MICHELE M. VITANZA ET AL. *v.*
THE UPJOHN COMPANY
(SC 16343)

Sullivan, C. J., and Borden, Norcott, Vertefeuille and Zarella, Js.

Argued April 17—officially released August 7, 2001

Counsel

Richard A. Silver, with whom were *Jonathan M. Levine* and *Peter M. Dreyer*, for the appellants (plaintiffs).

Timothy W. Donahue, with whom was *Tracey M. Lane*, for the appellee (defendant).

Charles D. Ray and *Alfred A. DiVincentis, Jr.*, filed a brief for the Connecticut Business and Industry Association as amicus curiae.

Jeffrey R. Babbin, *Jeremy G. Zimmermann*, *Naomi B. Graubard* and *Hugh F. Young, Jr.*, pro hac vice, filed a brief for the Product Liability Advisory Council, Inc., as amicus curiae.

William F. Gallagher and *David McCarry* filed a brief for the Connecticut Trial Lawyers Association as amicus curiae.

Opinion

BORDEN, J. The dispositive issue in this case is whether the learned intermediary doctrine bars the present action brought by the named plaintiff, Michele M. Vitanza, whose husband had died as a result of ingesting a sample of a prescription drug given to her by her physician. The learned intermediary doctrine provides, in general terms, that adequate warnings to a prescribing physician obviate the need for a manufacturer of a prescription drug to warn ultimate consumers. Pursuant to General Statutes (Rev. to 1999) § 51-199a and Practice Book § 82-1,[1] the United States Court of Appeals for the Second Circuit certified the following question of law to this court: ''On the facts of this case—where (i) a drug manufacturer distributed promotional free samples to physicians and provided appropriate warnings to the physicians, (ii) the drug sample states only that it is to be dispensed by prescription only, (iii) the drug sample is ingested by (and causes injury to) an otherwise unwarned person in the patient's household, and (iv) the drug manufacturer is sued for damages under the Connecticut Product Liability Act, [General Statutes § 52-272m et seq.]—is the drug manufacturer insulated from liability as a matter of law by the learned intermediary doctrine?'' *Vitanza* v. *Upjohn Co.*, 214 F.3d 73, 73–74 (2d Cir. 2000). We conclude that the learned intermediary doctrine does bar the present action as a matter of law.

The plaintiff[2] brought the underlying product liability complaint against the defendant, The Upjohn Company, pursuant to the Connecticut Product Liability Act (act), General Statutes § 52-572m et seq. The defendant removed the complaint to federal court on the basis of diversity jurisdiction. The defendant filed a special defense stating that, under the learned intermediary doctrine, it had no duty as a matter of law to provide a direct warning to the ultimate consumer of its product. The defendant moved for summary judgment on the basis of the learned intermediary doctrine. The plaintiff filed a cross motion for partial summary judgment seeking dismissal of the defendant's affirmative defense based on the learned intermediary doctrine. The United States District Court for the District of Connecticut granted the defendant's motion, denied the plaintiff's motion, and rendered judgment for the defendant. *Vitanza* v. *Upjohn Co.*, 48 F. Sup. 2d 124, 132 (D. Conn. 1999). The plaintiff then appealed to the Court of Appeals, which thereafter certified the question of law to this court.

The record certified by the Court of Appeals provides the following facts and procedural history.[3] The defendant manufactured and marketed the prescription drug Ansaid, which is an acronym for ''a nonsteroidal anti-inflammatory drug.'' Ansaid is indicated for the acute or long-term treatment of signs and symptoms of rheu-

matoid arthritis and osteoarthritis, as well as for less serious conditions. The defendant was aware that Ansaid could produce fatal reactions in persons allergic to aspirin or other nonsteroidal anti-inflammatory drugs.

In early 1992, a sales representative for the defendant provided samples of Ansaid to the plaintiff's physician, Gary Besser, who is a board certified obstetrician and gynecologist. The samples were distributed in a box containing nine blister cards. Each blister card contained four tablets. The labeling on the back of each blister card provided:

"Complimentary Package
Not for Sale
4 Tablets
Ansaid 100 mg. Tablets
FLURBIPROFEN
Each tablet contains flurbiprofen 100 mg.
Information for use and dosage—see insert.
Store at controlled room temperature 15°–30° C (59°–86° F)
Caution: Federal law prohibits dispensing without prescription."

In addition, each box of Ansaid samples contained one package insert that was eight columns long, single spaced, and contained information regarding clinical pharmacology, indications for use, contraindications, warnings, adverse reactions, precautions, drug interactions, overdosage, dosage and administration. The package insert referred to the possibility of allergic reactions to Ansaid, providing that: " 'ANSAID should not be given to patients in whom ANSAID, aspirin, or other nonsteroidal anti-inflammatory drugs induce asthma, urticaria, or other allergic-type reactions. Fatal asthmatic reactions have been reported in such patients receiving this type of drug.' " Although each box of Ansaid samples contained nine blister cards, there was only one insert per box, and the blister cards themselves did not contain any warnings. Samples of Ansaid were packaged in accordance with federal and state law. The defendant also reprinted the Ansaid package insert in its entirety in the 1989 Supplement to the Physicians' Desk Reference, which is a standard pharmaceutical reference text for the medical profession, and in each subsequent annual edition of the reference book up to the date of the decedent's death.

In June, 1992, the plaintiff visited Besser for a postpartum examination after the birth of her daughter, at which time she complained of a stiff neck. Besser provided her with several sample blister cards of Ansaid. The plaintiff was not provided with the Ansaid package insert. The plaintiff took the Ansaid tablets, which alleviated her stiff neck symptoms.

In October, 1994, over two years after Besser had

given the Ansaid tablets to the plaintiff, the decedent complained of a stiff neck. He found some remaining Ansaid tablets in the family medicine cabinet. The decedent had been advised by his doctors that he was allergic to aspirin and nonsteroidal anti-inflammatory drugs and that he should not take these drugs. The decedent consulted two medical reference books before taking the Ansaid: The Time Life Medical Reference Library: Prescription Drugs 1982–1983; and The New Lexicon Illustrated Medical Encyclopedia. Neither of these books contained any reference that Ansaid was a nonsteroidal anti-inflammatory drug or that persons with sensitivities to aspirin or nonsteroidal anti-inflammatory drugs should avoid Ansaid. He then ingested one Ansaid tablet.[4]

Shortly after taking the Ansaid tablet, the decedent experienced great difficulty breathing. He drove himself to the Stamford Hospital emergency room in Stamford. Within ten minutes of his arrival at the emergency room, and as a result of his reaction to the Ansaid, he suffered respiratory and cardiac arrest. The decedent died approximately one hour after his arrival at the emergency room. The cause of death was determined to be a severe anaphylactic reaction to Ansaid.

