[J-69A&B-2011]
IN THE SUPREME COURT OF PENNSYLVANIA
EASTERN DISTRICT

CASTILLE, C.J., SAYLOR, EAKIN, BAER, TODD, McCAFFERY, ORIE MELVIN, J.

PATSY LANCE, ADMINISTRATRIX FOR THE ESTATE OF CATHERINE RUTH LANCE, DECEASED,	: No. 17 EAP 2011
Appellee	: Appeal from the Judgment of Superior Court entered on 8/2/10 at No. 2905 EDA 2008, (reargument denied on 10/1/10) affirming in part, reversing in part, and remanding in part the judgment entered on 9/19/08 in the Court of Common Pleas, Philadelphia County, Civil Division at No. 0926 November Term 2006
v.	
WYETH, FORMERLY KNOWN AS AMERICAN HOME PRODUCTS CORPORATION,	: 4 A.3d 160 (Pa. Super. 2010)
Appellant	: ARGUED: September 13, 2011

PATSY LANCE, ADMINSTRATRIX FOR THE ESTATE OF CATHERINE RUTH LANCE, DECEASED,	: No. 18 EAP 2011
Appellant	: Appeal from the Judgment of Superior Court entered on 8/2/10 at No. 2905 EDA 2008 (reargument denied on 10/1/10) affirming in part, reversing in part, and remanding in part the judgment entered on 9/19/08 in the Court of Common Pleas, Philadelphia County, Civil Division at No. 0926, November Term 2006
v.	
WYETH, FORMERLY KNOWN AS AMERICAN HOME PRODUCTS CORPORATION,	: 4 A.3d 160 (Pa. Super. 2010)
Appellee	: ARGUED: September 13, 2011

OPINION

MR. JUSTICE SAYLOR[1] **DECIDED: January 21, 2014**

This appeal concerns whether, under Pennsylvania products-liability law, a pharmaceutical company is immune from the responsibility to respond in damages for a lack of due care resulting in personal injury or death, except per two discrete grounds, namely, on account of drug impurities or deficient warnings.

The designated appellant, Wyeth, was a Delaware corporation,[2] previously known as American Home Products Corporation. The company manufactured and/or supplied two related appetite suppressants which were prescribed by physicians and weight-loss clinics prolifically in the mid-1990s. The trade names of these pharmaceutical cousins were Pondimin and Redux.

Pondimin was fenfluramine, of which the active, appetite-suppressing ingredient was dexfenfluramine. Fenfluramine apparently was available since the 1970s but was not widely administered until two decades later.

In 1992, Pondimin came to be paired with phentermine, an amphetamine which was thought to offset at least some of the undesirable effects of fenfluramine. This drug regimen gave rise to the shorthand terms, "fen-phen" and "phen-fen." See generally In re Diet Drugs, 582 F.3d 524, 529-30 (3d Cir. 2009) (discussing this history); In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prod. Liab. Litig., 553 F. Supp.2d 442, 449-50 (E.D.Pa. 2008) (same).

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[1] This matter was reassigned to this author.

[2] Apparently, during the course of this litigation, Wyeth was acquired by Pfizer, Inc., and, after some internal restructuring, converted to a Delaware limited liability company known as Wyeth LLC. See, e.g., Okuda v. Pfizer, Inc., No. 1:04–cv–00080, slip op., 2012 WL 2602595, at *2 (D. Utah July 5, 2012).

Redux, which was purified dexfenfluramine, apparently was made to engender Pondimin's anorectic effect without the need for the drug pairing.[3] Redux was approved for use as a prescription drug in the United States by the Food and Drug Administration (the "FDA") in April 1996. Per the FDA's directive, the product packaging contained a prominent warning of an increased risk of pulmonary hypertension ("PPH").

By mid-1997, there were also reports of an association between dexfenfluramine and serious coronary impairments, including valvular heart disease. In September 1997, Wyeth and the FDA announced that Pondimin and Redux would no longer be made available in the United States. In the aftermath, thousands of lawsuits were filed asserting that the drugs caused injuries and deaths. See generally In re Diet Drugs, 553 F. Supp. 2d at 449 (characterizing the phenomenon as a "tidal wave of litigation"). The present civil action is one among these.

The case was commenced against Wyeth and affiliated entities in the fall of 2006 and was integrated into the First Judicial District Complex Litigation Center's mass tort program under an apparently loose application of the "phen-fen" denominator.[4] Pursuant to this program, Appellee (as the decedent's administratrix) lodged a short-form complaint, incorporating by reference the averments of a general master long-form complaint advanced against Wyeth and about two dozen other defendants under the docket, In re: "Phen-Fen" Litigation in Philadelphia Court of Common Pleas, May Term 1999, No. 0001. Appellee alleged that her daughter, Catherine Lance, ingested Redux

[3] According to Wyeth, dexfenfluramine was developed by a French company, Les Laboratoires Servier, which licensed the patent to Interneuron Pharmaceuticals, Inc.; whereas, eventually, Wyeth entered into a co-promotion agreement with Interneuron to market dexfenfluramine in the United States. See Wyeth's Motion for Summary Judgment at 3, Lance v. Wyeth, Nov. Term 2006, No. 000926 (C.P. Phila. Jan. 7, 2010).

[4] Wyeth explains that Redux is not "phen-fen," although it may sometimes have been prescribed with phentermine (resulting in a pairing sometimes dubbed "dexen-phen").

for several months in 1997 and that the drug caused PPH, from which she died within a month after her diagnosis in 2004.

Appellee couched her central claim as "Negligence – Unreasonable Marketing of a Dangerous Drug and Unreasonable Failure to Remove the Drug from the Market before January 1997." Short-Form Complaint at ¶12, Lance v. Wyeth, Nov. Term 2006, No. 000926. According to the complaint, Wyeth "owed a duty to [Catherine] not to introduce onto the market a drug that was unreasonably dangerous for any person to use," and Redux was "so unreasonably dangerous and defective in design that it should never have been on the market." Id. ¶¶13-14. An incorporated count from the master long-form complaint asserted that Wyeth "failed to exercise ordinary care in the design, research, development, manufacture, sale, testing, . . . and/or distribution of," inter alia, Redux. See Gen. Master Long-Form Complaint at ¶65, In re Phen-Fen, May Term, 1999, No. 1. Notably, as well, Appellee explicitly stated that she was not advancing a claim based upon inadequate labeling.

Wyeth lodged a motion for summary judgment, arguing that Appellee had failed to assert a cognizable cause of action. Centrally, Wyeth contended that the only allegations which would support liability against a pharmaceutical company based upon adverse effects from the use of a prescription drug were of impurities or deficient warnings. In furtherance of its theory that drug manufacturers should be shielded from products liability under any other legal theory, Wyeth discussed: the role of federal regulation, including the FDA's decision to approve Redux as safe and effective for prescription use;[5] the positioning of learned intermediaries (i.e., physicians) in a

[5] In terms of the FDA's view of Redux's risks as compared with its benefits, Wyeth also highlights that, in August 1997, four months after Catherine Lance stopped taking the drug, the agency denied a petition calling for the drug's withdrawal from the market, stating as follows:
(continued…)

decision-making role relative to the appropriate use of the drug in individual cases;[6] and this Court's refusal to extend strict liability to prescription drug manufacturers, see Hahn v. Richter, 543 Pa. 558, 560, 673 A.2d 888, 889 (1996), consistent with the treatment for "unavoidably unsafe products" reflected in comment k to Section 402A of the Restatement Second of Torts. RESTATEMENT (SECOND) OF TORTS §402A cmt. k (1965) (specifying a main avenue for pursuing strict products liability, per a widely accepted formulation of the American Law Institute).

The terms of comment k are set forth here, since these remarks are discussed prominently throughout the present litigation:

> k. Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite

(…continued)

> You make three claims in your petition: (1) Redux is not safe and effective; (2) Redux was not approved in conformity with the [FDCA] and applicable FDA regulations; and (3) the manufacturer of Redux has not submitted post marketing data to the FDA.
>
> The FDA finds the first of these claims to be without substantiation, and the second and third to be incorrect.

Wyeth's Motion for Summary Judgment at 4, Lance v. Wyeth, Nov. Term 2006, No. 000926 (quoting FDA letter denying citizen petition filed Aug. 14, 1997).

Although it was not Wyeth's main point at present, the company also contended that, in light of the involvement of strong federal regulation, federal law preempted Pennsylvania state tort law vis-à-vis FDA-regulated pharmaceuticals.

[6] Per the learned intermediary doctrine, the manufacturer's duty to warn is directed to physicians. See Incollingo v. Ewing, 444 Pa. 263, 288, 282 A.2d 206, 220 (1971) ("Since the drug was available only upon prescription of a duly licensed physician, the warning required is not to the general public or to the patient, but to the prescribing doctor." (citing Stottlemire v. Cawood, 213 F. Supp. 897, 899 (D.C. 1963)), overruled on other grounds, Kaczkowski v.Bolubasz, 491 Pa. 561, 421 A.2d 1027 (1980).

> incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warnings, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held strictly liable for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Id. (emphasis modified).

In the simplest terms, Wyeth expressed its position as follows:

> In essence, Plaintiff asserts that even though Wyeth adequately warned about all of the risks of Redux, and even though the FDA determined that Redux was both safe and effective and approved it for sale, the FDA was wrong and Redux should not have been on the market. Pennsylvania does not recognize such a claim for prescription drugs.

Wyeth's Motion for Summary Judgment at 2, Lance v. Wyeth, Nov. Term, No. 000926. According to Wyeth's submission, as well, "[j]uries and the judiciary do not have the requisite knowledge, resources, or societal mandate to make the decision as to a

prescription drug's relative worth." Id. at 7 (quoting Hahn v. Richter, 427 Pa. Super. 130, 151-52, 628 A.2d 860, 871 (1993) (Cavanaugh, J., concurring), aff'd, 543 Pa. 558, 673 A.2d 888 (1996)).

In its summary judgment motion, Wyeth did acknowledge that Redux ultimately was removed from the U.S. marketplace, but the company posited that this did not occur on account of the relationship between the drug and PPH, but, rather, because of "new, preliminary information" related to the risk of valvular heart disease. Id. at 4-5 (quoting Wyeth Notice of Withdrawal, dated Sep. 15, 1997).[7] In terms of what was conveyed to physicians about Redux, Wyeth stressed that the approved label featured a bold-faced warning of the risk of PPH.

The common pleas court granted summary judgment in favor of Wyeth. In doing so, that court initially (and mistakenly) attributed to this Court the following explanation from a decision of the Superior Court:

> Because of the desirability of permitting drugs of proven value to be marketed despite known or suspected risks in said drugs, courts have uniformly held that "a drug, properly tested, labeled with appropriate warnings, approved by the [FDA], and marketed properly under federal regulation, is, as a matter of law, a reasonably safe product. Accordingly, a person claiming to have suffered adverse effects from using such a drug, unless he can prove an impurity or an inadequacy in labeling, may not recover against the seller[."]

