UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

KENNETH MOSS, as executor of the estate of Lynn Gardner Moss, and KENNETH MOSS, individually

v.

WYETH INC., et al.

No. 3:04cv1511 (SRU)

MEMORANDUM OF DECISION

Defendants Wyeth, Inc. and Wyeth Pharmaceuticals, Inc. (collectively "Wyeth") have argued that Connecticut "does not recognize strict liability claims for design defects in prescription drugs" under the Connecticut Product Liability Act ("CPLA"). *See* Wyeth's Bench Br. Regarding Design Defect Claims Under Connecticut Law (doc. # 295), at 1. That assertion is based on comment k of section 402A of the Restatement (Second) of Torts, which the Connecticut Supreme Court has adopted in principle, but has not yet fully defined in scope and effect. On May 8, 2012, I issued a brief oral ruling on the effect of comment k on strict liability for design defects under Connecticut law.[1] Because the viability of a design defect claim directly affects the jury instructions in this case and likely will be the subject of appeal, I am issuing this memorandum of decision to more precisely explain my conclusion that Connecticut recognizes a claim for design defect in prescription drugs, but would also recognize an affirmative defense to such a claim.

[1] *See* Trial Tr. (May 8, 2012), at 534-40.

I. Background

This is a products liability action, before this court on diversity jurisdiction, involving combination hormone replacement therapy ("cHRT") products that allegedly caused breast cancer. The plaintiff is Kenneth Moss, individually and as executor for the estate of his late wife, Lynn Gardner Moss. Lynn Gardner Moss ("Mrs. Moss") passed away in December 2006 after a protracted battle with breast cancer. Wyeth is a pharmaceutical company that manufactures the hormone therapy drugs Premarin, an estrogren, and Prempro, a combination of Premarin and a progestin, which are both prescribed to combat the symptoms of menopause. The plaintiff claims that Premarin and Prempro were unreasonably dangerous, that Wyeth promoted the drugs without adequate warnings and without adequate clinical trials examining their safety, and that Mrs. Moss's use of the drugs was a substantial contributing factor in her development of breast cancer.

The Amended Complaint alleges eleven causes of action: failure to warn (Count I); strict liability for a defective product (Count II); negligence (Count III); misrepresentation as to safety and efficacy (Count IV); punitive damages for reckless failure to warn the public (Count V); breach of implied warranty (Count VI); breach of express warranty (Count VII); violation of the Connecticut Unfair Trade Practices Act ("CUTPA") (Count VIII); wrongful death (Count IX); loss of consortium (Count X); and fraudulent concealment, so as to toll the statute of limitations (Count XI). *See* Am. Compl. ¶¶ 103-69.

I granted summary judgment in favor of Wyeth on the breach of express warranty claim (Count VII) and the CUTPA claim (Count VIII). *See* Mot. Hr'g Tr. (Mar. 1, 2012), at 95-96 (doc. # 227). I also granted partial summary judgment on plaintiff's alternative design theory of

liability due to a lack of admissible expert testimony.[2] *See id.* at 94-95. I denied summary judgment on the remaining counts, but ruled that each of the separately pleaded claims would be treated as a single cause of action under the CPLA. *See id.* at 87.

Relevant to present purposes, the plaintiff seeks to put before the jury negligence-based theories of failure to warn and test, as well as the following theories of strict liability: (1) defective design; and (2) defective warnings.

II. Discussion

The CPLA, enacted in 1979, was intended to merge the various common law theories of products liability into a single cause of action in order to simplify pleadings and procedures. *See Lynn v. Haybuster Mfg., Inc*., 226 Conn. 282, 292 (1993) (summarizing the legislative history of Conn. Gen. Stat. § 52-572m *et seq*.). However, "the CPLA certainly retains the plaintiff's right to allege the traditional theories of recovery along with the statutory basis for recovery under one unified count denominated as a 'product liability claim.'" *Lamontagne v. E.I. DuPont de Nemours & Co., Inc.*, 834 F. Supp. 576, 587 (D. Conn. 1993) (internal quotation omitted).