Thereafter, the plaintiff filed this action in the Superior Court for the judicial district of Stamford-Norwalk. The plaintiff alleged that her husband's death was caused by the defendant's failure to provide, on its sample packets, adequate warnings of possible adverse effects of Ansaid.[5] After removing the case to the federal district court, the defendant filed an affirmative defense,[6] asserting that, based on the learned intermediary doctrine, it had no duty to provide a direct warning to the ultimate consumer of its product because it had provided a proper warning to the prescribing physician. The defendant thereafter moved for summary judgment. The plaintiff filed a cross motion for partial summary judgment seeking dismissal of the defendant's seventh affirmative defense on the grounds that no Connecticut court had recognized the learned intermediary doctrine, and that, even if the District Court were to adopt the learned intermediary doctrine as a matter of Connecticut law, it should not recognize that doctrine as an absolute defense.

The District Court granted the defendant's motion for summary judgment, denied the plaintiff's cross motion, and rendered judgment for the defendant. *Vitanza* v. *Upjohn Co.*, supra, 48 F. Sup. 2d 132. The plaintiff appealed from the judgment to the Court of Appeals, which certified to us the question of whether, under the facts of this case, the defendant is insulated from liability as a matter of law by the learned intermediary doctrine. *Vitanza* v. *Upjohn Co.*, supra, 214 F.3d 73–74. We conclude that: (1) the learned intermediary doctrine is part of our state law; and (2) its application to the

facts of this case bars the plaintiff's action.

Manufacturers in Connecticut are strictly liable for defective products under § 402A of the Restatement (Second) of Torts.[7] See *Giglio* v. *Connecticut Light & Power Co.*, 180 Conn. 230, 233, 429 A.2d 486 (1980) ("[i]n *Garthwait* v. *Burgio*, 153 Conn. 284, 216 A.2d 189 [1965], we accepted the principles adopted by the American Law Institute as contained in § 402A of the Restatement (Second), Torts, establishing strict liability in tort"). A product may be defective due to a flaw in the manufacturing process, a design defect or because of inadequate warnings or instructions. See, e.g., *Hill* v. *Searle Laboratories*, 884 F.2d 1064, 1067 (8th Cir. 1989) (" 'defect' need not be a matter of errors in manufacture . . . a product is 'defective' when it is . . . not accompanied by adequate instructions and warnings of the dangers attending its use"); *Koonce* v. *Quaker Safety Products & Mfg. Co.*, 798 F.2d 700, 716 (5th Cir. 1986) ("[t]he absence of adequate warnings or directions may render a product defective and unreasonably dangerous, even if the product has no manufacturing or design defects"); *Giglio* v. *Connecticut Light & Power Co.*, supra, 236 ("the failure to warn . . . is, of itself, a defect").

Under § 402A of the Restatement (Second) of Torts, a manufacturer is strictly liable for injuries suffered if the product was sold "in a defective condition unreasonably dangerous to the user . . . ." A product is "unreasonably dangerous" if it is "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it . . . ." 2 Restatement (Second), Torts § 402A, comment (i) (1965);[8] see also *Wagner* v. *Clark Equipment Co.*, 243 Conn. 168, 189, 700 A.2d 38 (1997) (expressly adopting definition of " 'unreasonably dangerous' " as articulated in comment [i]). Proper warnings, however, may prevent a product from being unreasonably dangerous. See 2 Restatement (Second), supra, § 402A, comment (j);[9] see also *Tomer* v. *American Home Products Corp.*, 170 Conn. 681, 689, 368 A.2d 35 (1976) (applying comment [j] to § 402A); *Prokolkin* v. *General Motors Corp.*, 170 Conn. 289, 300 n.6, 365 A.2d 1180 (1976) (same).

According to the Restatement (Second) of Torts, certain products, by their very nature, cannot be made safe. See 2 Restatement (Second), supra, § 402A, comment (k).[10] Prescription drugs generally fall within the classification of "unavoidably unsafe" products. See *Lindsay* v. *Ortho Pharmaceutical Corp.*, 637 F.2d 87, 90 (2d Cir. 1980) ("[u]nlike most other products . . . prescription drugs may cause untoward side effects despite the fact that they have been carefully and properly manufactured"); *Wolfgruber* v. *Upjohn Co.*, 72 App. Div. 2d 59, 61, 423 N.Y.S.2d 95 (1979), aff'd, 52 N.Y.2d 768, 417 N.E.2d 1002, 436 N.Y.S.2d 614 (1980) ("prescription drugs are [u]navoidably unsafe products" [internal

quotation marks omitted]).

A manufacturer of an unavoidably unsafe product can avoid strict liability if the product is ''properly prepared, and accompanied by proper directions and warning . . . .'' 2 Restatement (Second), supra, § 402A, comment (k). 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. See *Tomer* v. *American Home Products Corp.*, supra, 170 Conn. 689–90; 2 Restatement (Second), supra, § 388 (c). The learned intermediary doctrine, which is supported by comment (k) to the § 402A of the Restatement (Second) of Torts, is an exception to this general rule.

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.'' *Vitanza* v. *Upjohn Co.*, supra, 48 F. Sup. 2d 127, citing *Guevara* v. *Dorsey Laboratories, Division of Sandoz, Inc.*, 845 F.2d 364, 367 (1st Cir. 1988) (" 'warning should be *sufficient to appraise a general practitioner* . . . of the dangerous propensities of the drug' " [emphasis in original]); *Brooks* v. *Medtronic, Inc.*, 750 F.2d 1227, 1231 (4th Cir. 1984) (''[t]he restriction of the duty to warn to physicians alone in ethical drug cases stands as an exception to the general duty of manufacturers to warn ultimate consumers in products liability cases''); *Davis* v. *Wyeth Laboratories, Inc.*, 399 F.2d 121, 130 (9th Cir. 1968) (''[o]rdinarily in the case of prescription drugs warning to the prescribing physician is sufficient'').

Although Connecticut has adopted the principles underlying § 402A; see *Giglio* v. *Connecticut Light & Power Co.*, supra, 180 Conn. 233; this court has not directly adopted comment (k) to § 402A of the Restatement (Second) of Torts. We conclude that the policy considerations contained in comment (k) to § 402A are persuasive and are in accord with this state's product liability jurisprudence.