[7] As with several other factual assertions by Wyeth, Appellee contests the notion that the PPH risk had nothing to do with the withdrawal of Redux from the marketplace. See, e.g., Reply Brief for Cross-Appellant at 4 ("[I]n fact it is clear that the medication's overall risk profile, consisting of both PPH and [valvular heart desease] risks, led to the FDA's decision to prohibit entirely the use of Redux's active ingredients by anyone."). As further discussed below, in the present procedural posture of this case, the facts are viewed in the light most favorable to Appellee, putting a number of Wyeth's contested, subsidiary, fact-based assertions outside the scope of our present undertaking.

Lance v. Wyeth, Inc., Nov. Term 2006, No. 0926, slip op. at 5 (C.P. Phila. Jan. 7, 2010) (quoting Leibowitz v. Ortho Pharmaceutical Corp., 224 Pa. Super. 418, 433-34, 307 A.2d 449, 458 (1973) (en banc affirmance by an equally divided court) (quoting, in turn, Lewis v. Baker, 413 P.2d 400, 404 (Or. 1966))). Consistent with this reasoning (albeit, that of a lead opinion from a divided intermediate appellate court), the common pleas court credited Wyeth's theory of limited liability. Furthermore, the court indicated that the learned-intermediary doctrine "nullifies [the] novel claim by Plaintiff that [Redux] was unreasonably dangerous and unfit to be prescribed to anyone." Id. at 8.

On Appellee's appeal, a three-judge panel of the Superior Court (with one judge concurring in the result) found that Appellee should have been permitted to proceed with a claim of negligent design defect only. See Lance v. Wyeth, 4 A.3d 160 (Pa. Super. 2010). With regard to Appellee's assertion of negligence, on Wyeth's part, in the company's marketing of Redux, the panel reconceptualized this claim as one asserting strict liability.[8] Having done so, the panel then credited Wyeth's position, at least in part,

[8] The panel's reasoning in analyzing a negligence claim as one sounding in strict liability is neither clear nor apt. Initially, it seems that the panel equated the phrase "products liability" with "strict liability." See Lance, 4 A.3d at 164-65 (rejecting Appellee's claim of "Negligence—Unreasonable Marketing of a Dangerous Drug" because the "purported cause of action is a design defect claim sounding in products liability," followed by a treatment of the law of strict products liability). It also appears that the panel believed that the phrase "unreasonably dangerous" was unique to strict-liability theory. See id. at 165 (positing that "[a]lthough [Appellee] labels her claim as 'negligent and unreasonable marketing,' her proposed cause of action duplicates a design defect claim, seeking to impose strict liability on Wyeth because Redux was unreasonably dangerous").

To the contrary, however, strict liability is merely a subset of products liability law. But see David G. Owen, M. Stuart Madden & Mary J. Davis, OWENS HORNBOOK ON PRODUCTS LIABILITY §5.9 (3d ed. 2013) (explaining that strict liability, negligence, and warranty theory are each "principal theories of products liability" law). Moreover, the phrase "unreasonably dangerous" is derived from negligence theory; indeed, such derivation was the very justification employed by this Court in a seminal decision eschewing use of the term "unreasonably dangerous" before jurors in the strict-liability (continued…)

by reaffirming that the only two bases supporting strict products liability relative to a pharmaceutical company are manufacturing defect (or impurity) and failure to warn appropriately. See id. at 164-65 (citing, inter alia, Hahn, 543 Pa. at 560-61, 673 A.2d at 889-90, and RESTATEMENT (SECOND) OF TORTS §402A cmt. k)).

The panel next rejected Appellee's allegation that Wyeth negligently failed to withdraw Redux from the market, based on its reading of prior decisions refusing to impose a duty on manufacturers to recall or retrofit products. See Id. at 167 (citing, inter alia, Lynch v. McStome & Lincoln Plaza Assoc., 378 Pa. Super. 430, 440, 548 A.2d 1276, 1281 (1998)). As to this claim, the panel recognized a post-sale duty to warn but "defer[red] to the federal regulatory scheme and the FDA's decision as to whether a drug should lawfully remain on the market." Id. at 167. In terms of a duty to test, the panel reasoned that such allegation does not support a freestanding claim, but, rather, is merely subsumed within the principal liability theories. See id. at 169 (citing, inter alia, Kociemba v. G.D. Searle & Co., 707 F. Supp. 1517, 1527 (D. Minn. 1989)).

As previously noted, however, the panel credited Appellee's position that it had asserted a cognizable claim of negligent design defect against Wyeth. Initially, the panel discussed the distinction between strict-liability and negligence as follows:

> "Strict liability examines the product itself, and sternly eschews considerations of the reasonableness of the

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(…continued)
setting. See Azzarello v. Black Bros. Co., 480 Pa. 547, 555, 391 A.2d 1020, 1025 (1978).

Furthermore, under Pennsylvania law, as is the case elsewhere, the plaintiff "is the master of [her own] claim." See, e.g., Tucker v. Phila. Daily News, 577 Pa. 598, 630, 848 A.2d 113, 133 (2004). Given the material differences between strict liability and negligence theory, as discussed below, the panel's approach of analyzing Appellee's main claim – which was expressly stated in negligence – as if it were grounded upon strict liability, is deeply flawed.

> conduct of the manufacturer. In contrast, a negligence cause of action revolves around an examination of the conduct of the defendant."

Lance, 4 A.3d at 166 (quoting Phillips v. Cricket Lighters, 576 Pa. 644, 658, 841 A.2d 1000, 1008 (2003) (plurality)).

The panel's treatment then segued into a discussion of Section 395 of the Restatement Second, which provides:

> A manufacturer who fails to exercise reasonable care in the manufacture of a chattel which, unless carefully made, he should recognize as involving an unreasonable risk of causing physical harm to those who use it for a purpose for which the manufacturer should expect it to be used and to those whom he should expect to be endangered by its probable use, is subject to liability for physical harm caused to them by its lawful use in a manner and for a purpose for which it is supplied.

RESTATEMENT (SECOND) OF TORTS §395. The panel pronounced that Section 395 "addresses a manufacturer's negligent design of products." Lance, 4 A.3d at 166. Additionally, it emphasized that the provision is independent of Section 402A, to which comment k is appended, and reasoned that there was "no exemption or special protection for prescription drugs," relative to claims under Section 395. Id.

Finally, the panel alluded to Section 6(c) of the Restatement Third of Torts: Products Liability, which provides:

> A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.

RESTATEMENT (THIRD): PRODS. LIAB. §6(c) (1998). The panel did not evaluate the merits of such liability theory, but rather, simply stated, "[o]ur Supreme Court has never adopted this provision, and it runs contrary to law as stated in Hahn and the Restatement (Second) of Torts, § 402(a)." Lance, 4 A.3d at 169.[9]

Wyeth and Appellee lodged the present cross-appeals challenging, respectively, the Superior Court's holdings that pharmaceutical companies are not immune (under Pennsylvania law) from claims of negligent drug design, and that claims of negligent marketing, testing, and failure to withdraw are unviable. Our review of these legal issues is plenary.

In its brief, Wyeth leads with the argument that Appellee has forfeited any design-defect claim, in light of her alleged failure to adequately preserve and present such a claim. See Pa.R.A.P. 302(a). In this regard, the pharmaceutical company highlights that Appellee has consistently styled her central claim as one centered upon "negligent marketing and negligent failure to withdraw" –- not "negligent design defect." Brief for Wyeth at 12. Wyeth further contends that Appellee failed to advance a defective-design theory in her opposition to the company's summary judgment motion, in her statement of matters presented on appeal, see Pa.R.A.P. 1925(b), and in the statement of questions involved included in her appellate brief filed in the Superior Court, see Pa.R.A.P. 2116. Under the circumstances as asserted, Wyeth complains that "the Superior Court took the extraordinary step of creating a new cause of action, and did so without the benefit of briefing and argument from the parties." Brief for Wyeth at 16.

Substantively, Wyeth maintains that Pennsylvania law recognizes – and should recognize – only two liability theories based on adverse effects of prescription drugs.

[9] The panel's cryptic treatment overlooks the substantive overlap or intersection between Section 6(c) of the Restatement Third and the more general principles of negligence theory reflected in the Restatement Second. See infra note 37.

Under the company's arguments, and those of its amicus, the Product Liability Advisory Council, Inc., the Court should sanction redress against pharmaceutical companies only for manufacturing defects and inadequate warnings. According to Wyeth and its amicus, this regime strikes the appropriate balance between the policy interest in compensating injured individuals and the need to enforce reasonable limitations on the liability of pharmaceutical companies so as not to deter the continued availability and development of beneficial, albeit risk-laden, medicines. Accord, e.g., Grundberg v. Upjohn Co., 813 P.2d 89, 93-99 (Utah 1991) (discussing the range of policy considerations favoring limitations on the liability of drug companies pertaining to harmful side effects).[10] Wyeth maintains, additionally, that its position dovetails with this Court's adoption of the learned intermediary doctrine, requiring pharmaceutical manufacturers to direct warnings to physicians as prescribers, who then undertake an individualized risk-benefit analysis to determine the appropriate course of treatment for their patients. See, e.g., Coyle v. Richardson-Merrell, Inc., 526 Pa. 208, 217, 584 A.2d 1383, 1387 (1991).

In terms of the decisional law of this Court, Wyeth and the Council premise their position principally on Incollingo, Baldino v. Castagna, 505 Pa. 239, 478 A.2d 807 (1984), and Hahn. See, e.g., Brief for Wyeth at 17-18; Brief for Amicus Prod. Liab. Advisory Council, Inc. at 16-19. While, at least implicitly, Wyeth acknowledges the central role of determining the appropriate limits of strict products liability in this line of decisions, the company nevertheless observes a dearth of Pennsylvania case law

[10] Wyeth and its amicus also stress the substantial time, expense, and effort required to bring a new drug to the United States marketplace. See, e.g., Brief for Amicus Prod. Liab. Advisory Council, Inc. at 11 ("Developing the necessary data to establish the safety and efficacy of a prescription drug is a time-consuming and costly endeavor for the manufacturer[;] . . . [t]he cost of bringing a new drug to the market on average exceeds $1 billion." (citations omitted)).

concerning the independent application of negligent design-defect theory to prescription drugs. In light of this void, Wyeth finds it implausible that the subject matter has been entirely overlooked by the courts. See Brief for Wyeth at 20 ("In the face of this history, Plaintiff argues that an amorphous 'negligent design defect' claim has somehow survived, unnoticed, at the fringe of prescription drug litigation and has thus avoided appellate review by any court of this Commonwealth until now.").