Connecticut law provides for civil damages actions grounded in strict liability for defective products. Conn. Gen. Stat. § 52-572n. In general, Connecticut courts have adopted the strict liability test established in section 402A of the Restatement (Second) of Torts. *Garthwait v. Burgio*, 153 Conn. 284, 289-90 (1965). Section 402A imposes liability only when the product

[2] This ruling was premised on my earlier *Daubert* ruling that plaintiffs' proffered experts, Drs. Tilley and Austin, would not be permitted to testify on alternative designs for cHRT products that were developed years after Mrs. Moss's use of those products. *See* Mot. Hr'g. Tr. (Mar. 1, 2012), at 60 (doc. # 227).

is "unreasonably dangerous" to the ordinary consumer who purchases it. *Potter v. Chicago Pneumatic Tool Co.*, 241 Conn. 199, 211 (1997) (quoting § 402A, cmt. (i)).

Within the strict liability rubric, Connecticut recognizes a trifecta of product defects: (1) manufacturing defects; (2) design defects; and (3) warnings defects. *See Vitanza v. Upjohn Co.*, 257 Conn. 365, 373 (2001) ("A product may be defective due to a flaw in the manufacturing process, a design defect or because of inadequate warnings or instructions."). Generally speaking, a manufacturing defect is a mistake in the assembly process, which results in a product that differs from the manufacturer's intended result. *See Miller v. United Technologies Corp.*, 233 Conn. 732, 779 (1995). A design defect, in contrast, exists when the product is otherwise properly manufactured, but is nonetheless unreasonably dangerous because its attributes can cause unexpected injury. A product is defectively designed if: (1) it failed to perform as safely as an ordinary consumer would expect when used in a reasonably foreseeable manner (the "ordinary consumer expectations" test); or (2) in the case of complex products, the risk of danger inherent in the design of the product outweighs its utility (the "modified consumer expectations" test). *See Potter*, 241 Conn. at 211-12, 219-20. Lastly, a warning defect exists when a product is unreasonably dangerous because it lacks adequate warnings or instructions concerning the product's dangerous propensities. *See Sharp v. Wyatt, Inc.*, 31 Conn. App. 824, 833 (1993), *aff'd*, 230 Conn. 12, 16 (1994). In such cases, the failure to warn itself makes the product defective. *Id.*

A. Comment k

Although section 402A imposes strict liability on a seller who markets a product "in a defective condition unreasonably dangerous" to the consumer, comment k carves out an

exception to the strict liability rule in the case of products characterized as "unavoidably unsafe." Comment k provides:

> *Unavoidably unsafe products*. There are some products which, in the present state of human knowledge, are quite 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 warning, 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 to strict liability 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.

Restatement (Second) of Torts § 402A, cmt. (k). Thus, comment k provides a defense against strict liability to manufacturers of "unavoidably unsafe" products so long as the product is (1) properly manufactured and (2) proper warnings are given. *Id.* The comment provides a risk-benefit test for products that, given the present state of human knowledge, are incapable of being made safe for their intended uses. Products that satisfy the risk-benefit test are deemed "unavoidably unsafe" and will not be considered defective or unreasonably dangerous under section 402A because their known benefits to society at large exceed their known risks. The marketing of these products is therefore justified notwithstanding the inherent dangers they pose.

A few other aspects of comment k are worth nothing.

First, because the comment speaks explicitly of products "properly prepared" and accompanied by "proper directions and warnings," comment k does not exempt products from strict liability for manufacturing defects or warning defects. Rather, the exemption from strict liability applies only to allegations of defective design. *See, e.g., Castrignano v. E.R. Squibb & Sons, Inc.*, 546 A.2d 775, 780 (R.I. 1988); *Toner v. Lederle Laboratories*, 112 Idaho 328, 336 (1987); *Feldman v. Lederle Laboratories*, 97 N.J. 429, 447-48 (1984).

