Accutane poses a risk of serious injury to persons other than the user or consumer under *N.J.S.A.* 2A:58c-3b(2). The product had no usefulness to the plaintiff Sarah Clark, but the product is a treatment for severe acne that is useful to many people and has been used with success by dermatologists for many years. The court finds, therefore, that there is no cause of action for strict liability on a design defect claim under the NJPLA.

***10** Plaintiffs also allege that defendants violated the NJCFA. The NJCFA describes fraud in connection with the sale or advertisement of merchandise (including prescription drugs) as unlawful practice. *N.J.S.A.* 56:8-2. Given the adequacy of the warnings that defendants provided to purchasers about birth defects, there can be no finding that defendants engaged in a violation of the NJCFA.

The Utah Consumer Sales Practices Act, *Utah Code Ann.* § 13-11-2 (1953) also focuses on deceptive sales practices but would not apply under these facts.

The complaint is dismissed as to all plaintiffs and all causes of action.

Motion GRANTED.

XXXX Order is attached.

All Citations

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KeyCite Yellow Flag - Negative Treatment
Distinguished by Knipe v. SmithKline Beecham, E.D.Pa., September 30, 2008

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Only the Westlaw citation is currently available.

UNPUBLISHED OPINION. CHECK COURT RULES BEFORE CITING.

Superior Court of New Jersey,
Law Division, Bergen County.

Geri Lynn ABRAMOWITZ, Plaintiff,
v.
CEPHALON, INC., ABC Corp., and John Doe (said names being fictitious), Defendants.

Argued March 3, 2006.
|
Decided March 3, 2006.

Attorneys and Law Firms

Alice Beime, appearing on behalf of plaintiff, Geri Lynn Abramowitz.

John F. Brenner, (McCarter & English, LLP) appearing on behalf of defendant, Cephalon, Inc.

DONOHUE, J.

ORDER GRANTING SUMMARY JUDGMENT AND DISMISSING ALL CLAIMS AGAINST DEFENDANT CEPHALON, INC.

*1 This matter having been opened to the Court on application by McCarter & English, LLP, counsel for defendant Cephalon, Inc., for the entry of an Order granting summary judgment and dismissing all claims against Cephalon, Inc. and the Court having considered the submissions of the parties, and for good cause shown,

IT IS on this *3* day of *March* 2006,

Ordered that defendant's motion be and hereby is granted; as to failure to warn & breach of warranty.

IT IS FURTHER ORDERED that all claims against Cephalon, Inc. hereby are dismissed; and denied as to design defect

IT IS FURTHER ORDERED that the defendant shall serve a copy of this Order within *7* days of receipt.

OPINION

This matter comes before this court on the defendant, Cephalon's, motion for summary judgment. This action arises from a products liability action in which the plaintiff, Gerri Lynn Abramowitz, alleges that the prescription drug Actiq® caused her to suffer massive tooth decay, which led to the removal of all but four of her natural teeth and their subsequent replacement with dentures. The plaintiff alleges that the defendant is liable under the causes of action of failure to warn of the possible side effects, producing a product with a defective design, and breech of warranty. The defendant has brought summary judgment motions for all the counts contained in the plaintiff's complaint.

The plaintiff is a 34-year old woman who was diagnosed with a non-cancerous brain tumor at the age of eight. The tumor was surgically removed; unfortunately the surgery left the plaintiff with chronic and debilitating physical problems. In or around 1997 and 1998 the plaintiff developed extreme pain. The plaintiff's pain management doctor, Dr. Pappragallo, prescribed Actiq® for the plaintiff in 2000, after other pain management therapies failed to control the plaintiff's pain. Actiq®, which is manufactured and distributed by the defendant, is intended to be used to manage the pain for cancer patients who are experiencing "break through" pains. Actiq® is not administered in pill form, but rather the active drug is on a lollypop type plastic dispenser. The drug enters the bloodstream by passing through the membranes in the mouth. This allows for faster absorption and more immediate relief then if the patient were to take a pill. The active ingredient in Actiq® is Fentanyl. Fentanyl possesses an unpleasant taste that must be masked in order that the drug can be used effectively. The defendant used sucrose and liquid glucose to mask the unpleasant taste of the Fentanyl. The plaintiff has alleged that the sucrose and liquid glucose rotted her teeth. The plaintiff claims that neither her prescribing doctor nor the nurse practioner who worked for Dr. Pappragallo advised her that taking

Actiq® could cause tooth decay. The plaintiff claims that she did not become aware of the possibility that Actiq® could cause tooth decay until September 2002, and even though she had already suffered significant tooth decay, she decided to continue to use Actiq® because her and her doctor determined that the benefits outweighed the risk of further injury.