To the contrary, Wyeth and its amicus believe, design-defect theory is a non-starter under negligence doctrine as applied to pharmaceutical companies for the same reasons why it has been rejected for purposes of strict liability, namely, the considerations set forth in comment k. See id. at 23 (positing that comment k applies equally in negligence and strict liability, "as the core questions in either type of claim would be the same: whether the product was 'unreasonably dangerous' as designed, and whether there existed a feasible alternative design."). Indeed, according to Wyeth, "[t]he overwhelming majority of those comment k states have not recognized prescription drug 'negligent design defect' claims." Brief for Wyeth at 11; cf. AMERICAN LAW OF PRODS. LIAB. 3d §17.43 (2011) (describing a "traditional refusal by courts to impose tort liability for defective designs of prescription drugs").[11]

[11] As Wyeth otherwise recognizes, the comment k jurisprudence is not monolithic. For instance, many jurisdictions place the burden on manufacturer defendants to demonstrate that their products merit comment-k protection, inter alia, by establishing that the product passes a risk-utility test. See, e.g., David S. Torborg, Design Defect Liability and Prescription Drugs: Who's In Charge?, 59 OHIO ST. L.J. 633, 638-43 (1998) (surveying approaches to comment k and indicating that "[a] majority of courts that have considered the application of comment k have adopted the case-by-case approach, concluding that prescription drugs are not automatically shielded from design defect liability"). Others, however, including Pennsyvania, have taken a blanket approach applying comment k to preclude strict-liability design-defect claims for all prescription drugs. See id.; see also Hahn, 543 Pa. at 560, 673 A.2d at 889.

Devoting substantial, directed attention to comment k, Wyeth's brief stresses the American Law Institute's core recognition that prescription medications carry risks which are unavoidable. See RESTATEMENT (SECOND) OF TORTS §402A cmt. k. In view of such understanding, and because many drugs benefit society, Wyeth contends that Pennsylvania's adoption of comment k:

> (1) barred strict liability claims against prescription drug manufacturers; (2) left no room for design defect claims of any kind, whether "strict liability" or "negligence;" and (3) signaled a clear policy decision that prescription drugs are different from ordinary products.

Brief for Wyeth at 16-17; accord id. at 22-23 ("Thus, as comment k and this Court recognize, a prescription drug, 'properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.'" (quoting Hahn, 543 Pa. at 560 n.2, 673 A.2d at 890 n.2 (emphasis in original) (quoting, in turn, RESTATEMENT (SECOND) OF TORTS §402A cmt. k))).

Wyeth and the Council also posit that the "analytical underpinnings" of negligent-design-defect theory, as applied to prescription drugs, cannot withstand scrutiny. In the first instance, they contend that comment k's "unavoidably unsafe" rubric is inherently incompatible with the notion of a design defect, because the theoretical basis for a design-defect claim is that a product is avoidably unsafe. See, e.g., Brief for Wyeth at 22-23. According to Wyeth and its amicus, this understanding has led Pennsylvania courts to require evidence of an alternative safer design to support a design-defect claim outside the pharmaceuticals arena. See Brief for Wyeth at 31 & n.6 (citing Duchess v. Langston Corp., 564 Pa. 529, 559 n.24, 769 A.2d 1131, 1149 n.24 (2001)); Brief for Amicus Prod. Liab. Advisory Council, Inc. at 22 ("It is well-established under Pennsylvania Law that to sustain a claim of design defect, whether sounding in negligence or strict liability, the plaintiff must plead and prove the existence of a safer

'feasible alternative design.'" (citing, inter alia, Berrier v. Simplicity Mfg., Inc., 598 Pa. 594, 597 n.1, 959 A.2d 900, 902 n.1 (2008) (Saylor, J., concurring)).[12] Because, a drug can have no safer design (in the sense that any redesign would result in a completely different compound with different properties and its own unique benefits and risks), Wyeth and the Council contend that it follows that negligent design theory simply cannot be harmonized with prescription drugs. See Brief for Wyeth at 31-32. Further, they explain, any redesign would have to surmount the expensive and time-consuming regulatory-approval process, rendering it speculative whether such an alternative ever would be viable in any event. See id.

In this and other respects, the federal regulatory scheme retains a predominate role in Wyeth's presentation, as well as that of its amicus. See, e.g., Brief for Prod. Liab. Advisory Council, Inc. at 3 ("Through a series of complex federal statutes and regulations, the FDA, and its team of experts in toxicology, chemistry, pharmacokinetics, and biology, act as a 'gatekeeper' to the United States marketplace."); id. at 7 ("The FDA is a science-based public-health agency with over 12,000 employees and an annual budget of over $2 billion." (citation omitted)). The Council, in particular, details the FDA regulatory process, including a discussion of the agency's mission (i.e., promotion of the public health through clinical research and appropriate regulatory action to ensure, inter alia, that drugs are safe and effective, see 21 U.S.C. §393(b)); its statutory responsibility to ensure that drugs marketed in the United States are safe and effective, see Wyeth v. Levine, 555 U.S. 555, 567, 129 S. Ct. 1187, 1195-96 (2009); and the extensive screening process incorporating an initial Investigational New Drug Application as a predicate to clinical studies, a New Drug

[12] As further discussed below, the decisions on which Wyeth and the Council rely do not actually reflect a holding of this Court that evidence of an alternative safer design is an unyielding requirement in design-defect litigation in Pennsylvania. See infra note 36.

Application presenting the results of such studies and other evidence, and a risk-utility assessment by the FDA. See Brief for Amicus Prod. Liab. Advisory Council, Inc. at 9-12. Wyeth and its amicus highlight the deference which Pennsylvania courts have accorded to the FDA's considered judgments about the safety and efficacy of prescription medical products, for example, via reliance on the precept that compliance with governmental regulations is evidence of due care in the negligence setting. See, e.g., Brief for Wyeth at 33 (citing, inter alia, Groh v. Phila. Elec. Co., 441 Pa. 345, 349-50, 271 A.2d 265, 267 (1970)); accord Brief for Amicus Prod. Liab. Advisory Council, Inc. at 21. Additionally, Wyeth cites White v. Weiner, 386 Pa. Super. 111, 562 A.2d 378 (1989), which referenced criminal statutes pertaining to adulteration and misbranding in support of the following pronouncement: "Our legislature unequivocally has expressed a policy of deference to the federal scheme in the area of drug labeling, and we can ascertain no reason not to extend that policy to civil cases raising misbranding claims." Id. at 119-20, 562 A.2d at 383 (footnote and citations omitted).

Concerning federal regulatory involvement, Wyeth and the Council also continue to question the wisdom of putting judges and/or lay jurors in a position of reevaluating and "second-guess[ing]" the risk-benefit calculus of the FDA. Brief for Wyeth at 35; Brief for Amicus Prod. Liab. Advisory Council, Inc. at 19; accord Brief for Wyeth at 34 ("Pennsylvania's long-standing policy of deference to regulatory authorities is in conflict with the recognition of a cause of action that specifically undertakes to re-evaluate those regulators' decisions and predict what they might do differently."). According to Wyeth,

> [a]llowing the Superior Court's decision to stand would inevitably unleash a host of claims that, notwithstanding an FDA approval of a drug's risk-benefit profile as 'safe and effective,' its manufacturer was nevertheless 'negligent' in placing and keeping the drug on the market. The Court should not permit those claims, which are the antithesis of the deference that should be afforded to the FDA.

Brief for Wyeth at 36; accord Brief for Amicus Prod. Liab. Advisory Council, Inc. at 16 ("[T]he FDA is in the best position to make a uniform decision for the country, based on its rigorous regulatory process, regarding which medications provide valuable health benefits to patients that outweigh potential risks.").

Responding to the Superior Court's reliance upon Section 395 of the Restatement Second of Torts, Wyeth reasons that this provision does not concern negligent design, but rather, involves "Negligent Manufacture of Chattel Dangerous Unless Carefully Made," as its title expressly indicates. RESTATEMENT (SECOND) OF TORTS §395 (emphasis added). Further, Wyeth explains the difference between manufacturing and design flaws, in that the former entails a departure from the intended design, whereas the latter concerns an intended design which is unreasonably dangerous in the first instance. See Brief for Wyeth at 26 (citing Stecher v. Ford Motor Co., 779 A.2d 491, 502 (Pa. Super. 2001), vacated on other grounds, 571 Pa. 312, 812 A.2d 553 (2002)). The company also highlights that this Court has never specifically adopted Section 395 of the Restatement Second,[13] which, nonetheless, was the cornerstone of the Superior Court panel's approval of negligence-based, design-defect claims in the pharmaceuticals context.

Interwoven throughout its submissions, Wyeth advances a number of subsidiary propositions: that Appellee's claim is akin to one for recall or retrofit of a product, albeit, as the intermediate-court panel related, this Court has never imposed such a duty on manufacturers, see Lance, 4 A.3d at 167; that Appellee inappropriately seeks to hold

[13] It should be noted, however, that this Court has rather roundly endorsed the substantive principles reflected in both Sections 395 and 398 of the Restatement Second as having been "adopted in practically all jurisdictions." Foley v. Pittsburgh-Des Moines Co., 363 Pa. 1, 29-30, 68 A.2d 517, 531 (1949) (discussing parallel sections from the Restatement of Torts in the context of a discussion of the curtailment of the privity requirement in tort cases).

Wyeth liable over and against the assertion that a manufacturer's conduct is not required to exceed the state of the art, see, e.g., Brief for Wyeth at 36 n.7 (citing, inter alia, Hahn, 427 Pa. Super. at 145-46, 628 A.2d at 867-68); that Appellee's allusions to the withdrawal of Redux from the market inappropriately refer to subsequent remedial measures, see Second Brief for Wyeth at 11 & n.9; and that approval of any liability theory other than manufacturing defect and failure to warn "threatens to turn prescription drug manufacturers into insurers for their products," Brief for Wyeth at 10.[14]

Wyeth's analysis ultimately circles back to its policy position that the appropriate balance between allocating responsibility for injury and safeguarding development of valuable pharmaceutical products entails recognition only of manufacturing-defect and failure-to-warn claims against drug companies in the products liability arena. In conjunction, the company criticizes the Superior Court in the present case for "undermin[ing] the policy judgments undergirding this Court's prescription drug jurisprudence . . ., potentially dramatically expanding the scope of prescription drug litigation in Pennsylvania." Brief for Wyeth at 21. Finally, Wyeth admonishes that allowing such a claim "could also risk importing into the prescription drug arena the difficulties that have plagued strict liability and negligent design defect claims generally." Brief for Wyeth at 24-25 (citing Schmidt v. Boardman Co., 608 Pa. 327, 353-54, 11 A.3d 924, 940 (2011) (referencing "material ambiguities and inconsistencies" in Pennsylvania design-defect jurisprudence)).