Second, courts are split on whether comment k applies categorically to all prescription drugs or whether comment k should only be applied as an affirmative defense on a case-by-case basis. The majority of courts take the latter approach, holding that comment k does not provide all prescription drugs with blanket immunity from strict liability design defect claims. These courts apply comment k on a case-specific basis and as an affirmative defense to be proven by the defendant. *See, e.g., Hill v. Searle Laboratories*, 884 F.2d 1064, 1068 (8th Cir. 1989) ("We agree with those courts that view comment k as an affirmative defense."); *Weiss v. Fujisawa Pharm. Co.*, 2006 WL 3533072, at *3 (E.D. Ky. Dec. 7, 2006) ("[T]his Court agrees with the majority position that the case-by-case analysis is better supported by the language of comment k."); *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 836 (Neb. 2000) ("The majority of jurisdictions that have adopted comment k apply it on a case-by-case basis."); *Bryant v. Hoffmann-La Roche, Inc.*, 585 S.E.2d 723, 728 (Ga. App. 2003); *Adams v. G.D. Searle & Co.*, 576 So. 2d 728, 732-33 (Fla. App. 1991); *Castrignano*, 546 A.2d at 781; *Toner*, 732 P.2d at 308-09; *see also Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 657 (1st Cir. 1981). A minority of courts, "troubled by the lack of uniformity and certainty inherent in the case-by-case approach" and fearing "disincentive[s] for pharmaceutical manufacturers to develop new products," have interpreted comment k more broadly and provide all prescription drugs

categorical immunity from strict liability for design defects. *Grundberg v. Upjohn Co.*, 813 P.2d 89, 94-95 (Utah 1991); *see also Young for Young v. Key Pharmaceuticals, Inc.*, 922 P.2d 59, 64 (Wash. 1996) ("[U]nder Washington law, a separate determination of whether a product is unavoidably unsafe need not be made on a case-by-case basis if that product is a prescription drug."); *Brown v. Superior Court*, 751 P.2d 470 (Cal. 1988); *Stone v. Smith, Kline & French Labs.*, 447 So. 2d 1301, 1303-04 (Ala. 1984); *McKee v. Moore*, 648 P.2d 21, 23 (Okla. 1982); *Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 90–91 (2d Cir. 1980) (applying New York law).

B. Connecticut's Adoption of Comment k

In *Vitanza*, the Connecticut Supreme Court adopted the reasoning of comment k, but did so in specific context: to support the application of the learned intermediary doctrine to prescription drug warnings under Connecticut law. 257 Conn. at 376. ("Generally, a manufacturer's duty to warn of dangers associated with its products pertains only to known dangers and runs to the ultimate user or consumer of those products. . . . The learned intermediary doctrine, which is supported by comment (k) to § 402A of the Restatement (Second) of Torts, is an exception to this general rule."). According to the Connecticut Supreme Court:

> The learned intermediary doctrine provides that adequate warnings to prescribing physicians obviate the need for manufacturers of prescription products to warn ultimate consumers directly. The doctrine is based on the principle that prescribing physicians act as learned intermediaries between a manufacturer and consumer and, therefore, stand in the best position to evaluate a patient's needs and assess the risks and benefits of a particular course of treatment.

Id. at 375-76 (internal quotations omitted).

In an effort to buttress the learned intermediary doctrine, the *Vitanza* Court adopted comment k in sweeping terms, stating "the policy considerations contained in comment (k) to §

402A are persuasive and are in accord with this state's product liability jurisprudence." *Id.* at 375. But the learned intermediary doctrine is a *warnings* doctrine, which applies broadly to claims sounding in negligence as well as strict liability, and is therefore only indirectly supported by the language of comment k—a comment which, by its terms, only provides an exemption from design-defect strict liability claims. *See* § 402A, cmt. (k). Indeed, the Court addressed at some length the scope of liability for failure to warn, but barely mentioned liability for defective design. Thus, *Vitanza* embraced the principle of comment k in one context without offering any analysis on how it should apply in others. It remains unclear whether the Connecticut Supreme Court would apply comment k's strict liability exemption categorically to all prescription drugs, or whether it would apply the "case-by-case" approach discussed above.

According to *Vitanza*, a "manufacturer of an unavoidably unsafe product can avoid strict liability if the product is 'properly prepared, and accompanied by proper directions and warnings.'" *Id.* at 375 (quoting § 402A, cmt. (k)) (emphasis added). However, as at least one other federal court has noted, "[p]resently, no test exists in Connecticut law for determining when a product is unavoidably unsafe within the meaning of comment k." *Johannsen v. Zimmer, Inc.*, 2005 WL 756509, at *8 n.5 (D. Conn. Mar. 31, 2005). Because this Court, sitting in diversity, is faced with a question of state law that has not been fully resolved, I must "carefully predict how the state's highest court would resolve the uncertainties" of state law relevant to this matter. *Runner v. New York Stock Exch., Inc.*, 568 F.3d 383, 386 (2d Cir. 2009) (internal quotation omitted). This decision outlines my general predictions on the scope of strict liability for prescription drugs under Connecticut law. My analysis is tailored to the two strict liability claims asserted here: (1) design defects; and (2) warning defects.

