[J-69A-2011 and J-69B-2011] [MO: Saylor, J.]
IN THE SUPREME COURT OF PENNSYLVANIA
EASTERN DISTRICT

PATSY LANCE, ADMINISTRATRIX FOR THE ESTATE OF CATHERINE RUTH LANCE, DECEASED, Appellee v. WYETH, FORMERLY KNOWN AS AMERICAN HOME PRODUCTS CORPORATION, Appellant	: No. 17 EAP 2011 : : Appeal from the Judgment of Superior Court entered on 08/02/2010 at No 2905 EDA 2008, (reargument denied on 10/01/2010) affirming in part, reversing in part, and remanding in part the Judgment entered on 09/19/2008 in the Court of Common Pleas, Philadelphia County, Civil Division at No. 0926, November Term 2006. : : ARGUED: September 13, 2011

PATSY LANCE, ADMINISTRATRIX FOR THE ESTATE OF CATHERINE RUTH LANCE, DECEASED, Appellant v. WYETH, FORMERLY KNOWN AS AMERICAN HOME PRODUCTS CORPORATION, Appellee	: No. 18 EAP 2011 : : Appeal from the Judgment of Superior Court entered on 08/02/2010 at No 2905 EDA 2008, (reargument denied on 10/01/2010) affirming in part, reversing in part, and remanding in part the Judgment entered on 09/19/2008 in the Court of Common Pleas, Philadelphia County, Civil Division at No. 0926, November Term 2006. : : ARGUED: September 13, 2011

DISSENTING OPINION

MR. JUSTICE EAKIN **DECIDED: January 21, 2014**

I express no opinion on the underlying wisdom of adopting "negligent design defect" as a viable Pennsylvania cause of action against pharmaceutical companies. I

must dissent, however, as I believe the issue is not properly before us — if we are to acknowledge a new theory of liability, it should only be after full advocacy. That requires the issue be properly raised and preserved, not intuited into what is presented to us, a basic notion of appellate review. We have not heretofore created such a basis of liability; appellee, the Superior Court, and the majority fail to cite a single Pennsylvania case involving such a cause of action. It was not the issue before the Superior Court, which erred in raising it sua sponte.

This Court has repeatedly emphasized the importance of issue preservation and the role it plays in appellate due process. See, e.g., In re F.C. III, 2 A.3d 1201, 1211-12 (Pa. 2010) (citations omitted) (noting both fairness and judicial economy implicated by issue preservation). Here, appellee did not raise "negligent design defect" in her Rule 1925(b) statement. She did not include such a claim in her Superior Court Statement of Questions Involved, which specifically concern "negligent marketing" and "failure to withdraw" claims, and nothing more. Although she mentioned a "design defect" cause of action in her Superior Court brief, appellee did not develop the argument, nor did she cite any authority to support it. Any one of these omissions is sufficient to constitute waiver. See Pa.R.A.P. 1925(b)(4)(vii), 2116(a); Commonwealth v. Cox, 72 A.3d 719, 721 n.3 (Pa. Super. 2013) (citation omitted) ("[W]aiver of an issue results when an appellant fails to properly develop an issue or cite to legal authority to support his contention in his appellate brief."). Collectively, this issue is clearly not preserved.

Notwithstanding appellee's waiver of the issue, the Superior Court considered the "negligent design defect" claim sua sponte, formulating its own analysis and citing its own

authority.[1] In doing so, the court erred. See Steiner v. Markel, 968 A.2d 1253, 1257 (Pa. 2009) (citations omitted) ("Where the parties fail to preserve an issue for appeal, the Superior Court may not address that issue sua sponte."). Although this Court has, on rare occasion, made an exception to our waiver rules when determining whether a complaint states a valid cause of action, see McHugh v. Litvin, Blumberg, Matusow & Young, P.C., 574 A.2d 1040, 1042 (Pa. 1990) (citing Jefferson Memorial Park v. West Jefferson Hills School District, 156 A.2d 861, 863-64 (Pa. 1959)), our recent decision in Steiner makes clear that where an issue is neither preserved nor argued, the Superior Court is precluded from addressing it sua sponte. See Steiner, at 1257-60.

Faced with the Superior Court's disposition on a claim Wyeth considered abandoned,[2] Wyeth promptly requested reconsideration or reargument, pointing out that the issue was not properly before the court and asking that the "negligent design issue ... be the subject of full briefing and reargument[.]" Wyeth's Application for Panel Reconsideration or En Banc Reargument, at 9. However, the Superior Court denied the request, denying Wyeth the appellate review and due process to which it was entitled.

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[1] The court's reliance on an inapplicable section of the Restatement (Second) of Torts is an example of the pitfalls of appellate courts advocating on behalf of the litigants before it. See Lance v. Wyeth, 4 A.3d 160, 166 (Pa. Super. 2010) ("The Restatement (Second) of Torts, § 395 addresses a manufacturer's negligent design of products.").

[2] Wyeth's belief that appellee abandoned the negligent design defect claim is evidenced by its discussion of appellee's arguments to the Superior Court. See Wyeth's Superior Court Brief, at 10 ("In an attempt to avoid dismissal of her claim, [p]laintiff has postured two alternative causes of liability. First, Wyeth negligently placed Redux on the market. Second, Wyeth failed to timely withdraw Redux from the market.").