Comment (k) to § 402A of the Restatement (Second) of Torts provides that some products are ''incapable of being made safe for their intended and ordinary use.'' Nevertheless, certain ''unavoidably unsafe'' products provide such benefits to society that their use is ''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.'' (Emphasis in original.) 2 Restatement (Second), supra, § 402A, comment (k). Comment (k) provides that

a manufacturer of an ''unavoidably unsafe'' product should ''not . . . 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.'' Id. As this court has stated: ''Products liability law has thus evolved to hold manufacturers strictly liable for unreasonably dangerous products that cause injury to ultimate users. Nevertheless, strict tort liability does not transform manufacturers into insurers, nor does it impose absolute liability.'' *Potter* v. *Chicago Pneumatic Tool Co.*, 241 Conn. 199, 210, 694 A.2d 1319 (1997).

This court, moreover, previously has cited approvingly to *Basko* v. *Sterling Drug, Inc.*, 416 F.2d 417 (2d Cir. 1969), which applied the learned intermediary doctrine as a matter of Connecticut law. See *Tomer* v. *American Home Products Corp.*, supra, 170 Conn. 689–90. In *Basko* v. *Sterling Drug, Inc.*, supra, 419, the plaintiff had been prescribed three different drugs to treat a skin disease, lupus erythematosus, and as a result of taking the drugs, became almost completely blind. The United States Court of Appeals for the Second Circuit determined that this court ''ha[d] adopted the strict liability position taken by § 402A of the Restatement (Second) of Torts.'' Id., 425. The Court of Appeals stated: ''While § 402A imposes strict liability on the seller who markets a product 'in a defective condition unreasonably dangerous' to the consumer, comment (k) makes an exception to the strict liability rule in the case of products characterized as 'unavoidably unsafe.' . . . [C]omment (k) provides that such a drug is neither 'defective' nor 'unreasonably dangerous' in the § 402A sense if the manufacturer gives an adequate warning of the risks involved.'' Id. ''In the case of prescription drugs, the manufacturer can fulfill its duty to warn by warning the medical profession of the side effects of the drug.'' Id., 426.

In *Tomer* v. *American Home Products Corp.*, supra, 170 Conn. 682, the plaintiff brought an action to recover damages for the wrongful death of her husband, who had died as a result of being administered Halothane, an anesthetic agent. The principal issue in *Tomer* was whether the drug manufacturer had failed to warn the medical profession of the dangerous propensities of Halothane. Id., 683. Although the plaintiff had not claimed that the drug manufacturer had a duty to warn her husband, who had received the drug, this court cited *Basko* with approval: ''A product may be defective because a manufacturer or seller failed to warn of the product's unreasonably dangerous propensities. See *Prokolkin* v. *General Motors Corporation*, [supra, 170 Conn. 300 n.6; 2 Restatement (Second), supra, § 402A, comment (j)]; see also *Basko* v. *Sterling Drug, Inc.*, [supra, 416 F.2d 417], applying Connecticut law, and note, 53 A.L.R.3d 239 [260 (in prescription drug cases,

'warnings or instructions [are] required to be directed to the prescribing physician')]." *Tomer* v. *American Home Products Corp.*, supra, 689.

The conclusion that our strict liability jurisprudence includes the learned intermediary doctrine is consistent with the decisions of other jurisdictions that have dealt with this issue. Federal courts sitting in diversity have applied the learned intermediary doctrine as a matter of Connecticut law for more than thirty years. See *Basko* v. *Sterling Drug, Inc.*, supra, 416 F.2d 425–26; *Lamontagne* v. *E. I. Du Pont de Nemours & Co.*, 834 F. Sup. 576, 588 (D. Conn. 1993), aff'd, 41 F.3d 846 (2d Cir. 1994); *Desmarais* v. *Dow Corning Corp.*, 712 F. Sup. 13, 17 (D. Conn. 1989); *Hall* v. *Ashland Oil Co.*, 625 F. Sup. 1515, 1518 (D. Conn. 1986); *Goodson* v. *Searle Laboratories*, 471 F. Sup. 546, 548 (D. Conn. 1978). Furthermore, the overwhelming majority of other jurisdictions that have addressed this issue have adopted the learned intermediary doctrine.[11] The wealth of decisions adopting the doctrine is highly persuasive.

Having determined that the learned intermediary doctrine is part of our common law, we next address the effects of the act on the learned intermediary doctrine. The plaintiff claims that, even if this court determines that Connecticut recognized the learned intermediary doctrine at common law, under the warnings provision of the act; General Statutes § 52-572q;[12] there are no absolute defenses. The plaintiff argues that the legislature's failure to enumerate affirmative defenses in the act is indicative of its intent to abrogate those defenses. We disagree.

Connecticut passed a comprehensive product liability act in 1979. See Public Acts 1979, No. 79-483, as amended by Public Acts 1979, No. 79-631. " 'A principal purpose of the product liability statute [was] to protect people from harm caused by defective and hazardous products.' " *Gajewski* v. *Pavelo*, 36 Conn. App. 601, 614, 652 A.2d 509 (1994), aff'd, 236 Conn. 27, 670 A.2d 318 (1996). Another important purpose of the act was to "eliminate the complex pleading provided at common law . . . ." *Lynn* v. *Haybuster Mfg., Inc.*, 226 Conn. 282, 292, 627 A.2d 1288 (1993). The learned intermediary doctrine is not inconsistent with either of these purposes.

"Interpreting a statute to impair an existing interest or to change radically existing law is appropriate only if the language of the legislature plainly and unambiguously reflects such an intent. [W]hen a statute is in derogation of common law or creates a liability where formerly none existed, it should receive a strict construction and is not to be extended, modified, repealed or enlarged in its scope by the mechanics of [statutory] construction. . . . *Ahern* v. *New Haven*, 190 Conn. 77, 82, 459 A.2d 118 (1983). In determining whether or not a statute abrogates or modifies a common law rule

the construction must be strict, and the operation of a statute in derogation of the common law is to be limited to matters clearly brought within its scope. *Willoughby* v. *New Haven*, 123 Conn. 446, 454, 197 A. 85 (1937). Although the legislature may eliminate a common law right by statute, the presumption that the legislature does not have such a purpose can be overcome only if the legislative intent is clearly and plainly expressed. *State* v. *Sanchez*, 204 Conn. 472, 479, 528 A.2d 573 (1987). We recognize only those alterations of the common law that are clearly expressed in the language of the statute because the traditional principles of justice upon which the common law is founded should be perpetuated. The rule that statutes in derogation of the common law are strictly construed can be seen to serve the same policy of continuity and stability in the legal system as the doctrine of stare decisis in relation to case law. 3 J. Sutherland, Statutory Construction (5th Ed. Singer 1992 Rev.) § 61.01, pp. 172–73.'' (Internal quotation marks omitted.) *Lynn* v. *Haybuster Mfg., Inc.*, supra, 226 Conn. 289–90.