C. Design Defect Liability for Prescription Drugs

After reviewing the relevant precedent, I predict the Connecticut Supreme Court would interpret comment k narrowly, and therefore would decline to cloak all prescriptions drugs with blanket immunity from design defect claims. Connecticut would likely adopt the majority approach and apply comment k on a case-by-case basis as an affirmative defense that must be established by the defendant. I reach this conclusion for the following reasons.

First, although most prescription drugs can be categorized in some sense as "unavoidably unsafe," the language used in *Vitanza*, and the text of comment k itself, strongly implies that not all drugs automatically fall within the exemption from strict liability. In *Vitanza*, the Connecticut Supreme Court stated, in reference to comment k, that "[p]rescription drugs *generally* fall within the classification of 'unavoidably unsafe' products." 257 Conn. at 374-75 (emphasis added). Further, the text of comment k provides that "unavoidably unsafe" products are "especially *common* in the field of drugs." § 402A, cmt. (k) (emphasis added). Reference to prescription drugs as "generally" or "commonly" within the ambit of "unavoidably unsafe" products suggests that at least some unsafe drugs are not unavoidably so.

Second, the drafters of comment k did not intend to grant all manufacturers of prescription drugs a blanket exception to strict liability. As the Eighth Circuit has noted:

> Such an exception was proposed at the American Law Institute meeting where section 402A and comment k were adopted, but this proposal was defeated. 38 ALI Proc. 19, 90-98 (1961). The language of comment k suggests that only exceptional products, albeit such exceptional products are more likely to be found in the field of prescription drug products, should be excluded from the strict liability provisions. But more importantly, the example given—the vaccine for the Pasteur treatment of rabies—suggests that only special products, those with exceptional social need, fall within the gamut of comment k.

Hill, 884 F.2d at 1069. Comment k should not be given an interpretation broader than its own authors intended.

Third, the case-by-case approach is more consistent with Connecticut's existing strict product liability jurisprudence. Connecticut courts have traditionally taken a liberal view to design defect claims. For example, courts have held that "[i]t is not necessary that the plaintiff in a strict tort action establish a specific defect as long as there is evidence of some unspecified dangerous condition." *Potter*, 241 Conn. at 225 (quoting *Living & Learning Centre, Inc. v. Griese Custom Signs, Inc.*, 3 Conn. App. 661, 664 (1985)). Moreover, the Connecticut Supreme Court has consistently held that proof of a feasible alternative design (a euphemism for avoidability) is not an essential element of a plaintiff's prima facie case for defective design. *Id.* at 216-17 ("In our view, the feasible alternative design requirement imposes an undue burden on plaintiffs that might preclude otherwise valid claims from jury consideration. Such a rule would require plaintiffs to retain an expert witness even in cases in which lay jurors can infer a design defect from circumstantial evidence."); *Wagner v. Clark Equipment Co., Inc.*, 243 Conn. 168, 198 (1997) ("[T]he jury *may* consider the feasibility of a safer, alternative design in weighing a product's risks against its utility to determine whether a reasonable consumer would consider the product design unreasonably dangerous.") (emphasis added). In contrast, the courts that have interpreted comment k to provide blanket immunity from design defect liability are often in jurisdictions that take a narrower approach to design defect liability by requiring a plaintiff to prove the feasibility of an alternative design as part of her prima facie case. *See, e.g., Lovold v. Fitness Quest Inc.*, 2012 WL 529411, at *2 (W.D. Wash. Feb. 16, 2012) ("[W]hen relying on the risk-utility test, plaintiffs must prove the existence of an adequate alternative design.") (citing *Ruiz-Guzman v. Amvac Chem. Corp.*, 7 P.3d 795 (Wash. 2000)); *Brockert v. Wyeth*

Pharmaceuticals, Inc., 287 S.W.3d 760, 770-71 (Tex. App. 2009) ("A plaintiff must prove that there is a safer alternative design to recover under a design-defect theory.") (citing *Gen. Motors Corp. v. Sanchez*, 997 S.W.2d 584, 588 (Tex. 1999)). The case-by-case approach, therefore, is more consistent with the traditional scope of design defect liability under Connecticut law.

