THE RESTATEMENT SECTIONS SPECIFICALLY APPLICABLE TO PHARMACEUTICAL AND MEDICAL DEVICE CASES IN STATE COURT: A 50-STATE SURVEY

A Report of the Pharmaceuticals, Medical Devices and Biologicals Subcommittee of the Products Liability Committee

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I. Adoption of Restatement (Second) of Torts, Section 402A, Comment k

The Court of Appeals of Maryland adopted the Reinstatement (Second) Torts, Section 402A, in Phipps v. General Motors Corp., 363 A.2d 955, 963 (Md. 1976) ("[W]e adopt the theory of strict liability as expressed in § 402A of the Restatement (Second) of Torts."). Although Phipps did not specifically address Comment k, the Court of Appeals has since held that, in Phipps, it "implicitly adopted the substance of Comment k." Miles Laboratories, Inc. v. Doe, 556 A.2d 1107, 1117 (Md. 1989).

II. Application of Restatement (Second) of Torts, Section 402A, Comment k

Comment k is part of the Maryland common law, yet it has rarely been applied in reported decisions in the state courts. The leading discussion is found in the Miles Laboratories decision. This case, which was pending in the U.S. District Court for the District of Maryland, involved a plaintiff who contracted HIV in 1983 when she was given a blood transfusion consisting of the defendant's product, "Konyne," a blood clotting factor concentrate that contained human blood plasma. See Miles Laboratories, 556 A.2d at 1109. Although federal courts applying Maryland law had previously held that Comment k had been adopted in Maryland, see, e.g., Werner v. Upjohn Co. Inc., 628 F.2d 848, 858 (4th Cir. 1980), Weinberger v. Bristol-Myers Co., 652 F. Supp. 187, 191 (D. Md. 1986), the District Court certified certain questions to the Maryland Court of Appeals, including the question of whether the sale of blood/blood products in Maryland was subject to § 402A, and if so, whether such products fall within the strict liability exception of Comment k. See Miles Laboratories, 556 A.2d at 1112.

a) Factors Considered in Determining Whether a Product is Unavoidably Unsafe.

In determining whether the blood product at issue was "unavoidably unsafe," the Court of Appeals looked to decisions by the highest courts of other jurisdictions. Relying heavily on reasoning expressed by the Supreme Court of Colorado in Belle Bonfils Memorial Blood Bank v. Hansen, 665 P.2d 118 (Colo. 1983), the court concurred with the position of the Belle Bonfils court that the chief purpose of strict liability is to force some hazardous products out of the market. See Miles Laboratories, 556 A.2d at 1121 (citing Belle Bonfils, 665 P.2d at 124). Surveying Belle Bonfils and similar blood/blood product cases, the court introduced "four common threads" found in their holdings that the sale of blood/blood products should not be subjected to strict liability: (1) the nonexistence (at the time) of any scientific test capable of detecting the viral agent which contaminated the blood at the time of injury; (2) the great utility of the product; (3) the lack of any substitute for the product; and (4) the relatively small risk of

the disease being transmitted by the product. Miles Laboratories, 556 A.2d at 1118.

On appeal of the U.S. District Court's eventual grant of summary judgment to Miles Laboratories, the U.S. Court of Appeals for the Fourth Circuit characterized the "four common threads" identified by the Maryland Court of Appeals as the "fundamental criteria" for balancing the risk of a product against its benefits and the inability to avoid the risks inherent in the product. See Doe v. Miles Laboratories, Inc., 927 F.2d 187, 191 (4th Cir. 1991). If the balance tipped in favor of the latter, Comment k is invoked to preclude the imposition of strict liability. See id.

The Miles Laboratories decision remains the only published decision from Maryland state courts on the application of Comment k. Since that decision is limited to the particular set of facts involved, it remains unclear how the Court of Appeals would apply Comment k to sales of pharmaceuticals or other medical devices.

b) Statutory Approval of Comment k

Miles Laboratories cites to Maryland statutes concerning potentially lifesaving products which provide protections from strict liability similar to those found in Comment k. See Miles Laboratories, 556 A.2d at 1110. Particularly, Maryland has a statute which provides that legally authorized persons who obtain, process, store, distribute, or use whole human blood, tissue, organs, or bones, or substances derived from those things, are not subject to strict liability for any injuries which result from the use of such products for injection, transplantation, or transfusion. Md. Code Ann., Health-Gen. I § 18-402 (1982, amended 1986) (citing Md. Code Ann, Cts. & Jud. Proc § 5-630). The Maryland General Assembly has also absolved producers of blood-derivative products from implied warranties of merchantability and fitness. Md. Code Ann., Cts. & Jud. Proc. § 5-630. The Court of Appeals has stated that § 18-402 was "tantamount to legislative acceptance of the basic substance of Comment k. . ." Miles Laboratories, 556 A.2d at 1121.

c) Who Decides Whether a Product Is Unavoidably Unsafe? Judge or Jury?

In its decision regarding the Miles Laboratories appeal, the Fourth Circuit held that under Maryland law, the determination of whether strict liability applies to the sale of a particular product is a question for the judge, unless material factual issues remain which require resolution by the jury. See Doe v. Miles Laboratories, 927 F.2d 187, 191 (4th Cir. 1991) (citing Lundgren v. Ferno-Washington Co., 565 A.2d 335 (Md. Ct. Spec. App. 1989)).[12] Such determination ensures legal consistency of judgments from case to case. See id. In the particular case of

[12] In Lundgren, the Maryland Court of Special Appeals held that the initial determination of whether a product in a design defect case poses an "inherently unreasonable risk" is to be made by the courts. See Lundgren, 565 A.2d at 338-39. The bases for this holding is that the imposition of strict liability involves the consideration of important policy issues--a balance best left to the courts--and that judicial determination of this question prevents strict liability from being imposed inconsistently. See id. at 339. Only if a product does not pose an "inherently unreasonable risk" is a jury called upon to balance risk versus utility and determine whether a product is reasonably safe. See id. at 338.

Konyne, the Fourth Circuit upheld the District Court's determination that the product was unavoidably unsafe under Comment k as a matter of law. See id. at 193.

III. Adoption of Restatement (Third) of Torts, Section 6

As of the date of this publication, Section 6 of the Restatement (Third) of Torts has not been cited to or adopted by Maryland courts in reported decisions.

IV. Practice Pointers

It is currently unclear to what degree pharmaceuticals and non-blood product medical devices will be classified as "unavoidably unsafe" products by Maryland courts. This determination is most likely to be made on a product-by-product basis through evaluation of the "four common threads" set out in Miles Laboratories. From the outset of a case, counsel should consider how best to develop facts and evidence to support an argument that the product meets or does not meet the criteria necessary to fall within the ambit of Comment k.