[14] Wyeth finds the "absolute liability" moniker particularly appropriate, in light of the inability of pharmaceutical companies to unilaterally change a drug's FDA-approved design. See Brief for Wyeth at 31 (citing James A. Henderson, Jr. & Aaron D. Twerski, Drug Designs Are Different, 111 YALE L.J. 151, 167 (2001) (positing that "[n]o expert could honestly opine that [regulatory] approval would have been granted [for a contemplated 'alternative' drug] without engaging in rank speculation").

Appellee, on the other hand, vigorously denies that she has waived the ability to pursue a design-defect claim. She observes that Wyeth constructed its summary judgment effort around the notion that there are two, and only two, scenarios giving rise to liability on the part of a pharmaceutical company for FDA-approved drugs – manufacturing defect and failure-to-warn – to the exclusion of all others. Moreover, the argument continues, the common pleas court credited such claim. Consequently, Appellee explains, her approach throughout the litigation to this juncture has been to parry the asserted restriction, rather than to advance any particular liability premise. See, e.g., Brief for Appellee at 14 ("Had Wyeth directly challenged plaintiff's ability to maintain a claim for negligent design defect, plaintiff assuredly would have responded in opposition to Wyeth's argument."). In any event, Appellant asserts, she referenced her design-defect claim at every stage of the litigation and her various contentions are overlapping and interrelated. See, e.g., id. at 16 ("In other words, it is and has always been one of plaintiff's main arguments that as a result of Wyeth's negligent design of Redux, resulting in a medication whose risks outweighed its benefits as to all classes of patients, Wyeth was negligent in ever bringing Redux to the market."); id. at 18 ("Regardless of whether plaintiff's claims against Wyeth are characterized as claims alleging negligent marketing and negligent failure to withdraw from the market; claims alleging negligent failure to test; or claims alleging negligent design defect, such claims are recognized as valid under Pennsylvania law." (quoting Brief for Appellant at 17, Lance v. Wyeth, 4 A.3d 160 (Pa. Super. 2010)) (emphasis in original).

On the merits, Appellee and her own amici, the American and Pennsylania Associations for Justice, posit that this Court's adoption of comment k in the strict-liability setting should in no way be taken to foreclose claims of negligent design. Among other decisions, they reference Phillips v. Cricket Lighters, 576 Pa. at 658, 841

A.2d at 1008 (lead opinion) (rejecting as "deeply flawed" the argument that the unavailability of a strict-liability claim premised on design-defect theory necessarily forecloses a claim premised on negligent design).[15] Appellee also cites other Superior Court decisions as lending additional credence to her position, primarily Wright v. Aventis Pasteur, Inc., 14 A.3d 850, 874 (Pa. Super. 2011) (en banc) (determining that "Comment K does not outright bar all design defect claims against FDA-approved drugs"), superseded in part by Bruesewitz v. Wyeth LLC, ___ U.S. ___, ___, 131 S. Ct. 1068, 1082 (2011) (holding that the National Childhood Vaccine Injury Act preempts state law design-defect claims relative to certain vaccines). She also discusses the series of cases from other jurisdictions which have rejected a blanket application of comment k to all prescription drugs. See Brief for Appellee at 25-27 (citing, inter alia, Toner v. Lederle Labs., 732 P.2d 297, 309-11 (Idaho 1987)); see also supra note 11. Responding to Wyeth's assertion that there is a dearth of decisional law in her favor, Appellee rejoins that Wyeth also "cites absolutely no law that is directly on point in support of its argument that this Court should not recognize a negligent design defect claim against the manufacturer of a prescription drug." Brief for Appellee at 27; accord Brief for Am. & Pa. Ass'ns for Justice at 9 ("Nothing in this Court's failure-to-warn trilogy departs from [the] view that negligent design liability is essential to compel drug companies to maintain an appropriate level of vigilance about the safety of the products they sell.").

In terms of policy reasons supporting the allowance of a negligent-design claim against pharmaceutical companies, these are encapsulated in the following passage from amici's submission:

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[15] On this score, Appellee does not engage the counter-point made by Wyeth, namely, that Phillips did not address the subject matter of comment k (namely, unavoidably unsafe products).

> The tort of negligent design . . . threatens to hold Wyeth liable for unreasonably marketing a drug with risks that far outweigh its benefits. It places responsibility squarely on the manufacturer to remain alert for serious drug hazards that emerge both during clinical trials and after the drug has entered the market and creates powerful incentives for the manufacturer to act upon that emerging risk information and to promptly disclose it to the FDA. Most importantly, the tort of negligent design provides a critical remedy for consumers who are injured when a drug manufacturer disregards these responsibilities.

Brief for Am. & Pa. Ass'ns for Justice at 10.

Appellee also references the Restatement Third position as at least overlapping with her own, see supra note 9, while further noting that courts and commentators have criticized the new Restatement as being unduly restrictive. See Brief for Appellee at 28 (citing Freeman v. Hoffman La-Roche, Inc., 618 N.W.2d 827, 839-40 (Neb. 2000) (reasoning that the Restatement Third position on design-based liability for prescription drugs is "too strict of a rule, under which recovery would be nearly impossible")). Nevertheless, even under the new Restatement's constrained approach, Appellee claims, "the FDA's decision barring the sale of Redux for any purpose whatsoever conclusively establishes that 'reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug . . . for any class of patients.'" Id. (quoting RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. §6(c)).

Regarding deference to the FDA, Appellee cites Levine, 555 U.S. 555, 129 S. Ct. 1187 (rejecting the argument that federal law preempts state-law claims against pharmaceutical companies), as informing the degree of deference required. Furthermore, Appellee contends:

> Wyeth's argument about the need to defer to the expertise of the FDA also proves too much. That argument, if accepted, would deny a claim under Pennsylvania law for negligent

> failure to warn, despite this Court's repeated holdings that such a claim exists and may be pursued by plaintiffs injured as a result of ingesting dangerous prescription drugs. Even though the FDA approves the warnings that accompany a prescription drug, Pennsylvania law nevertheless allows claims against the manufacturers of prescription drugs for negligent failure to warn. Thus, the mere fact that the FDA approves a prescription drug for sale should likewise not preclude a claim for negligent design defect against the manufacturer of a prescription drug.

Brief for Appellee at 31-32. Appellee also references commentary favoring circumspection about the FDA's gatekeeping role. See id. at 32 (quoting George W. Conk, The True Test: Alternative Safer Designs for Drugs and Medical Devices in a Patent-Constrained Market, 49 UCLA L. REV. 737, 754 (2002) (suggesting that there are regulatory weaknesses in the federal system for which state-law tort schemes compensate)).

As to the purported requirement of an alternative safer design, Appellee distinguishes cases in which a medication persists in the marketplace from those where the drug has been deemed to be too dangerous to be offered for sale to any potential class of patients. See Brief for Appellee at 34. Citing, once again, to the Restatement Third, Appellee contends that "[t]he central principle that Section 6(c) recognizes is that a prescription drug whose risks outweigh its benefits as to all potential classes of patients qualifies as defectively designed without any need to show that some other alternative design would produce a medication that was equally effective yet less risky." Id. at 34; see also Tobin v. Astra Pharmaceutical Prods., Inc., 993 F.2d 528, 540 (6th Cir. 1993). Appellee also references Brown v. Superior Court, 751 P.2d 470 (Cal. 1988), for the proposition that "defendants' attempt to confine the issue to whether there is an 'alternative design' for [a drug] poses the problem in an 'unreasonably narrow' fashion." Id. at 478. According to Appellee, a prescription drug carrying risks which

outweigh its benefits as to all possible classes of patients, as Appellee has alleged of Redux, "is defectively designed by definition because it serves no useful purpose whatsoever." Brief for Appellee at 11.

Finally, Appellee casts Wyeth's subsidiary arguments as mischaracterizations. For example, responding to the company's claim that she seeks imposition of absolute liability, Appellee explains that nothing could be further from the truth, since she intends to prove fault on the company's part in the form of a lack of due care. See, e.g., Reply Brief for Cross-Appellant at 9. Appellee also notes the incongruity in Wyeth's recharacterization of her claim –- that a dangerous and effectively useless drug should have been kept by its maker out of the hands of the public –- as suggesting a "recall" or "retrofit" of Redux. Id. at 10; accord Brief for Am. & Pa. Ass'ns for Justice at 14 ("Plaintiff does not assert that Wyeth was under a common law duty to recall Redux tablets that had already been distributed on the market[;] [r]ather, Plaintiff contends that, given what Wyeth knew or should have known about the dangers of Redux in early 1997, it was negligent of the company to continue to sell the product at that time." (citation omitted)). As to the company's reliance on the state-of-the-art defense, Appellee explains that this is in irreconcilable tension with the manner in which Wyeth framed its matter-of-law, summary-judgment challenge, particularly since Appellee vigorously contends that "the 'state of the art' . . . is assuredly a contested fact." Reply Brief for Cross-Appellant at 11. Concerning the matter of the evidentiary role of the withdrawal of Redux from the United States marketplace, Appellee indicates:

> On the issue of subsequent remedial measure, plaintiff does not rely on Wyeth's later voluntary withdrawal of Redux from the market as evidence of Wyeth's negligence. Rather, plaintiff is instead relying on the FDA's decision, which occurred after Wyeth's withdrawal of the medication, that the active ingredient contained in Redux was too unsafe to be prescribed to any class of patients for any purpose

> whatsoever. It is the FDA's ultimate conclusion about Redux's unsuitability for any patient that is the most critical evidence in this case. To the extent that Wyeth's voluntary withdrawal is relevant, it is for the purpose of establishing "feasibility of precautionary measures," which does not run afoul of the rule limiting the introduction into evidence of subsequent remedial measures. See Pa. R. Evid. 407 ("This rule does not require the exclusion of evidence of subsequent measures when offered for impeachment, or to prove other matters, if controverted, such as ownership, control, or feasibility of precautionary measures.").

Reply Brief for Cross-Appellant at 11-12.

I. Waiver

As Appellee explains: 1) her substantive claim for relief from the outset has centered on Wyeth's responsibility for a drug put into the marketplace by that company and carrying risks which are alleged to outweigh the drug's benefits to anyone; 2) Wyeth has plainly understood, from early on in the litigation, that Appellee's "central allegation . . . is that 'Redux was so unreasonably dangerous and defective in design that it should never have been on the market,'" Wyeth's Motion for Summary Judgment at 5, Lance v. Wyeth, Nov. Term, No. 000926 (quoting Complaint at ¶17, Lance v. Wyeth, Nov. Term, No. 000926, ¶17 (emphasis added)); and 3) it was Wyeth which selected the strategy of pursuing summary judgment on the basis that no products liability claim which does not concern a manufacturing defect or a deficient warning should be recognized relative to prescription drugs.