***2** Since the plaintiff has conceded the issue of breach of warranty, that leaves only two questions for this court to answer. First, is if there is a question of fact as to whether the warnings contained in the package insert and provided to physicians are sufficient under state and federal law. The second question for this court is whether the plaintiff can establish a prima facie case for a defective design claim.

New Jersey has adopted the "learned intermediary" rule with regard to a pharmaceutical manufacturer's duty to warn the user of a drug of its side effects and dangerous propensities. The "learned intermediary" rule stands for the principal that a pharmaceutical manufacturer can discharge its duty to warn the ultimate users of a drug of any side effects the drug may cause by properly warning the doctor who prescribes the drug. *Bacradi v. Holzman,* 182 *N.J.Super.* 422, 425, 442 A.2d 617 (App.Div.1981). In this case it is undisputed that the defendant included a warning about the side effects, which the plaintiff ultimately suffered. The FDA approved package insert and the information provided to physicians stated the following.

> Inactive Ingredients: Sucrose, liquid glucose (2000 PDR)
>
> Adverse Reactions:
>
> Digestive: tooth caries, tooth disorder (2000 PDR)
>
> Information for Patients and Their Caregivers (2002 product instructions and warnings).

Frequent consumption of sugar-containing products many increase the risk of dental caries (each Actiq unit contains approximately 2 grams of sugar [sucrose, liquid glucose]). The occurrence of dry mouth associated with the use of opioid medications (such as Fentanyl) may add to this risk. Therefore, patients using Actiq® should consult their dentist to ensure appropriate oral hygiene.

The warnings in 2000 and 2002 clearly inform the doctor and, by way of the "learned intermediary" rule, the patient also that sugar is present in Actiq® and that tooth decay is a possible side effect. This issue before this court is whether these warnings were sufficient.

N.J.S.A. § 2A:58C-4 states:

> In 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 ... An adequate 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 ordinary knowledge common to, the persons by whom the product is intended to be use, or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician.

This statue, while limiting liability when an adequate warning label is used, leaves open a state claim for liability under failure to warn if the plaintiff can establish that the warning provided by the manufacturer was not an "adequate product warning or instruction" under the statute.

***3** Although *N.J.S.A.* § 2A:58C-4 offers an avenue to pursue a failure to warn claim, the New Jersey courts have limited the availability of such a claim when the warnings have been FDA approved. The New Jersey Supreme Court has found that any duty to warn physicians about prescription drug dangers is presumptively met by compliance with federal labeling and that compliance with FDA regulations serves as compelling evidence that a manufacturer satisfied its duty to warn the physician about potentially harmful side effects of its product. However, that presumption is not absolute. *Perez v. Wyeth Laboratories,* 161 *N.J.* 1, 24, 734 A.2d 1245 (1999).

Using the standard laid out in *N.J.S.A.* § 2A:58C-4 and considering the authority that New Jersey case law grants to FDA approval, this court finds that a reasonable juror could not find that the defendant did not provide an adequate warning. The plaintiff's doctor was provided with information that sugars were present in Actiq®. The warning stated that use of the drug could lead to tooth caries or a tooth disorder.

In this case the plaintiff suffered from tooth caries or the rotting of the teeth. Although it is very unfortunate injury, the plaintiff was warned through her doctor that this could happen. The plaintiff has indeed suffered a loss, but our legislatures and courts have determined that plaintiffs can not pursue a failure to warn claim for injuries they suffer as a result of taking a prescribed drug if that injury or side effect was included in an approved warning.