Lastly, the majority of courts that have addressed this issue have concluded that policy considerations weigh in favor of interpreting comment k as an affirmative defense that applies on a case-by-case basis. *See, e.g.*, *Hill*, 884 F.2d at 1069 ("Furthermore, the premise generally relied on by those courts applying comment k to all prescription drugs—that the public interest in the development of prescription drug products requires the user to bear all the costs of injury unless the drug product was negligently manufactured or designed or unaccompanied by proper warnings—is unconvincing. In our view, this policy has no greater relevance to prescription drug products than to other products having life-saving or life-bettering characteristics."); *Castrignano*, 546 A.2d at 781 ("[W]e believe the societal interest in ensuring the development and marketing of prescription drugs will be adequately served by extending comment-k protection to prescription drugs on a case-by-case basis. We therefore adopt the case-by-case approach to determine whether a prescription drug is exempt from strict liability for defective design.").

Thus, in my view, the Connecticut Supreme Court would adopt the following approach to strict liability defective design claims for prescription drugs. First, the plaintiff must establish a prima facie case for defective design by showing the drug was unreasonably dangerous under the familiar "consumer expectations" and "modified consumer expectations" tests.[3] Under the

[3] The "modified consumer expectations" test will likely apply to most claims involving prescription medications. The modified test applies whenever the product involves complex

learned intermediary doctrine, however, the relevant expectations are those of the *physician*, not the ultimate consumer. *See Vitanza*, 257 Conn. at 392 ("The anticipated awareness of an expected user with respect to the dangers of the product is not an issue in prescription drug cases because the 'expected user' is the physician."). Thus, the analysis involves weighing the risks and benefits of the drug for the plaintiff in light of the expectations and expertise of her prescribing physician.

If the plaintiff establishes a prima facie case, then the defendant, at its option, may assert comment k as an affirmative defense to strict liability. In order to qualify for the defense, the defendant must establish the basic elements articulated under comment k: (1) the drug must be "unavoidably unsafe," meaning that (i) the drug is incapable of being made more safe, and (ii) the danger is justified because the societal benefits of the drug exceed its inherent risks given the scientific knowledge available at the time the drug was marketed; (2) the drug must be "properly prepared," meaning free of any manufacturing defects that would otherwise render the drug "avoidably" unsafe; and (3) the drug must be "accompanied by adequate warnings," meaning the drug does not otherwise suffer from a warning defect. *See* § 402A cmt. (k). If the defendant proves the elements of the affirmative defense, then recovery for design-defect liability is precluded.

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designs "in which an ordinary consumer may not be able to form expectations of safety." *Potter*, 241 Conn. at 219. The modified expectation test employs a risk-utility analysis, in which the fact-finder must consider whether the risks of the product as designed outweigh its benefits as the basis for determining whether the product was unreasonably dangerous. *Id.* at 220. Among the factors considered are: the usefulness of the product, the likelihood and severity of the danger posed by the design, the feasibility of alternative designs, the cost of improvements, the ability to alter the design without harming the product's usefulness or price, and the possibility of spreading potential loss by increasing the product's price. *Id.* at 221. The plaintiff may show the availability of a feasible design alternative to establish that the risks outweigh the utility, but this showing is not necessary to prove the claim of design defect. *Id.*

The burden-shifting approach outlined above has been adopted in a number of jurisdictions. *See, e.g., Bartlett v. Mutual Pharmaceutical Co.*, 731 F. Supp. 2d 135, 150-51 (D.N.H. 2010) ("[C]ourts generally place the initial burden of proving the various [comment k] factors on the defendant."), *aff'd*, __ F.3d __, 2012 WL 1522004 (1st Cir. May 2, 2012); *Freeman*, 618 N.W.2d at 840 ("Under this rule, an application of the comment does not provide a blanket immunity from strict liability for prescription drugs. Rather, the plaintiff is required to plead the consumer expectations test, as he or she would be required to do in any products liability case. The defendant may then raise comment k. as an affirmative defense. The comment will apply to except the prescription drug product from strict liability when it is shown that (1) the product is properly manufactured and contains adequate warnings, (2) its benefits justify its risks, and (3) the product was at the time of manufacture and distribution incapable of being made more safe."); *Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142, 1149 (D. Or. 1989) ("Most of the courts which have considered the issue have concluded that a prescription drug is unavoidably unsafe if it meets all of the requirements of Comment k . . . . These requirements include a showing that the product is incapable of being made safe for its intended and ordinary use; that the benefits of the product justify its marketing and use despite the unavoidable risks; that the product is properly prepared and marketed; and that the product is accompanied by proper directions and warnings. Comment k is an affirmative defense, and the defendant bears the burden of proving its applicability."); *Martinkovic v. Wyeth Laboratories, Inc.*, 669 F. Supp. 212, 216-17 (N.D. Ill. 1987) ("As a precondition to pursuing a comment k defense, however, [defendant] must establish that the vaccine was both properly prepared, and accompanied by proper directions and warnings.") (internal quotation omitted).