Through the present, Wyeth is still urging this Court to adopt a potent, bright-line rule, applicable across the Commonwealth, closely restricting claims against pharmaceutical companies. At the same time, however, Wyeth insists that we may not specifically consider the wisdom of foreclosing one type of claim (negligence-based design-defect) among those claims which would be forever barred.

We reject Wyeth's waiver argument, for the reasons outlined by Appellee. In particular, it is our considered judgment that –- since it is Wyeth which has asked for an edict banning design-defect claims (amongst any and all others extrinsic to the specified impurities/warnings scenarios) – it is Wyeth which has been duty-bound, throughout, to address the landscape of potential claims which it wants extinguished. Stated otherwise, Wyeth is ill-heard to complain that it lacked a fair opportunity to address any form of claim or liability within the scope of the preclusion it desires.[16]

II. Factual Perspective On Summary Judgment

Summary judgment is appropriate in cases where there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. See, e.g., Summers v. Certainteed Corp., 606 Pa. 294, 307, 997 A.2d 1152, 1159 (2010). See generally Pa.R.C.P. No. 1035.2(1). Facts and reasonable derivative inferences are generally considered in the light most favorable to the non-moving party, and doubts are resolved against the moving party. See Summers, 606 Pa. at 307, 997 A.2d at 1159.

Significantly, there are two main avenues per which summary relief may be granted. Employing the first of these, a movant may rely on uncontroverted facts, and/or allow that the factual allegations made by the non-moving party could be true, while contending that, even accepting such facts, judgment should be rendered for the

[16] Notably, it is otherwise Wyeth's position that, substantively, Appellee's negligent-design-defect claim wholly overlaps her other theories, of which Wyeth plainly was aware. See Brief for Wyeth at 11 ("Plaintiff's . . . '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[.]"); cf. id. at 35 (asserting that Appellee's claim that Redux should never have been marketed at all, or should have been removed from the market sooner – "is simply an attempt to resuscitate and repackage Plaintiff's improper 'negligent marketing' and/or 'negligent failure to remove' claims"). For this reason as well, Wyeth's assertion that it lacked a fair opportunity to respond, in substance, to Appellee's position is not well taken.

movant as a matter of law. See Pa.R.C.P. No. 1035.2(1). Alternatively, after discovery, a party may challenge the ability of the non-moving party to adduce evidence of facts material to establishing a claim or defense. See id. No. 1035.2(2).

Wyeth has proceeded per the former avenue, advocating our adoption of a rule of law which would eschew Appellee's liability theory, even given the facts she has averred. Accordingly, for present purposes of testing the validity of Wyeth's position, we will accept that the company did precisely what Appellee alleges, namely, that it manufactured and tendered Redux into the marketplace, although it had actual or constructive knowledge that the risks of adverse health effects exceeded the drug's benefits to any class of patients. Short-Form Complaint at ¶¶13-14, Lance v. Wyeth, Nov. Term 2006, No. 000926. Since the FDA was, at the time Catherine Lance ingested Redux, of the view that the drug was safe and effective, a reasonable, attendant inference is that Wyeth failed to share relevant information with the federal agency,[17] or that the agency also had actual or constructive notice of the unacceptable risk but was remiss in its own duty to protect the public. Furthermore, we can reasonably infer, for the present, that the information which was or should have been in Wyeth's hands did not reach prescribing physicians (since the allegation is that, factually, Redux was so dangerous that no reasonable physician, appropriately apprised, would have prescribed it). See id.

Again, given the manner in which Wyeth posed its summary judgment effort, we are not in a position to evaluate the veracity of Appellee's averments. Rather, they are merely taken as true in our present review of the trial and intermediate courts' treatment and as a predicate to assessing the rule of law which Wyeth asks us to adopt through

[17] Indeed, Appellee has advanced this specific assertion. See, e.g.. Brief for Appellee at 6.

the summary-judgment vehicle. Accord Lance, 4 A.3d at 163 (observing that the present appeal does not concern a failure of proof, but rather, centers on Wyeth's legal theory that Appellee had not pursued a viable cause of action).

Accordingly, although the company does not articulate its position in such terms, Wyeth is asking, for policy reasons, that we should insulate pharmaceutical companies from liability even for a patent lack of due care so deleterious as to create an untenable threat to human health.[18]

III. An Issue of First Impression

As noted, Wyeth and its amicus urge that their position is vindicated in three existing decisions of this Court (Incollingo, Baldino, and Hahn), such that there is no need for a fresh policymaking assessment of the immunity they favor. In point of fact, however, in none of these decisions was the Court considering allegations –- accepted as true for purposes of summary judgment – of a lack of due care resulting in an untenably dangerous product being put into the marketplace.[19]

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[18] Notably, while Wyeth and its amicus allow that manufacturing-defect and warnings cases may be advanced, both of these theories are inapposite to the above factual context. Thus, per Wyeth's position, there should be no redress in Pennsylvania for a pharmaceutical company's lack of due care on the terms indicated above.

We make this point as one of emphasis, since, in its brief, Wyeth generally cast its own conduct, and that of pharmaceutical companies at large, in the best possible light. This, of course, leaves the impression that Appellee's assertion of a lack of due care is a marginal aspect of the case. Indeed, this liberty pervades Wyeth's arguments, which obviously take on a different color with the recognition that Wyeth seeks to insulate pharmaceutical companies from liability even in situations in which a lack of due care may be manifest.

[19] For example, Hahn's reasoning and holding are focused on distinguishing strict liability from negligence in the warnings arena and are encapsulated in the following explanation: "[W]here the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, (continued…)

We also do not believe that this Court's adoption of comment k in the strict-liability context impedes an independent assessment of its validity relative to Appellee's liability theory. In the first instance, comment k is not itself a model of clarity. See, e.g., Richard L. Cupp, Jr., Rethinking Conscious Design Liability for Prescription Drugs: The Restatement (Third) Standard Versus a Negligence Approach, 63 GEO. WASH. L. REV. 76, 81-82 (1994) (observing that "[w]riters have labeled the comment 'an enigma,' 'unclear in many respects,' 'poorly drafted and internally inconsistent,' 'a masterpiece of confusion and double-speak,' and a 'monumental failure.'" (footnotes omitted)); Henderson & Twerski, Drug Designs Are Different, 111 YALE L.J. at 180 ("Most observers are in general agreement that the guidelines set forth a half-century ago in section 402A, comment k of the Restatement (Second) are unintelligible[.]" (footnote omitted)). Moreover, it seems plain enough that the comment is premised on the assumption that all products within its scope carry some net benefit (relative to risks) for some class of consumers. See RESTATEMENT (SECOND) §402A cmt. k (characterizing

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(…continued)
i.e., the manufacturer's negligence, is the only recognized basis of liability." Hahn, 543 Pa. at 563, 673 A.2d at 891 (emphasis added). Such a decision, centered on warning issues, cannot obviate all other negligence-based avenues for establishing liability. Similarly, qualifying language appears in relevant passages of Baldino, see Baldino, 505 Pa. at 244, 478 A.2d at 810 (explaining that "assuming proper preparation and warning, a manufacturer of drugs is not strictly liable for unfortunate consequences attending the use of otherwise useful and desirable products which are attended with a known but apparently reasonable risk" (emphasis added)), and Incollingo, see Incollingo, 444 Pa. at 287-88, 282 A.2d at 219-20 (following the reasoning of comment k in addressing a product "which is safe for use if [a warning] is followed" or which is marketed in circumstances in which the manufacturer did not know, and should not be charged with, knowledge of the absence of a net benefit (emphasis added)).

In other words, products which a manufacturer or supplier knows or should know are too dangerous for any class of users are simply outside the purview of the Hahn/Baldino/Incollingo line of decisions, just as they are extrinsic to the contemplation of comment k. See infra.

subject products as "apparently useful and desirable").[20] Accordingly, the remarks simply do not encompass the scenario which must be envisioned to confront Wyeth's matter-of-law attack on Appellee's central claim –- that a pharmaceutical company's lack of due care resulted in the dissemination of a product which is not apparently useful and desirable, but rather, is effectively useless and dangerous.

Furthermore, we differ with the position of Wyeth and its amicus that comment k, a facet of the law of strict liability under the Restatement Second, readily translates into the negligence arena, particularly given the very distinct treatment of strict-liability versus negligence theory required under the foundational Pennsylvania decision in Azzarello, 480 Pa. 547, 391 A.2d 1020; cf. Graham v. Wyeth Labs., Div. of Am. Home Prods. Corp., 906 F.2d 1399, 1406 n.10 (10th Cir. 1990) ("Exempting manufacturers from strict liability clearly differs from exempting them from negligence liability." (referencing, inter alia, Brown v. Superior Court, 751 P.2d 470, 482 n.12 (Cal. 1988)); Lake-Allen v. Johnson & Johnson, L.P., No. 2:08CV00930DAK, slip op., 2009 WL 2252198, at *3 (D. Utah July 27, 2009) (indicating that the Utah Supreme Court's decision in Grundberg – prominently cited by Wyeth in the present case in support of its policy position – has been limited in its application to strict liability claims); Freeman v. Hoffman-La Roche, Inc., 618 N.W.2d at 845 (stating that, "even if a comment k. defense is determined to apply to exempt the defendant from strict liability, the plaintiff can

[20] Indeed, in a number of jurisdictions, even in the strict-liability setting in which comment k finds its home, courts require the defendant to prove that the benefits of their products justifies their marketing and use despite the unavoidable risks, as a prerequisite to invoking comment-k protection. See, e.g., Moss v. Wyeth, Inc., 872 F. Supp. 2d 162, 171 (D. Conn. 2012).

always attempt to show that the defendant acted negligently" (citing Toner, 732 P.2d 297)).[21]

We recognize that there is some merit to Wyeth's argument that "unreasonably dangerous," as used in comment k, should mean the same thing across the conceptual strict-liability-negligence divide. However, Pennsylvania courts have made a point of institutionalizing observed differences between such liability theories and have adopted and devised numerous associated rules and conventions, in part to cabin the potency of liability in the absence of fault.[22] One of the primary distinctions which has been vigorously maintained is that strict products liability is said to be concerned solely with

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[21] Wyeth is quick to point out that many other jurisdictions have not implemented a blanket approach to comment k, as it pertains in the strict-liability arena, and, thus, it takes the position that such cases are irrelevant. We do not share Wyeth's view, however, that blanket application of the commentary for purposes of strict liability and preclusion of negligence-based liability premises necessarily go hand-in-hand. Indeed, it is our perspective that this Court applied a rather one-dimensional analysis in its adoption of a blanket approach to comment k in the first instance. For example, the terse opinion in Hahn does not so much as mention, let alone evaluate, the reasons why many other jurisdictions had interpreted comment k to require a case-by-case assessment concerning the availability of its protections. Compare, e.g, Hahn, 543 Pa. at 560-63, 673 A.2d at 889-91, with Toner, 732 P.2d at 304-09.