In interpreting the effect of the act on the learned intermediary doctrine, we first look to the express language of the act. As we have stated: ''[T]he legislature is capable of providing explicit limitations when that is its intent.'' Id., 290. Our act makes no explicit mention of abrogating the learned intermediary doctrine. In the absence of explicit language, we ordinarily will not presume that the legislature intended to act in derogation of the common law. We point out, moreover, that subsection (d) of § 52-572q, although inartfully drafted, in effect restates the learned intermediary doctrine. Subsection (d) of § 52-572q provides: ''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.'' We interpret this language to restate the duty of a product seller to provide suitable warnings to ''the person best able to take or recommend precautions against the potential harm.''

The learned intermediary doctrine is a rule of law stating a duty, i.e., that a drug manufacturer has a duty to warn prescribing physicians of the dangers associated with its product, and not the ultimate consumer. The existence of a duty is ordinarily a question of law. See *Mendillo* v. *Board of Education*, 246 Conn. 456, 483, 717 A.2d 1177 (1998). It would be highly extraordinary for the legislature to have enacted a statute making whether a duty exists a question of fact. We should require a very strong showing of legislative intent to do so, which is utterly lacking here. On the contrary, subsection (d) of § 52-572q is more plausibly read as consistent with the learned intermediary doctrine because it defines to whom the duty of providing an adequate warning runs, namely, to the appropriate

party, which in the case of a prescription drug would be the prescribing physician.

We next turn to the legislative history of the act. There is nothing in the legislative history to suggest that the act abrogated the learned intermediary doctrine. As this court has stated: ''The intent of the legislature was to eliminate the complex pleading provided at common law: breach of warranty, strict liability and negligence. 22 S. Proc., Pt. 14, 1979 Sess., pp. 4637–38; 22 H.R. Proc., Pt. 20, 1979 Sess., pp. 7021–22.'' *Lynn* v. *Haybuster Mfg., Inc.*, supra, 226 Conn. 292. This intent is supported by the following exchange in the Senate on the day that Public Act 79-483 was passed. ''[Senator Richard C. Bozzuto]: Senator [Salvatore C.] DePiano, as I understand it, adoption of this statute will in effect, wipe out existing case law. Is there any advantage to that as opposed to adopting statutory language? Would you comment?

''[Senator DePiano]: I wouldn't say we would be abolishing all case law, what we're really abolishing is the various causes of actions that have been brought in cases which we normally would call products liability cases. For example, the theory of strict liability, warranty, negligence and contract. They would all [now be] merged into one cause of action which has been created by statute.'' 22 S. Proc., supra, p. 4639.

Furthermore, the language of § 52-572q (d) and the legislative history recognize the continued vitality of the learned intermediary doctrine after passage of the act. Section 52-572q (d) provides that a manufacturer ''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.'' The learned intermediary doctrine stands for the proposition that, as a matter of law, the prescribing physician of a prescription drug is the person best able to take or recommend precautions against the harm. This doctrine is consistent with the purposes of the act, namely, to protect injured parties from defective products and to streamline the pleading process. As Senator DePiano stated during discussion of Public Act 79-483 on the Senate floor: ''[W]hen warnings about a product are required, they must be adequate and devised to be read and understood by the person best able to take the proper precaution. Which person *most likely will be the user of the product but can include others*.'' (Emphasis added.) 22 S. Proc., supra, p. 4638. The learned intermediary doctrine is consistent with this legislative pronouncement that there are times when warnings may be directed to someone other than the ultimate user.

Subsequent legislative debate regarding § 52-572q; see Public Acts 1990, No. 90-191, § 2, which modified, inter alia, § 52-572q (d);[13] also supports our interpretation that the act did not abrogate the learned intermedi-

ary doctrine. As Representative Richard J. Balducci remarked: "This bill . . . somewhat broadens the defense to product liability actions, that is the defense of product liability actions by recognizing that often a product is given by a manufacturer to someone who then must distribute it to a large number of people who may not actually see the warnings on a particular product. So, in its final section, it points out that a warning would be adequate if it is given to the person who is best able to recommend to a third party what precautions they should take from exposure to a product." 33 H.R. Proc., Pt. 9, 1990 Sess., pp. 3034–35. This addition to § 52-572q (d) further expresses the legislature's intent that strict liability is not tantamount to absolute liability and that warnings may be directed at persons other than the ultimate user of a product.

An analysis of the act's legislative history would be incomplete without reference to the proposed 1978 product liability act; Public Acts 1978, No. 78-380; which was vetoed by then Governor Ella Grasso. See Conn. Senate Journal, Pt. 2, Veto Message (June 7, 1978). Of particular relevance to the present case is the fact that the 1978 act specifically exempted prescription drugs from the failure to warn provision of the statute. See Public Act 78-380, § 5.[14] Although it is true that the rejection of one proposed statutory scheme in favor of a different scheme may provide evidence of legislative intent; see, e.g., *Elliot* v. *Sears, Roebuck & Co.*, 229 Conn. 500, 509 n.11, 642 A.2d 709 (1994) ("[s]ubstantial differences between the product liability act and its vetoed predecessor provide additional evidence that the legislature's omission of 'claimant' from General Statutes § 52-572p was intentional"); we conclude that in the present case, our analysis of the 1979 act's legislative history shows that there is no evidence that the legislature intended to abrogate the learned intermediary doctrine.

We note, moreover, that our act is based on the Draft Uniform Product Liability Law (draft act); 44 Fed. Reg. 2996–3019 (1979); which was proposed by the United States Department of Commerce on January 12, 1979. Section 52-572q; see footnote 12 of this opinion; is modeled after § 104 (C) (3) of the draft act.[15] Section 104 (C) (3) of the draft act provides: "A product seller may not be considered to have provided adequate warnings or instructions unless they were devised to communicate with the person(s) best able to take precautions against the potential harm."

Because our act is modeled on § 104 (C) of the draft act, we look for guidance to the commentaries on that section. See, e.g., *Potter* v. *Chicago Pneumatic Tool Co.*, supra, 241 Conn. 230–31. The commentary to § 104 (C) provides: "Subsection (3) indicates that the warnings or instructions should be devised so as to communicate with the person best able to take suitable

precautions.'' 44 Fed. Reg. 3006. The language of § 104 (C) and its commentary strongly suggest that the draft act included affirmative defenses such as the learned intermediary doctrine.[16]

There is no explicit language in the act abrogating the learned intermediary doctrine, which, as a matter of law, bars the plaintiff's action because adequate warnings were given to the prescribing physician. We have found no evidence in the legislative history, moreover, to support the contention that the legislature intended to abrogate the learned intermediary doctrine. We conclude, therefore, that the act did not abrogate the doctrine.