Wyeth argues, however, that *Vitanza* forecloses this narrower interpretation of comment k. In support, Wyeth points to *Basko v. Sterling Drug, Inc.*, 416 F.2d 417 (2d Cir. 1969), a decision the *Vitanza* Court cited in support of the learned intermediary doctrine. In *Basko*, the Second Circuit, applying Connecticut law, stated that "there is no strict liability under comment k unless *the consumer first establishes* a breach of the manufacturer's duty to warn." 416 F.2d at 426 (emphasis added). Wyeth argues this language bars any interpretation of comment k as an affirmative defense, because the burden to "establish[] a breach of the manufacturer's duty to warn" always remains with the plaintiff. *See id.*

Basko is not controlling for two reasons. First, *Basko* was decided a decade before the CPLA was adopted and more than three decades before Connecticut officially adopted comment k. Thus, *Basko* could not have been decided in light of Connecticut's interpretations of the product liability statute. Second, *Basko* assumed, prior to *Vitanza*, that comment k applied categorically to all prescription drugs and therefore confined its analysis to *warning defects*. As explained above, comment k by its own terms does not exempt unavoidably unsafe products from warning defect liability. Thus, *Basko* is perfectly consistent with the formulation described above in so far as *Basko*'s holding relates to warning defects rather than design defects: the burden to establish a warning defect is always on the plaintiff and the burden-shifting analysis for unavoidably unsafe products subject to design defect claims does not apply to warning defect claims.

Moreover, despite Wyeth's contentions to the contrary, there is nothing inherently contradictory about the inverse burdens of proof in a warning defect claim versus a comment k defense to design defect liability. Although the defendant's burden to prove the adequacy of the warning in a comment k defense is the mirror image of the plaintiff's burden to prove the

inadequacy of the warning in a warning defect claim, there is little risk of inconsistent verdicts. Only in the rarest of cases, where the evidence is in complete equipose, will the warnings be found adequate for purposes of one claim and inadequate for purposes of the other. In that extraordinary circumstance alone would the burden of proof become decisive. In the vast majority of cases, however, the result will be consistent verdicts despite the different placement of the burden of proof.

D. Warning Defect Liability for Prescription Drugs

The proper scope of warning defect liability for prescription drugs is less controversial. Nevertheless, in the interest of completeness, I briefly address below the extent of strict liability for warning defects liability under Connecticut law.

Section 52-572q governs civil actions for warning defects. The statute imposes liability on a product seller that failed to provide adequate warnings or instructions.

Section 52-572q provides:

> (a) A product seller may be subject to liability for harm caused to a claimant who proves by a fair preponderance of the evidence that the product was defective in that adequate warnings or instructions were not provided.
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> (b) In determining whether instructions or warnings were required and, if required, whether they were adequate, the trier of fact may consider: (1) The likelihood that the product would cause the harm suffered by the claimant; (2) the ability of the product seller to anticipate at the time of manufacture that the expected product user would be aware of the product risk, and the nature of the potential harm; and (3) the technological feasibility and cost of warnings and instructions.
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> (c) In claims based on this section, the claimant shall prove by a fair preponderance of the evidence that if adequate warnings or instructions had been provided, the claimant would not have suffered the harm.
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> (d) A product seller may not be considered to have provided adequate warnings or instructions unless they were devised to communicate with the person best able to take or recommend precautions against the potential harm.

Conn. Gen. Stat. § 52-572q.