We emphasize that we are not revisiting Hahn; rather, our point is only that the truncated analysis in the Hahn line offers a poor foundation for extrapolation. See generally infra section IV.

[22] It is necessary to maintain limiting principles, as we have previously eschewed the notion of a pure loss-spreading tort system, and, thus, hold to the understanding that it is not for the courts to make manufacturers and suppliers insurers for their products. See, e.g., Cafazzo v. Cen. Med. Health Servs., Inc., 542 Pa. 526, 535, 668 A.2d 521, 526 (1995) ("To assign liability for no reason other than the ability to pay damages is inconsistent with our jurisprudence."); Coyle, 526 Pa. at 217, 584 A.2d at 1387 (finding "[r]eliance on cost-shifting as the only factor to be considered in whether a given party should be exposed to liability" insufficient to support liability because it "would result in absolute liability rather than strict liability").

the product itself. See, e.g., Phillips, 576 Pa. at 656, 841 A.2d at 1007 (lead opinion) (asserting that "[s]trict liability focuses solely on the product, and is divorced from the conduct of the manufacturer").[23] There is greater flexibility, however, with regard to traditional, fault-based liability – i.e., negligence – where the conduct of manufacturers and/or suppliers is squarely in issue. See, e.g., id. at 654-55, 841 A.2d at 1006 (explaining that the precept that "a party who could have foreseen and avoided injuring another, but who fails to do so, is held liable for any injuries caused" is "memorialized in our tort law as a negligence cause of action").

Indeed, in the same line of cases upon which Wyeth relies, which have constrained the application of strict liability theory vis-à-vis pharmaceutical companies, this Court has described their obligations relative to their conduct in the following broad and exacting terms:

> There is no question that manufacturers of potentially dangerous drugs are held to a high degree of care. . . . [T]he public interest requires the holding of companies which make and sell drugs and medicine for use in the human body to a high degree of responsibility under both the criminal and civil law for any failure to exercise vigilance commensurate with the harm which would be likely to result from relaxing it.

Incollingo, 444 Pa. at 286-87, 282 A.2d at 219 (emphasis in original) (internal citation and quotation marks omitted).[24] Significantly, neither Wyeth nor its amicus references

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[23] Parenthetically, we have acknowledged difficulties with some of the concepts and conventions which have been employed to buttress the theoretical divide between strict products liability and negligence theory. See Schmidt, 608 Pa. at 353, 11 A.3d at 940. While it is beyond the scope of this opinion to provide the needed reconciliation, clarification, or modification, we recently allowed appeal in Tincher v. Omega Flex, Inc., ___ Pa. ___, 64 A.3d 626 (2013) (per curiam), with the hopes of doing so in such case.

[24] Moreover, as Appellee observes, the United States Supreme Court has explained that federal law also imposes post-marketing duties on pharmaceutical companies, (continued…)

any decision of this Court retrenching from this position as it pertains to fault-based liability. While for policy reasons this Court has declined to extend strict liability into the prescription drug arena, it simply has not immunized drug companies from other governing aspects of Pennsylvania tort law delineating product-manufacturer duties and liabilities.

In view of the above, we would be remiss if we did not conduct a fresh assessment of the issue which Wyeth has put before us, which we treat as one of first impression.

IV. Judicial, Common-Law, Substantive Lawmaking

In seeking a bright-line, substantive rule of prohibition across broad classes of cases, Wyeth's advocacy is in tension with the nature of common-law lawmaking. Initially, it is axiomatic that the holding of a judicial decision is to be read against its facts. See, e.g., Oliver v. City of Pittsburgh, 608 Pa. 386, 395, 11 A.3d 960, 966 (2011) (citing Commonwealth v. McCann, 503 Pa. 190, 195, 469 A.2d 126, 128 (1983)). This

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(…continued)
including the obligation to "ensur[e] that [their] warnings remain adequate as long as the drug is on the market." Levine, 555 U.S. at 571, 129 S. Ct. at 1197-98. Obviously, a company with actual or constructive knowledge that its product is too dangerous to be used by anyone violates such duty during any period of time during which it thereafter continues to market the commodity.

Furthermore, the law of Pennsylvania is consistent with Restatement Second, Section 398, entitled "Chattel Made Under Dangerous Plan or Design," which recognizes the responsibility of a manufacturer to answer in damages for "a plan or design which makes [a product] dangerous for the uses for which it is manufactured," adopted in the absence of reasonable care, where others suffer physical harm as a result. RESTATEMENT (SECOND) OF TORTS §398. As Appellee's amici note, moreover, Section 398 "is a special application of the rule stated in §395," id. cmt. a, which was the subject of the Superior Court's design-defect analysis. See Lance, 4 A.3d at 166. While Appellee has not referenced Section 398, we need not "adopt" it here to confirm its alignment with prevailing fault-based principles in this Commonwealth.

precept protects against an unintentional extension of governing principles beyond scenarios to which they rationally relate. See id. (citing Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc., 586 F.3d 500, 512 (7th Cir. 2009) (explaining that "uncritical generalization is a path to error" and that "[o]ne form of uncritical generalization . . . is reading general language literally")).[25]

Further, this Court recently had the opportunity to discuss the nature of common-law decision making in Seebold v. Prison Health Servs., Inc., ___ Pa. ___, 57 A.3d 1232 (2012). One of our main points of emphasis there was that the adjudicatory process does not translate readily into the field of broad-scale policymaking. See id. at ___, 57 A.3d at 1245 (citing Official Comm. of Unsecured Creditors of Allegheny Health Educ. & Research Found. v. PriceWaterhouseCoopers, LLP, 605 Pa. 269, 301-02, 989 A.2d 313, 333 (2010) (explaining that, "[u]nlike the legislative process, the adjudicatory process is structured to cast a narrow focus on matters framed by litigations before the Court in a highly directed fashion")).[26] For this reason, and because the Legislature possesses superior policymaking tools and resources and serves as the political

[25] To the extent Hahn, Baldino, and Incollingo may contain language which might appear to extend beyond the scenarios before the Court in those cases, it is important to bear in mind that none of these decisions addressed a claim that a pharmaceutical company manifested a lack of due care by marketing a medication during a time in which it knew, or should have known, that the product was too dangerous to be used by anyone.

[26] Accord Program Admin. Servs., Inc. v. Dauphin Cnty. Gen. Auth., 593 Pa. 184, 192, 928 A.2d 1013, 1017-18 (2007) ("[I]t is the Legislature's chief function to set public policy and the courts' role to enforce that policy, subject to constitutional limitations."); Naylor v. Twp. of Hellam, 565 Pa. 397, 408, 773 A.2d 770, 777 (2001) (recognizing the Legislature's superior ability to examine social policy issues and determine legal standards so as to balance competing concerns); Torres v. State, 894 P.2d 386, 389 (N.M. 1995) (explaining that "[p]olicy determines duty," and, "[w]ith deference always to constitutional principles, it is the particular domain of the legislature, as the voice of the people, to make public policy").

branch, we took the position in Seebold that we would not direct the substantive common law away from well-established general norms in the absence of some clear predominance of policy justifications. See id. (citing Cafozzo, 542 Pa. at 537, 668 A.2d at 527, for the proposition that, "[b]efore a change in the law is made, a court, if it is to act responsibly must be able to see with reasonable clarity the results of its decision and to say with reasonable certainty that the change will serve the best interests of society" (citation omitted)). Moreover, to support a judicial pronouncement of new, policy-based facets of substantive law, we strongly suggested in Seebold that litigants should engage in a comprehensive discussion of the competing policies and present the sort of record (including empirical information) which would support an informed, legislative-type judgment, again, grounded in a clear predominance of justifications. See id. at ___ & n.24, 57 A.3d at 1248-51 & n.24.

V. The Invitation to Narrow Common-Law Duties

We regard the present appeal as presenting, essentially, the flipside of Seebold. In that case, a plaintiff sought to expand the common-law duties imposed on medical professionals to encompass a new, affirmative duty to third parties to the physician-patient relationship. See id. at ___, 57 A.3d at 1247 (explaining that requests, such as the plaintiff's, "push the inquiry outside [the] ordinary boundaries" of the field of existing duties). Here, on the other hand, as related above, we find that Wyeth is asking, in substance, that we should invoke policy justifications to scale back the existing duty of pharmaceutical companies to independently and vigilantly protect against unreasonable health risks which may be posed by products made for human consumption.[27]

[27] Again, in this regard, we have little difficulty in finding that the allegations concerning Wyeth's conduct, accepted for purposes of our summary-judgment review – that is, that there is an absence of due care in tendering into the marketplace a product whose (continued…)

Here, as in Seebold, we conclude that the proponent of a new duty regime has failed to present a full and balanced record covering the range of relevant policy matters. For example, Wyeth's reluctance to discuss the factual elements of Appellee's claim in the light most favorable to her clouds the policy discussion from the outset. See supra section II. Additionally, while Wyeth complains of the enormous cost of bringing a new drug to market and posits that tort liability greatly impinges the development of new drugs, it does not discuss, at all, the degree of the advantage created by the federal patent system, which excludes others from exploitation of a patented design for a period of up to twenty years. See generally 69 C.J.S. PATENTS §324 (2013).[28] Without any treatment of such quid pro quo incentives and other variables which Wyeth omits and/or understates, we have no means of reasonably evaluating the impact of maintaining liability for the sort of lack of due care reflected in Appellee's allegations, which must be accepted as true for present purposes.[29] In these

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(…continued)
dangers are known (or should be known) to outweigh its benefits – manifests a failure of "vigilance commensurate with the harm which would be likely to result from relaxing it." Incollingo, 444 Pa. at 286-87, 282 A.2d at 219 (emphasis in original). Certainly, it would be self-defeating for Wyeth to say that it has no duty to refrain from tendering into the marketplace a product which it knows or should know is too hazardous to be used by anyone, and, of course, it does not say so.

[28] It is the perspective of some commentators, at least, that "large setbacks for pharmaceuticals defendants remain rare and (in relation to profits and gross sales revenues for the industry) trivial." Anita Bernstein, Enhancing Drug Effectiveness and Efficacy Through Personal Injury Litigation, 15 J.L. & POL'Y 1051, 1054 (2007). We do not credit or discredit such perspectives here. Rather, we simply highlight that Wyeth has provided no empirical information of any kind which would bear out its own views concerning the impact of personal-injury litigation on the pharmaceutical trade.