The plaintiff claims, to the contrary, that the defendant's failure to put a warning on its sample packets of Ansaid, even though it provided adequate warnings to the prescribing physician,[17] creates a factual question concerning whether the defendant properly fulfilled its duty to warn of the hazards associated with its product under § 52-572q (b) and (d). According to the plaintiff, the determination of the adequacy of the warnings and of the proper recipient of the warnings should be made by the trier of fact because the Appellate Court, in construing § 52-572q (b) in cases involving the analogous common-law ''sophisticated user'' defense; see *Gajewski* v. *Pavelo*, supra, 36 Conn. App. 612–13; *Sharp* v. *Wyatt, Inc.*, 31 Conn. App. 824, 849, 627 A.2d 1347 (1993), aff'd, 230 Conn. 12, 644 A.2d 871 (1994); has held that that defense does not, as a matter of law, absolve the manufacturer of its obligation to provide direct warnings to the ultimate consumer. We disagree.

''The existence of a duty is a question of law and only if such a duty is found to exist does the trier of fact then determine whether the defendant violated that duty in the particular situation at hand. . . . *RK Constructors, Inc.* v. *Fusco Corp.*, 231 Conn. 381, 384, 650 A.2d 153 (1994).'' (Internal quotation marks omitted.) *Mendillo* v. *Board of Education*, supra, 246 Conn. 483. At common law, the manufacturer of a prescription drug owed a duty to warn of the dangers associated with its product only to the prescribing physician. As we have explained, there is no evidence to support the plaintiff's assertion that passage of the 1979 act abrogated the learned intermediary doctrine, or that § 52-572q (d) somehow made the question of whether a duty is owed, which is traditionally a question of law, a question of fact.

The plaintiff further claims that there is no rational basis to distinguish between the learned intermediary doctrine and the sophisticated user doctrine. According to the plaintiff, both doctrines are analogous statements of the same premise, namely, that the presence of a sophisticated intermediary absolves the manufacturer of the duty to provide a direct warning to the ultimate user and permits it to fulfill its duty to warn by providing

a warning to the sophisticated intermediary. The plaintiff argues that, because under the sophisticated user doctrine whether the manufacturer may rely exclusively on warnings to the intermediary or also must provide a direct warning to the consumer is a question of fact for the jury; see *Gajewski* v. *Pavelo*, supra, 36 Conn. App. 612–13; *Sharp* v. *Wyatt, Inc.*, supra, 31 Conn. App. 849; the same is true under the learned intermediary doctrine. We are unpersuaded.

Although it is true that the two doctrines are premised on the theory that a manufacturer may be relieved of liability to the ultimate user who is injured if it provided adequate warnings to an appropriate intermediary, the doctrines are not analogous. Under the learned intermediary doctrine ''a product manufacturer is excused from warning each patient who receives the product when the manufacturer properly warns the prescribing physician of the product's dangers.'' *Porterfield* v. *Ethicon, Inc.*, 183 F.3d 464, 467–68 (5th Cir. 1999). The learned intermediary doctrine applies particularly to the medical field, and generally involves unavoidably unsafe products; see 2 Restatement (Second), supra, § 402A, comment (k); which by law can go from the manufacturer to the ultimate user only by way of a prescribing physician.

The sophisticated user doctrine, on the other hand, ''protects a manufacturer from liability only if the chain of distribution is such that the duty to warn ultimate users should fall on an intermediary in that chain, rather than on the manufacturer.'' *In re Brooklyn Navy Yard Asbestos Litigation*, 971 F.2d 831, 838 (2d Cir. 1992). The sophisticated user doctrine may be applied to any type of product, not just those that are unavoidably unsafe. Likewise, the chain of distribution can be more attenuated under the sophisticated user doctrine, because a product can pass through many hands before it reaches the ultimate user who is injured. The safeguards in place under the learned intermediary doctrine, namely, the highly personal doctor-patient relationship and the fact that the product can be obtained legally only from a physician, simply do not exist under the sophisticated user doctrine. See, e.g., *Menschik* v. *Mid-America Pipeline Co.*, 812 S.W.2d 861, 864 (Mo. App. 1991) (rationale for learned intermediary exception cannot be stretched to apply to bulk seller of chemicals); *Todalen* v. *U.S. Chemical Co.*, 424 N.W.2d 73, 79 (Minn. App. 1988) (medical context of learned intermediary doctrine contains significant safeguards to ultimate user that are not present in industrial workplace), overruled on other grounds, *Tyroll* v. *Private Label Chemicals, Inc.*, 505 N.W.2d 54, 62 (Minn. 1993).

The fact that the two doctrines apply to significantly different types of products, and provide different safeguards to the ultimate users of those products, strongly indicate that the two doctrines are not analogous. The

plaintiff's reliance on *Gajewski* v. *Pavelo*, supra, 36 Conn. App. 612–13, and *Sharp* v. *Wyatt, Inc.*, supra, 31 Conn. App. 849, which dealt solely with the sophisticated user doctrine and the factual determinations made under § 52-572q (b), is misplaced.[18]

The factors that the Appellate Court relied on in analyzing the sophisticated user doctrine are simply not in issue in the prescription drug context. As the Appellate Court stated: "[P]ursuant to § 52-572q (b), the anticipated awareness of an expected user with respect to the dangers of a particular product factors into the trier's determination of whether warnings were required and if so whether those provided were adequate. In relegating the issue of a user's anticipated awareness to a mere factor in the trier's determination of liability, our warnings statute minimizes the risk that product sellers and purchasers will simultaneously rely on one another to provide warnings with the result that none is issued to the ultimate product user." *Sharp* v. *Wyatt, Inc.*, supra, 31 Conn. App. 849; see also *Gajewski* v. *Pavelo*, supra, 36 Conn. App. 617. 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. Likewise, there is not the same concern in prescription drug cases that warnings will somehow slip through the cracks, i.e., "that product sellers and purchasers will simultaneously rely on one another to provide warnings with the result that none is issued to the ultimate product user"; *Sharp* v. *Wyatt, Inc.*, supra, 849; because prescription drugs may be obtained legally only through a prescribing physician who is in the best position to convey adequate warnings based upon the highly personal doctor-patient relationship.