The Connecticut Supreme Court has never explicitly held that the standards for strict liability for a warning defect are entirely equivalent to negligent failure to warn. That court has indicated, however, that the notion of "foreseeability," a concept clearly appropriated from negligence law, may be implicated by subsection (b) in determining whether warnings were adequate. *Sharp v. Wyatt, Inc.*, 230 Conn. 12, 16 n.7 (1994) ("[F]oreseeability may be implicated under subsection (b), because . . . subsection (b) calls on the trier of fact to consider the 'likelihood that the product would cause the harm suffered by the plaintiff' as a factor in determining whether a product is defective for failure of its seller to provide adequate warnings."). Moreover, Connecticut appellate courts have stated, at least in dicta, that warning defect claims parallel negligent failure-to-warn claims. *See Gajewski v. Pavelo*, 36 Conn. App. 601, 611 (1994) ("[I]n practical terms, there is no difference between the statutory strict liability of § 52-572q and negligence with respect to the law of warnings.") (citing *Sharp v. Wyatt*, 31 Conn. App. 824, 848 (1993), *aff'd*, 230 Conn. 12 (1994)).

In my view, whether formulated under a strict liability or a negligence theory, section 52-572q only requires that a manufacturer warn of dangers about which it knew or should have known. Although the cases have not always been precise in distinguishing between the two theories, Connecticut courts addressing warning defect liability have stated that a "seller is under a duty to give adequate warnings of unreasonable dangers involved in the use of which he knows, or should know." *Giglio v. Connecticut Light & Power Co.*, 180 Conn. 230, 234 (1980). That is, there is only a duty to warn of those dangers that are known, or that are reasonably foreseeable, to the defendant. *See Tomer v. American Home Products Corp.*, 170 Conn. 681, 689-90 (1976) ("A product may be defective because a manufacturer of [sic] seller failed to warn

of the product's unreasonably dangerous propensities. . . . If a manufacturer *knows or should know* that a product may cause serious injury to users, but does not warn of the potentially injurious effects either through negligence or because of concern that sales of the product would thereby be reduced, he cannot be absolved from the imposition of strict liability in tort because an 'appreciable number of users' would not be adversely affected.") (citing § 402 A, cmt. (j)) (emphasis added).

Strict liability obviously differs from negligence in that it eliminates the necessity of proving that the manufacturer breached a duty of care; strict liability focuses not on the conduct of the manufacturer, but on the product itself and finds the manufacturer liable if the product was defective. By requiring manufacturers to warn only of those dangers of which they had actual or constructive knowledge, the standard for warning defects effectively merges with the standard for negligent failure to warn. Although this test departs somewhat from the concept that underlies the doctrine of strict liability, Connecticut law cannot be read to require manufacturers to warn of dangers that are unknowable. Imposing strict liability on drug manufacturers for unknowable or unforeseeable dangers would make them virtual insurers of their products, a burden expressly rejected by the Connecticut Supreme Court. *See Vitanza*, 257 Conn. at 377 ("[S]trict tort liability does not transform manufacturers into insurers, nor does it impose absolute liability.") (quoting *Potter*, 241 Conn. at 210).[4]

[4] I note that one Connecticut appellate court has stated the following in dicta: "We agree that if the jury had been instructed unequivocally to use a common law negligence standard to determine whether warnings were required and, if they were required, to determine, by using a common law standard, whether they were adequate, there would be a reversible error." *Gajewski*, 36 Conn. App. at 611. I understand this passage to mean that, if a jury is instructed only on the elements of negligence (i.e., duty, breach, causation, and damages) rather than the elements enumerated under section 52-572q, the instruction would be erroneous. That is not what I propose here. Rather, I read section 52-572q as incorporating the familiar concept from

III. Conclusion

In sum, my view is that the Connecticut Supreme Court would most likely adopt the majority approach to comment k: the exemption applies on a case-by-case basis and permits a defendant to prove an otherwise unavailable affirmative defense to strict liability for design defects. Further, strict liability for warning defects only attaches to warnings of dangers about which the defendant either knew or should have known. The conclusions set forth in this memorandum of decision will be reflected in the jury instructions in this case.

It is so ordered.

Dated at Bridgeport, Connecticut, this 24th day of May 2012.

/s/ Stefan R. Underhill
Stefan R. Underhill
United States District Judge

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negligence law that a manufacturer need only warn of risks that are either known or reasonably foreseeable. Put another way, a product cannot be defective merely because it fails to provide warnings of unknown, unknowable, or unforeseeable risks.