[29] Another example of the limited scope of Wyeth's policy argument is discussed in section VI, below, which concerns the federal regulatory involvement.

circumstances, we are simply unable to conduct the sort of overaching policy assessment essential to the vindication of Wyeth's position.[30]

We appreciate that negligent design-defect claims implicate policies favoring access to beneficial medicines and guarding against unduly deterring prescription-drug manufacturers from developing new drugs. This, of course, must be balanced against the right to a remedy, also enshrined in the Commonwealth charter. See PA. CONST. art. I, §11. Whatever the intuitions of individual Justices on the subject may be, Seebold makes clear that, going forward, we are not inclined to act instinctively or intuitively. Furthermore, Wyeth's allusions to absolute liability are not well taken, since Appellee's liability theory is expressly and inherently fault-based and, thus, encompassed within the traditional avenue of civil redress.[31]

A subtext of Wyeth's position (discounting the company's disinclination to address squarely the troubling factual circumstances which must be accepted in the present review), is that the likelihood that a pharmaceutical company would actually tender an essentially worthless and dangerous drug into commerce is so minimal, and the burden of responding to meritless claims so great, that it is not sound to preserve an avenue for redress even for legitimate claims. We do not discount the impact of litigation on the pharmaceutical industry, but we simply do not know enough about it to undertake any kind of reasoned comparison of the social policy effects of curtailing fault-based liability in Pennsylvania. See supra note 28. Indeed, courts traditionally

[30] To the degree that Wyeth is uncomfortable with our jury-based civil-justice system, its complaint is with the Pennsylvania Constitution. See PA. CONST. art. 1, §6 ("Trial by jury shall be as heretofore and the right therof remain inviolate.").

[31] Wyeth's recharacterization of Appellee's claim as seeking to impose liability without fault reflects another manifestation of its non-adherence to the appropriate review perspective implicated by the company's matter-of-law attack on Appellee's complaint. See supra note 18.

have regarded the fault-based tort system as a beneficial check encouraging responsible conduct on the part of manufacturers and suppliers. See generally Levine, 555 U.S. at 578, 129 S. Ct. at 1202. In the circumstances, and given the range of information necessary to make these sorts of legislative-type judgments, the arguments are obviously better considered in the legislative branch.

Along these lines, it is noteworthy that, when Congress eliminated civil liability for the unavoidable, adverse side-effects of certain vaccines, as part of a quid pro quo, it implemented a no-fault compensation program for injured persons. See 42 U.S.C. §§300aa-10-19; see also Bruesewitz, ___ U.S. at ___, 131 S. Ct. at 1073-74. The judicial branch, on the other hand, lacks the legislative tools required to consider these sorts of measured responses to the social-policy concerns Wyeth raises. Rather, we are asked to curtail an avenue of traditional, fault-based tort liability as an all-or-nothing proposition. Based on the presentation and record before us, however, we are unable to see with reasonable clarity the results of such decision and to say with reasonable certainty that the change will serve the best interests of society. See Cafozzo, 542 Pa. at 537, 668 A.2d at 527. Accordingly, we are not in a position to make a responsible, substantive change in the law. See id.

VI. Federal Regulatory Involvement

In Levine, the United States Supreme Court explained that, in establishing and refining the federal regulatory scheme governing drugs and drug labeling, Congress evidently determined that widely available state rights of action provided appropriate relief for injured consumers. See Levine, 555 U.S. at 574, 129 S. Ct. at 1199. Along these lines, the Court highlighted that the federal lawmaking body had enacted an express preemption provision relative to medical devices but had not done so for prescription drugs. See id. at 574, 129 S. Ct. at 1200 (citing 21 U.S.C. §360k(a)). The

Supreme Court also observed that the FDA has only limited resources to monitor the thousands of drugs in the marketplace, as well as to assess new entrants, and that the tort system may be particularly helpful in redressing new risks which may emerge postmarketing. See id. at 578-79, 129 S. Ct. at 1202.

We have respect for the FDA and its ongoing efforts to protect the health of the citizenry. As with other regulatory bodies, however, this is reflected in the practice of Pennsylvania courts permitting defendants to adduce evidence of compliance with governmental regulation in their efforts to demonstrate due care (when conduct is in issue). Wyeth offers little to address the limitations of the federal regulatory process observed by the United States Supreme Court or the wealth of commentary discussing the downsides of according absolute deference to a regulatory body.[32] We have no intent here to endorse any criticism of the FDA; our only point is that Wyeth – as the proponent of a contraction of existing tort law – has failed to persuade us that federal regulatory involvement warrants a departure from Pennsylvania's system of civil

[32] See Catherine T. Struve, The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation, 5 YALE J. HEALTH POL'Y L. & ETHICS 587 (2005) (discussing asserted deficiencies in the FDA's post-market surveillance); Allen Rostron, Prescription for Fairness: A New Approach to Tort Liability of Brand-Name and Generic Drug Manufacturers, 60 DUKE L.J. 1123, 1191 (2011) (asserting that "[t]he FDA's regulatory oversight repeatedly has proven insufficient to prevent unreasonably dangerous drugs from reaching consumers"); James T. O'Reilly, Losing Deference in the FDA's Second Century: Judicial Review, Politics, and a Diminished Legacy of Expertise, 93 CORNELL L. REV. 939, 962-78 (2008) (positing that political influence has damaged the FDA's scientific integrity); Christopher Placitella & Justin Klein, The Civil Justice System Bridges the Great Divide in Consumer Protection, 43 DUQ. L. REV. 219, 220-21 (2005) (opining that the FDA appears to be falling under the influence of regulated industries and the political pressures of the executive administration in power); Henderson & Twerski, Drug Designs Are Different, 111 YALE L.J. at 162-63 (explaining that the Restatement Third's treatment for prescription drugs attempts to account for the fact that "the FDA occasionally makes mistakes by approving worthless drugs that no competent provider would prescribe for any class of patients").

redress, where there is a demonstrated lack of due care in the face of an existing duty. See Incollingo, 444 Pa. at 286-87, 282 A.2d at 219.[33]

VII. Learned Intermediaries

Preliminarily, on the subject of the learned intermediary doctrine, some of the underpinnings of the principle have come into question in light of changed practices in the prescription drug industry. These include the emergence of direct-to-consumer advertising and the evolution of the health-care delivery system encompassing new forms of managed care. See, e.g., State ex rel. Johnson & Johnson Corp. v. Karl, 647 S.E.2d 899, 913-14 (W. Va. 2007) (rejecting the learned intermediary doctrine based on such factors).[34]

Presently, we need not consider the wisdom of modifications or exceptions to the doctrine, because Appellee has staked her claim on the premise that Wyeth knew or should have known of information that it did not convey to prescribing physicians, i.e., that Redux was so dangerous that it should not have been ingested by anyone. In such scenarios, the prescribing physician, as an intermediary, is not likely to be appropriately "learned" relative to the critical subject matter. Accordingly, in a situation in which no warning would be sufficient, the learned intermediary doctrine should not apply to

[33] We recognize that the application of Appellee's theory of liability would present more difficult questions in a circumstance in which a prescription drug maintained its FDA approval, it remained on the market, and U.S. doctors continued to prescribe it. The assertion that no reasonable physician would prescribe the drug (knowing what the manufacturer knew or should have known) is capable of gaining greater traction when, as here, the inquiry is more in the nature of a post-mortem.

[34] See also Vicki L. MacDougall, The Impact of the Restatement (Third) of Torts: Products Liability (1998) on Product Liability Law, 62 CONSUMER FIN. L.Q. REP. 105, 114 (2008) (asserting that "direct-to-consumer advertising has injected itself into the doctor/patient relationship and has eroded the policy justifications for the learned intermediary doctrine").

diminish the duties of pharmaceutical companies, or to insulate them from liability for a lack of due care. Accord Henderson & Twerski, Drug Designs Are Different, 111 YALE L.J. at 174 ("[W]hen physicians misprescribe drugs . . . that should never have been marketed in the first place – that provide no net benefits to any class of patients – then the manufacturers of those products should share the responsibility.").[35]

VIII. Design-Defect, Negligent Marketing, Failure-to-Warn, and Other Grounds for Relief in Negligence

We now consider which styling or stylings overlaid upon Appellee's assertion of negligence should surmount Wyeth's matter-of-law attack upon her complaint. Initially, we agree with Appellee and her amici that adherence to the three-prong manufacturing/design-defect/warnings overlay is more consistent with the strict-liability arena (where this Court has maintained that the focus is exclusively on the product) than it is to negligence (as to which the main focus is on conduct). A company which is responsible for tendering into the market a drug which it knows or should know is so

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[35] It should be noted that physicians may be in a particularly difficult position with regard to newer drug therapies, which may give hope to patients whose conditions have been resistant to other interventions. One commentator notes, for example:

> Physicians frequently must try different medications at different dosages until they find the one that seems to work best in a particular patient, and they may have to try various combinations. In some cases, a patient proves to be refractory to the "drug of choice" but responds well to a second- or third-line (often more dangerous) therapeutic agent. . . . These characteristics make pharmaceutical products fundamentally unlike must consumer goods, which anyone equipped with basic information could select and use successfully to achieve the product's intended purpose.

Lars Noah, This is Your Products Liability Restatement on Drugs, 74 BROOK. L. REV. 839, 856 (2009) (footnotes omitted).

dangerous that it should not be taken by anyone can be said to have violated its duty of care either in design or marketing. Accord Brief for Amici Am. & Pa. Ass'ns for Justice at 3 ("[A] manufacturer's negligent conduct can occur at any stage of the marketing process: in the initial design of the drug, in the failure to investigate information about the risks the drug poses, and in its decision to continue to sell the drug despite those unreasonable risks. The defendant's unreasonable behavior at any point in this process should be sufficient to give rise to negligence liability when that conduct results in injury."). In other words, in the negligence arena at least, the substantive allegations are more important than the labels.

As to the design element, we acknowledge Wyeth's point that Appellee's central claim is not an easy fit measured against conventional design theory, not the least because proof of a reasonable alternative design is a typical device used to establish defect,[36] and on account of speculativeness concerning whether FDA approval could

[36] Wyeth and its amicus's assertion, however, that this Court has required proof of an alternative safer design as an absolute prerequisite to the advancement of a design-defect claim is in error. Wyeth, for example, relies on Duchess v. Langston Corp., 564 Pa. 529, 769 A.2d 1131 (2001), for the proposition that such evidence "is an essential element of the plaintiff's liability case." Brief for Wyeth at 31 n.6 (quoting Duchess, 564 Pa. at 559 n.24, 769 A.2d at 1149 n.24) (emphasis added). The company, however, omits material, qualifying language from the quotation. In this regard, Duchess explains that evidence of an alternative safer design "is an essential element of the plaintiff's liability case predicated on a theory of design defect based upon the availability of an alternative safer design." Duchess, 564 Pa. at 559 n.24, 769 A.2d at 1149 n.24 (emphasis added). Read in its appropriate context, the discussion in Duchess reflects only the unremarkable proposition that plaintiffs (such as those before the Court in Duchess) who have premised their own liability cases on the availability of an alternative safer design need to prove their claim on its own terms in order to succeed.