We are equally unpersuaded by the plaintiff's argument that this court should fashion a new exception to the learned intermediary doctrine. The plaintiff argues that this court should create an exception that requires manufacturers to provide a direct consumer warning on promotional free samples of drugs that pose a known risk of causing immediately fatal adverse reactions. The plaintiff contends that the learned intermediary doctrine is premised on an obsolete image of healthcare delivery under which it made sense to assume that physicians effectively communicated drug warnings to patients. See, e.g., *Perez* v. *Wyeth Laboratories, Inc.*, 161 N.J. 1, 4, 734 A.2d 1245 (1999) ("[o]ur medical-legal jurisprudence is based on images of health care that no longer exist"). According to the plaintiff, the assumptions underlying the learned intermediary doctrine and the proper limits of the doctrine need to be reassessed due to "changing conditions in health care, including patient choice, managed care, and medical advertising . . . ." *Vitanza* v. *Upjohn Co.*, supra, 214 F.3d 78.

Although the health care industry has undergone sub-

stantial changes since the learned intermediary doctrine was first announced in *Sterling Drug, Inc.* v. *Cornish*, 370 F.2d 82, 85 (8th Cir. 1966), especially regarding the doctor-patient relationship and the marketing of prescription drugs, courts have the ability to deal with changing circumstances, and have done so by recognizing several exceptions to the learned intermediary doctrine. Thus, courts have recognized exceptions regarding: (1) vaccine inoculations; *Davis* v. *Wyeth Laboratories, Inc.*, supra, 399 F.2d 131; (2) oral contraceptives; *MacDonald* v. *Ortho Pharmaceutical Corp.*, 394 Mass. 131, 135–36, 475 N.E.2d 65, cert. denied, 474 U.S. 920, 106 S. Ct. 250, 88 L. Ed. 2d 258 (1985); (3) contraceptive devices; *Hill* v. *Searle Laboratories*, supra, 884 F.2d 1070–71; (4) drugs advertised directly to consumers; *Perez* v. *Wyeth Laboratories, Inc.*, supra, 161 N.J. 21; (5) overpromoted drugs; *Proctor* v. *Davis*, 291 Ill. App. 3d 265, 279–84, 682 N.E.2d 1203, cert. denied, 175 Ill. 2d 553, 689 N.E.2d 1146 (1997); and (6) drugs withdrawn from the market; *Nichols* v. *McNeilab, Inc.*, 850 F. Sup. 562, 565 (D. Mich. 1993).

These exceptions involve situations where there is a lack of communication between patients and their physicians or where patients essentially control the selection of the product. See, e.g., *Hill* v. *Searle Laboratories*, supra, 884 F.2d 1070–71 (final choice of birth control option to use remains that of patient); *Davis* v. *Wyeth Laboratories, Inc.*, supra, 399 F.2d 131 (drug dispensed to all comers at mass immunization clinic without individualized balancing by physician of risks involved); *MacDonald* v. *Ortho Pharmaceutical Corp.*, supra, 394 Mass. 137 (prescribing physician relegated to relatively passive role in patient's decision to use oral contraceptive). Without deciding whether our law also should recognize any of these exceptions, we see no reason to create an entirely new exception on the facts of the present case, where the traditional doctor-patient relationship existed, there were no communication problems, and adequate warnings were provided to the prescribing physician.

The certified question is answered: Yes.

No costs will be taxed in this court to either party.

In this opinion the other justices concurred.

[1] General Statutes (Rev. to 1999) § 51-199a provides: "(a) This section may be cited as the 'Uniform Certification of Questions of Law Act'.

"(b) The Supreme Court may answer questions of law certified to it by the Supreme Court of the United States, a court of appeals of the United States or a United States district court when requested by the certifying court if there are involved in any proceeding before it questions of law of this state which may be determinative of the cause then pending in the certifying court and as to which it appears to the certifying court there is no controlling precedent in the decisions of the Supreme Court of this state.

"(c) This section may be invoked by an order of any of the courts referred to in subsection (b) of this section upon the court's own motion or upon the motion of any party to the cause.

"(d) A certification order shall set forth: (1) The questions of law to be answered; and (2) a statement of all facts relevant to the questions certified and showing fully the nature of the controversy in which the questions arose.

"(e) The certification order shall be prepared by the certifying court, signed by the judge presiding at the hearing, and forwarded to the Supreme Court by the clerk of the certifying court under its official seal. The Supreme Court may require the original or copies of all or of any portion of the record before the certifying court to be filed with the certification order, if, in the opinion of the Supreme Court, the record or portion thereof may be necessary in answering the questions.

"(f) Fees and costs shall be the same as in civil appeals docketed before the Supreme Court and shall be equally divided between the parties unless otherwise ordered by the certifying court in its order of certification.

"(g) Proceedings in the Supreme Court shall be those provided in the rules of said court.

"(h) The written opinion of the Supreme Court stating the law governing the questions certified shall be sent by the clerk under the seal of the Supreme Court to the certifying court and to the parties.

"(i) This section shall be so construed as to effectuate its general purpose to make uniform the law of those states which enact it."

Practice Book § 82-1 provides: "The supreme court may answer questions of law certified to it by the supreme court of the United States, a court of appeals of the United States or a United States district court when requested by the certifying court if there are involved in any proceeding before it questions of law of this state which may be determinative of the cause then pending in the certifying court and as to which it appears to the certifying court there is no controlling precedent in the decisions of the supreme court of this state."

[2] The plaintiff brought this action as executrix of the estate of Timothy E. Vitanza for his wrongful death, and individually for loss of consortium.

[3] The parties filed a joint statement of undisputed and disputed facts for the purpose of their summary judgment motions. All facts are undisputed unless otherwise indicated.

[4] For the limited purpose of resolving the question of law in the present case, the defendant accepts as true the plaintiff's allegation that the decedent ingested Ansaid.

[5] The plaintiff alleged that "the drug was defective and unreasonably dangerous in that free foil-packed samples of the drug were intended to and did reach ultimate consumers of the drug in packaging that failed to warn users of the serious adverse side effects, including death, that defendant knew or should have known could result from ingestion of the drug."

[6] In its seventh affirmative defense, the defendant alleged: "The package insert which was included in the sample packages provided to licensed physicians was devised to communicate with the dispensing physician who as a learned intermediary was the individual best able to instruct the potential user of the indications and contraindications of the drug."

[7] Section § 402A of the Restatement (Second) of Torts provides: "(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

"(a) the seller is engaged in the business of selling such a product, and

"(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

"(2) The rule stated in Subsection (1) applies although

"(a) the seller has exercised all possible care in the preparation and sale of his product, and

"(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller."