The majority believes Wyeth was not denied appellate due process because appellee's substantive claim for relief centered on Wyeth's responsibility for producing a bad drug; it claims Wyeth "plainly understood" its negligent design of Redux was appellee's "central allegation," citing Wyeth's submissions. Majority Slip Op., at 24. Of course, that was a central allegation, but a factual allegation does not comprise the statement of a theory of liability. Wyeth did refer, repeatedly, to the unreasonably dangerous and defective design of Redux as the "central allegation" of appellee's complaint, but that complaint expressly delineated theories of liability to which the factual allegation was central — alternatively, negligent marketing and failure to withdraw. Wyeth had every reason to believe a separate "design defect" claim was abandoned when it was not discussed in appellee's response to summary judgment, not raised in her Rule 1925(b) statement, not listed in her Statement of Questions Involved, and not developed in the Superior Court beyond a few conclusory statements in her brief.

Appellee's use of the term "negligent marketing," a claim related to how a product is promoted rather than designed, and the factual averments and legal arguments she put forth under that rubric show she did not preserve a "negligent design defect" claim by presenting a "negligent marketing" claim.[3] "Negligent marketing" claims involve a manufacturer's promotion of a product in a way that increases the risk of consumers

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[3] I discuss only "negligent marketing" because there appears no colorable argument that appellee's "failure to withdraw" claim, which alleges Wyeth negligently kept the drug on the shelves after receiving reports of its side effects, preserved a claim that the product should not have been developed and sold to begin with, given the temporal separation between the two allegations and the different types of evidence necessary to prove them.

injuring themselves or others.[4] They typically fall under one of the following three categories: (1) marketing toward unsuitable users; (2) failing to supervise retail sellers; or (3) encouraging the marketing/distribution of the product in a way that increases the risk of harm, known as "overpromotion." Id. "[S]ince negligent marketing focuses on the marketing process rather than whether the product is defective," and therefore "allows parties who sue under this theory to sidestep the defect issue[,]" id., at 913, substituting "negligent marketing" for "negligent design defect" is more than a stylistic change.

Here, in addition to labeling her claim "negligent marketing," appellee pled facts in her complaint directly relevant to the "negligent marketing" theory described above, specifically, "overpromotion," and has cited authority in support of that theory. First, the long-form complaint, which appellee incorporated by reference into her short-form complaint,[5] alleged Redux and its derivatives had been "aggressively marketed often by encouraging unapproved off-label combination use of the products."[6] More important, in

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[4] See, e.g., Richard C. Ausness, Will More Aggressive Marketing Practices Lead to Greater Tort Liability for Prescription Drug Manufacturers?, 37 Wake Forest L. Rev. 97, 123 (2002). While "negligent marketing" claims can be based on a product's design, such claims normally involve a product with a particular design feature that increases the risk of harm by enhancing its attractiveness to unsuitable users, not a product claimed to be defective by design for all users. See Richard C. Ausness, Tort Liability for the Sale of Non-Defective Products: An Analysis and Critique of the Concept of Negligent Marketing, 53 S.C. L. Rev. 907, 912 (2002) (citation omitted).

[5] Short-Form Complaint, 11/13/06, at 1.

[6] Master Long-Form Complaint, 5/17/99, at 16. Interestingly, Ausness, supra, used Redux litigation as an example of "negligent marketing" claims based on this type of "overpromotion" and outlined the very argument appellee incorporated from the long-form complaint. See Ausness, 37 Wake Forest L. Rev. at 134-35 ("The recent experience with the diet drug, Fen-Phen, illustrates another aspect of negligent marketing, the promotion of 'off-label' uses by product manufacturers. … [I]f there is further litigation, (continued…)

both her response to Wyeth's summary judgment motion and her Superior Court brief, appellee claimed Baldino v. Castagna, 478 A.2d 807 (Pa. 1984), "acknowledged the validity of [her] negligent marketing theory of liability against a drug manufacturer" when it described the holding of Incollingo v. Ewing, 282 A.2d 206 (Pa. 1971), as "'recogniz[ing] a cause of action against drug manufacturers for the overpromotion of a drug that nullif[ies] otherwise adequate warnings.'" Appellee's Response in Opposition to Wyeth's Motion for Summary Judgment, 4/21/08, at 7 (quoting Baldino, at 810); Appellee's Superior Court Brief, at 10 (quoting Baldino, at 810). While in many other parts of her pleadings and briefs appellee may have implicated the design of Redux by couching her "negligent marketing" claim in terms of the safety of the drug itself, I believe her decision to also incorporate factual averments and legal arguments directly under the "negligent marketing" framework, a framework that does not involve proof of a design defect, makes her phrasing of the claim dispositive. Thus, by couching her claim on appeal as one for "negligent marketing" instead of "negligent design defect," she preserved her claim for the former and waived any claim for the latter.[7]

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plaintiffs are likely to argue that the manufacturers of Fen-Phen encouraged doctors to prescribe these drugs for mildly overweight people when little was known about the possible effects of long-term use or use of these drugs in combination with each other.").