Similarly, Wyeth's amicus indicates that "[i]t is well-established under Pennsylvania law that to sustain a claim of design defect . . . the plaintiff must plead and prove the existence of a safer 'feasible alternative design.'" Brief for Amicus Prod. Liab. Advisory Council, Inc. at 22 (citation omitted). In terms of this Court's decisions, however, (continued…)

ever be had for a new "design." See Henderson & Twerski, Drug Designs Are Different, 111 YALE L.J. at 175 ("Replicating the FDA process is [a] task beyond judicial competence[.]"). Wyeth, however, does not discuss the potential for a plaintiff to refer to other existing medications, treatments, or interventions as a substitute for a drug so dangerous that it should not be used. Noah, This is Your Products Liability Restatement on Drugs, 74 BROOK. L. REV. at 847 (discussing the potential role of substitutability in design-defect analysis relative to prescription drugs); Henderson & Twerski, Drug Designs Are Different, 111 YALE L.J. at 152 (same). Moreover, the American Law Institute has chosen to categorize the type of claim Appellee has advanced under the rubric of design defect, see RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. §6(c), and, significantly, the general requirement otherwise pertaining under the

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(…continued)
amicus merely misreferences a concurring statement appended to a per curiam order, as if it were precedent of the Court. See id. (citing Berrier v. Simplicity Mfg., Inc., 598 Pa. 594, 596 n.1, 959 A.2d 900, 902 n.1 (2008) (Saylor, J., concurring), albeit without the attribution to this author). Moreover, the referenced comment made by this author in Berrier also pertained to the circumstances at hand in the case, not the pronouncement of an overarching rule. See Berrier, 598 Pa. at 596 n.1, 959 A.2d at 902 n.1 (Saylor, J., concurring) ("It seems clear that the plaintiffs' claim of an alternative safer design was at the center of both their negligence and strict liability claims.").

We take no issue with the observation that plaintiffs frequently attempt to demonstrate the availability of an alternative safer design to establish a product defect. Neither Wyeth nor its amicus, however, have cited any decision of this Court making an alternative safer design an absolute prerequisite to any and all design-based claims (although this is the general approach of the Restatement Third, outside special contexts such as those involving prescription drugs and medical devices, see RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. §§2(b), 6(c)).

Restatement of a reasonable alternative design to establish a design defect, see id. §2(b), has not been extended to the prescription-drugs context. See id. §6(c).[37]

Another way to conceptualize Appellee's claim is in relation to manufacturers' duty to warn. In this regard, Appellee has explained that the reason why she did not present a warnings claim is because, in her view, no warning concerning Redux would be sufficient. Thus, her position suggests that the law of negligence establishes a duty, on the part of manufacturers, which can be viewed on a continuum from the requirements of: a warning of dangers, through a stronger warning if justified by the known risks, through non-marketing or discontinuance of marketing when it becomes or should become known that the product simply should not be used in light of its relative risks. We agree with Appellee that this entire continuum is within the scope of the general framework of the applicable duty of care, while highlighting our disapproval of Wyeth's petition for manufacturer immunity at the most severe end of the scale. To the degree Appellee wishes to couch the lack of due care manifested in such circumstances as negligent marketing, this is consistent with her prerogative as master of her own claim. See supra note 8.[38]

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[37] As previously noted, this appeal does not present the opportunity for us to consider adoption of an approach or approaches favored by the American Law Institute in the Restatement Third. We do credit Appellee's position, however, that Pennsylvania law at the very least overlaps or intersects with the Restatement Third principle that a manufacturer marketing a prescription drug which it knows or should know is too dangerous for anyone to use violates the standard of due care and may be held liabile under fault-based tort law. See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. §6(c). Since Appellee is pursuing her claims essentially within the four corners of the Restatement Third model, discussion of the degree to which Pennsylvania law may be less restrictive is left for another day.

[38] Wyeth also takes the position that the only cognizable variant of negligent marketing is in the form of overpromotion, to the degree that a company may be shown to have (continued…)

IX. Wyeth's Subsidiary Contentions

Briefly, we will touch on some of Wyeth's subsidiary contentions which have not yet been addressed.

Regarding Wyeth's comparisons of Appellee's theories with a post-sale duty to recall or retrofit, we agree with Appellee and her amici that the comparison is unuseful. Whatever the policy considerations may be in the recall/retrofit arena, we are convinced that a manufacturer or supplier has a duty to cease further distribution of a product at such point as it may know, or may reasonably be charged with knowledge that the commodity is too dangerous to be used by anyone.[39]

(…continued)
effectively negated warning labels. See, e.g., Brief for Wyeth at 22. We reiterate that Pennsylvania law embodies a less rigid view of negligence theory.

In terms of failure to test, Appellee indicates that she is content for this to be viewed as part and parcel of her negligent-marketing claim. See Reply Brief for Cross-Appellant at 7. Accordingly, we defer our consideration of whether or not a negligent failure to test might serve as a stand-alone premise for liability.

Appellee's "failure to withdraw" claim is obviously corollary to her position concerning negligent marketing. Throughout her explanatory submissions, Appellee has generally conceptualized her overarching claim as a unitary one, and, assuming she is able to adduce sufficient, competent evidentiary support, we know of nothing which would preclude her from presenting this claim to a jury on such terms.

[39] In this regard, we are in general agreement with the following remarks of Appellees' amici:

> FDA approval of a drug permits the manufacturer to market it, but it does not require the manufacturer to do so. If the manufacturer concludes that its product is [too] unsafe [to be used by anyone], it can and must take it off the market. . . . Plaintiff's negligent marketing claim is simply that it was negligent of Wyeth not to take that action sooner, prior to the time that the drug caused injury to Ms. Lance.

(continued…)

As to the admissibility of evidence of the withdrawal of Redux from the marketplace and/or the FDA's subsequent position as to the drug's safety, we leave these questions for development in the pre-trial and/or trial process. Again, the present controversy concerns a threshold, matter-of-law challenge to the legal sufficiency of Appellee's complaint. Whether she can adduce sufficient, competent proof concerning her material allegations is beyond the scope of the present inquiry.[40]

Wyeth's references to criminal statutes pertaining to adulteration and misbranding add little to our assessment, since neither those provisions nor the intermediate-court's discussion of them reflects immunity from civil liability for a lack of due care, based upon blanket deference to the federal regulatory scheme. See White, 386 Pa. Super. 111, 562 A.2d 378.

Concerning the state-of-the-art defense, as noted Appellee has raised a factual dispute concerning what the actual state of the art in the relevant time period reflected. Accordingly, Wyeth's present invocation of the defense is also irrelevant to our review at this time.

(…continued)
Brief for Amici Am. & Pa. Ass'ns for Justice at 14.

[40] We do differ with Appellee's argument to the degree she is suggesting that a post-hoc disapproval, by the FDA, of Redux persuasively establishes that Wyeth previously knew (or should have known) the drug was too dangerous to be used by anyone. Indeed, it may well be that Wyeth took sufficient measures and additional information about the drug merely surfaced in the ordinary course of Redux's deployment. It may also be that Redux was not, in fact, too dangerous to be used by anyone, but that it was removed from the marketplace as a precautionary measure.

Appellee, however, does allude to other asserted evidence here, including the company's alleged concealment of a database of diseases suffered by consumers from the FDA. See Brief for Appellee at 6. In any event, her ability to establish that there are genuine issues of material fact is not in question at this time, on consideration of Wyeth's present, matter-of-law challenge.

X. The Dissenting Opinion

The dissent posits that we presently are creating a new cause of action, i.e., "'negligent design defect' . . . against pharmaceutical companies." Dissenting Opinion, slip op. at 1; see also id. at 8-9 ("As I see it, Wyeth sought to preclude the creating of new claim, not to 'extinguish' ones already in existence."). Certainly, however, the dissent does not deny that negligent design defect claims long have been recognized against product manufacturers generally in this Commonwealth. Accordingly, its position must rest upon some source of authority establishing an already existing, special rule immunizing pharmaceutical companies in the negligence arena. The dissent, however, offers no reference to any such authority. Indeed, we have addressed the salient decisions above and have found no such viable rule grounded in any precedent of this Court concerning negligence doctrine which would insulate pharmaceutical companies from civil liability for manufacturing and/or disseminating products which they know or should have known are simply too dangerous to be used. Accord Incollingo, 444 Pa. at 287, 282 A.2d at 219 ("[T]he public interest requires the holding of companies which make and sell drugs and medicine for use in the human body to a high degree of responsibility under both the criminal and civil law for any failure to exercise vigilance commensurate with the harm which would be likely to result from relaxing it." (quoting Henderson v. Nat'l Drug Co., 343 Pa. 601, 610, 23 A.2d 743, 748 (1971) (emphasis in original))). The essential difference in our frame of reference, as compared to that of the dissent, concerning the character and scope of existing negligence principles is central to our dispositions of the waiver and substantive issues presented in these appeals.

XI. Summary

As the United States Supreme Court explained in Levine, primary responsibility for drug safety rests with the manufacturer, which has "superior access to information about [its] drugs, especially in the postmarketing phase as new risks emerge." Levine, 555 U.S. at 578-79, 129 S. Ct. at 1202. Under Pennsylvania law, pharmaceutical companies violate their duty of care if they introduce a drug into the marketplace, or continue a previous tender, with actual or constructive knowledge that the drug is too harmful to be used by anyone. There has been no supported presentation here which would persuade us to immunize companies from the responsibility to respond in damages for such a lack of due care resulting in personal injury or death. Indeed, Congress and the Legislature are in the best position to make these sorts of weighty and consequence-laden policymaking judgments impacting a traditional, state-law, civil, remedial scheme. Neither body has conferred such immunity, however, albeit Congress has taken measured action relative to certain vaccines and prescription medical devices.

The order of the Superior Court is affirmed in part and reversed in part, per the terms of this opinion.

Former Justice Orie Melvin did not participate in the decision of the case.

Mr. Justice Baer, Madame Justice Todd, and Mr. Justice McCaffery join the opinion.

Mr. Justice Eakin files a dissenting opinion in which Mr. Chief Justice Castille joins.