[8] Comment (i) to § 402A of the Restatement (Second) of Torts provides in relevant part: "The rule stated in this Section applies only where the defective condition of the product makes it unreasonably dangerous to the user or consumer. Many products cannot possibly be made entirely safe for all consumption . . . . The article sold must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics. . . ."

[9] Comment (j) to § 402A of the Restatement (Second) of Torts provides in relevant part: "In order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warning, on the container, as to its use. . . . [I]n the case of poisonous drugs, or those unduly dangerous for other reasons, warning as to use may be required. . . ."

[10] Comment (k) to § 402A of the Restatement (Second) of Torts provides in relevant part: "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. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. [This] is true of many . . . drugs, vaccines, and the like, many of which . . . cannot legally be sold except to physicians, or under the prescription of a physician. . . . 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.'' (Emphasis in original.)

[11] Our survey of case law throughout the United States has revealed that state courts and federal courts applying state law have adopted the learned intermediary doctrine in forty-four other jurisdictions. Those jurisdictions in alphabetical order by state are as follows: *Stone* v. *Smith, Kline & French Laboratories*, 447 So. 2d 1301, 1303 n.2 (Ala. 1984); *Shanks* v. *Upjohn Co.*, 835 P.2d 1189, 1195 n.6 (Alaska 1992); *Dyer* v. *Best Pharmacal*, 118 Ariz. 465, 468, 577 P.2d 1084 (1978); *West* v. *Searle & Co.*, 305 Ark. 33, 39–41, 806 S.W.2d 608 (1991); *Stevens* v. *Parke, Davis & Co.*, 9 Cal. 3d 51, 65, 507 P.2d 653, 107 Cal. Rptr. 45 (1973); *Caveny* v. *CIBA-GEIGY Corp.*, 818 F. Sup. 1404, 1406 (D. Colo. 1992); *Lacy* v. *G. D. Searle & Co.*, 567 A.2d 398, 400–401 (Del. 1989); *Felix* v. *Hoffmann-LaRoche, Inc.*, 540 So. 2d 102, 104 (Fla. 1989); *Presto* v. *Sandoz Pharmaceuticals Corp.*, 226 Ga. App. 547, 548, 487 S.E.2d 70, cert. denied, 227 Ga. App. 912 (1997); *Craft* v. *Peebles*, 78 Haw. 287, 304, 893 P.2d 138 (1995); *Martin* v. *Ortho Pharmaceutical Corp.*, 169 Ill. 2d 234, 238–39, 661 N.E.2d 352 (1996); *Ortho Pharmaceutical Corp.* v. *Chapman*, 180 Ind. App. 33, 44, 388 N.E.2d 541 (1979); *Humes* v. *Clinton*, 246 Kan. 590, 605–606, 792 P.2d 1032 (1990); *Snawder* v. *Cohen*, 749 F. Sup. 1473, 1480 (D. Ky. 1990); *Mikell* v. *Hoffman-LaRoche, Inc.*, 649 So. 2d 75, 79–80 (La. App. 1994); *Violette* v. *Smith & Nephew Dyonics, Inc.*, 62 F.3d 8, 13 (1st Cir. 1995), cert. denied, 517 U.S. 1167, 116 S. Ct. 1568, 134 L. Ed. 2d 667 (1996) (applying Maine law); *Doe* v. *American National Red Cross*, 866 F. Sup. 242, 248 (D. Md. 1994); *MacDonald* v. *Ortho Pharmaceutical Corp.*, 394 Mass. 131, 135–36, 475 N.E.2d 65, cert. denied, 474 U.S. 920, 106 S. Ct. 250, 88 L. Ed. 2d 258 (1985); *Reaves* v. *Ortho Pharmaceutical Corp.*, 765 F. Sup. 1287, 1290 (D. Mich. 1991); *Mulder* v. *Parke Davis & Co.*, 288 Minn. 332, 335–36, 181 N.W.2d 882 (1970); *Wyeth Laboratories, Inc.* v. *Fortenberry*, 530 So. 2d 688, 691 (Miss. 1988); *Johnston* v. *Upjohn Co.*, 442 S.W.2d 93, 94 (Mo. App. 1969); *Davis* v. *Wyeth Laboratories, Inc.*, 399 F.2d 121, 130 (9th Cir. 1968) (applying Montana law); *Uribe* v. *Sofamor, SNC*, Docket No. 8:95CV464, 1999 U.S. Dist. WL 1129703, pp. *13–14 (D. Neb. August 16, 1999); *Moses* v. *Danek Medical, Inc.*, Docket No. CV-S-95-512PMP RLH, 1998 U.S. Dist. WL 1041279, p. *5 (D. Nev. December 11, 1998); *Brochu* v. *Ortho Pharmaceutical Corp.*, 642 F.2d 652, 656 (1st Cir. 1981) (applying New Hampshire law); *Perez* v. *Wyeth Laboratories, Inc.*, 161 N.J. 1, 21, 734 A.2d 1245 (1999); *Hines* v. *St. Joseph's Hospital*, 86 N.M. 763, 765, 527 P.2d 1075 (1974); *Martin* v. *Hacker*, 185 App. Div. 2d 553, 554–55, 586 N.Y.S.2d 407 (1992); *Foyle* v. *Lederle Laboratories*, 674 F. Sup. 530, 535–36 (D.N.C. 1987); *Tracy* v. *Merrell Dow Pharmaceuticals, Inc.*, 58 Ohio St. 3d 147, 149–50, 569 N.E.2d 875 (1991); *McKee* v. *Moore*, 648 P.2d 21, 24 (Okla. 1982); *McEwen* v. *Ortho Pharmaceutical Corp.*, 270 Or. 375, 386–87, 528 P.2d 522 (1974); *Taurino* v. *Ellen*, 397 Pa. Super. 50, 55, 579 A.2d 925 (1990); *Brooks* v. *Medtronic, Inc.*, 750 F.2d 1227, 1231 (4th Cir. 1984) (applying South Carolina law); *Yarrow* v. *Sterling Drug, Inc.*, 263 F. Sup. 159, 162 (D.S.D. 1967), aff'd, 408 F.2d 978 (8th Cir. 1969); *Pittman* v. *Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994); *Wyeth-Ayerst Laboratories Co.* v. *Medrano*, 28 S.W.3d 87, 91 (Tex. App. 2000); *Barson* v. *E. R. Squibb & Sons, Inc.*, 682 P.2d 832, 835 (Utah 1984); *Pfizer, Inc.* v. *Jones*, 221 Va. 681, 684, 272 S.E.2d 43 (1980); *Terhune* v. *A. H. Robins Co.*, 90 Wash. 2d 9, 13–14, 577 P.2d 975 (1978); *Pumphrey* v. *C. R. Bard, Inc.*, 906 F. Sup. 334, 337–38 (D. W. Va. 1995); *Lukaszewicz* v. *Ortho Pharmaceutical Corp.*, 510 F. Sup. 961, 963 (D. Wis.), modified by *United States* v. *Kilroy*, 523 F. Sup. 206 (D. Wis. 1981); *Jacobs* v. *Dista Products Co.*, 693 F. Sup. 1029, 1036 (D. Wyo. 1988).