[7] The majority approves the Superior Court allowing appellee to have her cake and eat it too. Many courts faced "negligent marketing" claims, similar to the one here, in firearms litigation, but saw through plaintiffs' attempts to sidestep the defect issue by phrasing their negligence claims as claims for "negligent marketing." See Timothy D. Lytton, Halberstam v. Daniel and the Uncertain Future of Negligent Marketing Claims Against Firearms Manufacturers, 64 Brook. L. Rev. 681, 684 (1998) (discussing "tendency among courts to view negligent marketing claims against firearms manufacturers as being essentially design defect claims in disguise and to insist that plaintiffs allege a defective (continued...)

The majority attempts to discredit Wyeth's assertion it was not afforded a fair opportunity to respond in the Superior Court by suggesting Wyeth itself equated the "negligent design defect" theory to the claims that were properly preserved; this is somewhat misleading. See Majority Slip Op., at 24-25. Having been surprised at the Superior Court, Wyeth points out that appellee omitted what it considers a necessary element of any "negligent design defect" claim — namely, a feasible alternative design — and relied solely upon the arguments she used to support her "negligent marketing" and "failure to withdraw" claims below; hence, she has merely "repackage[d]" those claims into one and labeled it a "negligent design defect" claim.[8] Wyeth made this same

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condition in the weapon in order to recover"). Similarly, even if Redux's defective design is appellee's "central allegation," she should not be allowed to label her claim "negligent marketing" and avoid the traditional proof requirements for "design defect" claims.

[8] The quoted passages read as follows:

> Plaintiff's failure to put forth any feasible alternative design makes clear that her "negligent design defect" cause of action is nothing more than disguised claims that Redux should never have been approved by the FDA, or should have been withdrawn sooner than it was — claims that even the Superior Court recognized are not cognizable under Pennsylvania law.
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> Plaintiff's purported "negligent design defect" claim necessarily conflicts with the deference afforded under Pennsylvania law to FDA-approved designs, because, as noted above, Plaintiff did not even attempt to plead a feasible alternative design. As such, what Plaintiff passes off as a "negligence" theory is in reality more onerous even than strict liability, which requires proof of alternative designs. Plaintiff has argued that, despite FDA approval, Redux should never have been marketed at all, or should have been removed from the market. Because these allegations serve as the sole basis of Plaintiff's newfound "negligent design defect" claim in this case, this is simply an attempt to resuscitate

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argument — that appellee did not plead the elements of a "negligent design defect" claim — in its application for reconsideration or reargument. Wyeth's Application for Panel Reconsideration or En Banc Reargument, at 9-11.

By making these statements, Wyeth does not expressly or implicitly concede the arguments appellee now offers in support of her "negligent design defect" claim are the same as the ones she offered in support of her "negligent marketing" and "failure to withdraw" claims below — even if Wyeth did make such a concession, it would not follow that Wyeth conceded the three are equivalent or, more important, that the legal and public policy arguments it would have put forth to challenge the former are the same as those it put forth to challenge the latter.[9] Thus, I believe these statements do little to establish that, notwithstanding appellee's obvious waiver of the claim at various stages of this litigation, Wyeth had anything approaching a full and fair opportunity in the Superior Court to respond to whether "negligent design defect" is an appropriate avenue for redress in prescription drug cases.

The majority also states it was Wyeth's obligation to "address the landscape of potential claims which it wants extinguished" since it argued claims against drug companies were limited to those involving manufacturing defects and inadequate warnings. Majority Slip Op., at 25. I disagree. As I see it, Wyeth sought to preclude

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> and repackage Plaintiff's improper "negligent marketing" and/or "negligent failure to remove" claims.

Appellant's Brief, at 11, 35 (internal citations omitted).

[9] Indeed, Wyeth has made substantive arguments to this Court that it had no reason to make below, to wit, appellee's failure to set forth a feasible alternative design, as it understandably considered the "design defect" claim waived.

the creation of new claims, not "extinguish" ones already in existence. At trial, the burden was on appellee; as appellant in the Superior Court, the burden to preserve and develop the "design defect" theory of liability was hers, not Wyeth's. See Pa.R.A.P. 1925(b); Heim v. Medical Care Availability and Reduction of Error Fund, 23 A.3d 506, 511 (Pa. 2011) (citation omitted) (noting appellee does not bear burden of issue preservation). Relieving appellee of her burden to properly raise and preserve the "negligent design defect" theory because of the relief sought by Wyeth is, in my judgment, unwarranted.

In sum, I believe the Superior Court erred by addressing an issue not preserved or developed by the parties. Given the significant public policy implications of allowing "negligent design defect" claims to be brought in prescription drug cases, this Court should wait for a full, developed record on a properly preserved claim, in order that we may consider advocacy on both sides expressing the various incentives and disincentives created by changing this area of products liability law. Accordingly, I would reverse the decision of the Superior Court as to the "negligent design defect" claim and remand for consideration of those claims properly raised and preserved.

Mr. Chief Justice Castille joins this dissenting opinion.