The court has considered that the defendant did receive 250 Med Watch forms from prescribing doctors reporting instances of tooth decay. However, the court agrees with the defendant that 250 reports out of the millions of prescriptions that were written is a negligible amount and falls within the 1% occurrence that the defendant warned could occur. Furthermore, the court finds that there is no evidence to suggest that the defendants attempted to hide or suppress this information. The defendants reported the occurrences to the FDA as is required by federal law.

This court has found that that there is insufficient evidence for the plaintiff to pursue a failure to warn claim against the defendant under New Jersey state law. However, absent this finding it is the court's opinion that pursuant to the newly released federal regulation, the FDA's decision to approve the defendant's label for Actiq® would preempt a state claim for failure to warn.

In The Federal Register, Vol. 71, No. 15, Tuesday, January 24, 2006, the FDA issued a regulation stating that it "believes that under existing preemption principals, FDA approval of labeling under the act, whether it be in the old or the new format, preempts conflicting or contrary state law." While this court recognizes that that federal regulation does not preempt all state claims, it does find that this particular claim would be preempted. In this instance the plaintiff is claiming that an FDA approved label was insufficient, and hence, that the FDA decision to approve the label was inappropriate. It is clear that FDA has assumed authority over the regulation and approval of pharmaceutical labels in the United States, and therefore, any state claim that would challenge an FDA approved warning is preempted.

***4** The New Jersey courts have addressed the issue of preemption of state claims by federal regulations. In *R.F. v. Abbott Laboratories,* 162 *N.J.* 596, 620, 745 A.2d 1174 (2000), the New Jersey Supreme Court found that a state law can be preempted by a federal regulation when the federal agency intends to preempt state law and the agency was acting within the scope of it authority. In the instant case, the FDA clearly intends for FDA approval of labels, both those approved in the past and those to be approved, to preempt state claims. The FDA is acting within its authority and, as such, the New Jersey state claim is preempted in this matter. The newly released regulation is not a blanket prohibition against state claims, but rather, the FDA delineates what type of state claims are preempted and what state claims can go forward. While recognizing that the FDA is not a judicial body, this court must respect its decision with regard to preemption of state claims for failure to warn as per the New Jersey Supreme Courts decision in *RF v. Abbott Laboratories.*

For the reasons stated the defendants motion for summary judgment on the failure to warn claim is granted.

The second issue this court must address is whether or not the plaintiff can establish a prima facie case for defective design. *N.J.S.A.* 2A:58C-3(a) lays out the limitations of products liability claim premised on defective design; the statute states a manufacturer shall not be liable if:

> (1) At the time the product left the control of the manufacturer, there was not a practical and technically feasible alternative design that would have prevented the harm without substantially impairing the reasonably anticipated or intended function of the product; or
>
> (2) The characteristics of the product are known to the ordinary consumer or user, and the harm was caused by an unsafe aspect of the product that is an inherent characteristic of the product and that would be recognized by the ordinary person who uses or consumes the product with the ordinary knowledge common to the class of persons for whom the product is intended, except that this paragraph shall not apply to industrial machinery or other equipment used in the

workplace and it is not intended to apply to dangers posed by products such as machinery or equipment that can feasibly be eliminated without impairing the usefulness of the product; or

(3) The harm was caused by an unavoidably unsafe aspect of the product and the product was accompanied by an adequate warning or instruction as defined in section 4 of this act.

The question of whether there was a technically feasible alternative design that would have prevented the harm without substantially impairing the reasonably anticipated use is a question of fact. The plaintiff's expert contends that such a design existed the defendants contend that it did not.

Part three asks if the harm was caused by an "unavoidably unsafe aspect of the product" and whether the product was accompanied by an adequate warning. This court has already established that the warning provided by the defendants was indeed adequate. However, the issue of whether the plaintiff lost her teeth due to an "unavoidably unsafe aspect" of the product is less clear. The plaintiff suffered her injury as a result of the sugars that were put in Actiq® to mask the taste of the active ingredient. Had the tooth decay been caused by the Fentanyl, then it would be clear that the defendant would be shielded from liability. However this court finds that the question of whether the use of sugar in the Actiq® produced in 2000 was unavoidably unsafe or whether another product could have been used is a question of fact for jury to decide. Therefore the defendant's motion for summary judgment on the design defect claim is denied.

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