[12] General Statutes § 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.

''(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.

"(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.

"(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."

[13] After the amendment by Public Act 90-191, § 2, General Statutes (Rev. to 1991) § 52-572q (d) provided: "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." (Emphasis added.)

[14] Public Acts 1978, No. 78-380, § 5, provided: "(a) Warnings required under this act shall be regarded as adequate if they would put intended users of ordinary skill and judgment on notice of the material risks of the product in question. There is no duty to warn of risks that are open and obvious or which are generally known to users of the product. Where warnings identify material risks to be avoided, it shall be necessary to specify the precautions to be taken only where those precautions are not reasonably apparent to intended product users.

"(b) Instructions required under this act shall be regarded as adequate if they provide intended users of ordinary skill and judgment with reasonable information about the use, application, administration or limitations of the product in question. Any warnings about the risks associated with the failure to follow the proper instructions shall be measured in accordance with the standards set out in this section.

"(c) In any products liability action based upon the failure of the defendant to provide the user with adequate warnings of the risk in any product or instructions as to its proper use, administration, application or limitations, the plaintiff shall be required to establish each of the following elements of the cause of action by a preponderance of the evidence:

"(1) The product was the proximate cause of the personal injury, death or property damage of which the plaintiff complains; and,

"(2) (A) In the case of manufacture, either (i) upon parting with possession and control of its product, that the defendant failed to provide in its pamphlets, booklets, inserts or other warnings accompanying its product, adequate warnings about any material risk known to the defendant or which with reasonable diligence should have been known or that it failed to provide adequate instructions as to the product's proper use, administration, application or limitations; or (ii) after parting with possession and control of its product, that a material risk was learned of by the defendant or became generally recognized upon reasonable and credible evidence, and that the defendant thereafter failed to make reasonable efforts to provide adequate warnings or instructions about such risks to users; (B) In the case of a nonmanufacturing seller, lessor or bailor, either (i) upon parting with possession and control of the product, that the defendant failed to provide to the person to whom he relinquished possession and control of the product any pamphlets, booklets, labels, inserts or other written warnings or instructions received while the product was in its possession and control; or (ii) after parting with possession and control of the product, that the defendant failed to make reasonable efforts to provide those warnings and instructions to users which it thereafter received; and

"(3) If adequate warnings and instructions had been received, the user would have responded to them by not using the product as it was in fact used; and

"(d) Upon establishing the elements set forth in subdivisions (2) and (3) of subsection (c) of this section the plaintiff shall recover only for those damages that would not have been sustained had the required warnings or instructions been provided.

"(e) Proof of any element contained in subsection (c) of this section shall not create or support any presumption, either rebuttable or conclusive, about any other element of the plaintiff's cause of action.

"(f) This section shall not apply to prescription products."

[15] Section 104 of the draft act provides in relevant part: "The Basic Standards of Responsibility

''A product seller may be subject to liability for harm caused to a claimant who proves by a preponderance of the evidence that one or more of the following conditions apply: the product was defective in construction (Subdivision 104A); the product was defective in design (Subdivision 104B); or the product was defective in that adequate warnings or instructions were not provided (Subsection 104C). . . .'' 44 Fed. Reg. 2998.

Section 104 (C) of the draft act provides: ''The harm was caused because the product seller failed to provide adequate warnings or instructions about the dangers and proper use of the product.

''(1) In determining whether adequate instructions or warnings were provided, the trier of fact shall consider:

''(a) The likelihood at the time of manufacture that the product would cause the harm suffered by the claimant;

''(b) The seriousness of that harm;

''(c) The product seller's ability 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

''(d) The technological feasibility and cost of warnings and instructions.

''(2) In claims based on Section 104(C), the claimant shall prove that if adequate warnings or instructions had been provided, a reasonably prudent person would not have suffered the harm.

''(3) A product seller may not be considered to have provided adequate warnings or instructions unless they were devised to communicate with the person(s) best able to take precautions against the potential harm.'' Id.

[16] Although our act was patterned after the draft act, which was released on January 12, 1979, the United States Department of Commerce subsequently released a Model Uniform Product Liability Act (model act); 44 Fed. Reg. 62,714–50 (1979); on October 31, 1979. We note that the model act expressly incorporated the learned intermediary doctrine into § 104. The model act thus clarified the intent of the draft act, i.e., that the draft act included affirmative defenses.

Section 104 (C) (5) of the model act provides in relevant part: ''A manufacturer is under an obligation to provide adequate warnings or instructions to the actual product user unless the manufacturer provided such warnings to a person who may be reasonably expected to assure that action is taken to avoid the harm, or that the risk of the harm is explained to the actual product user.

''For products that may be legally used only by or under the supervision of a class of experts, warnings or instructions may be provided to the using or supervisory expert. . . .'' 44 Fed. Reg. 62,721.

The commentary to § 104 (C) (5) of the model act provides in relevant part: ''[Subsection (c) (5)] indicates that a warning or instruction may be given to a person who may be reasonably expected to assure that action is taken to avoid the harm, or that the risk of the harm is explained to the actual product user. *By way of example,* the Act sets forth situations where such a process is appropriate. Thus, communication to a using or supervising expert is explicitly stated to be adequate when the product—such as a prescription drug or radioactive material—is one which may be legally used only by, or under, the supervision of such an expert. . . .'' (Emphasis added.) 44 Fed. Reg. 62,725.

[17] ''The plaintiff does not appear to contest the adequacy of the defendant's [warnings] to the medical community or to [Besser] directly, nor could she, given that the defendant warned of the specific risk at issue in this case.'' *Vitanza* v. *Upjohn Co.,* supra, 48 F. Sup. 2d 132 n.9.

[18] We also note that the factors articulated in subsection (b) of § 52-572q, unlike subsection (d), cover the *content* of the warnings, which concededly were adequate here. See footnote 17 of this opinion. Subsection (b) factors, which by their terms are committed to the ''trier of fact,'' do not in any way involve the question of to whom the duty is owed, which is covered by subsection (d) of § 52-572q. The plaintiff's reliance on subsection (b) is thus misplaced.