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## Products Liability--Doctrine of Unavoidably Unsafe Products Applied to Manufacturer of Polio Vaccine

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**PRODUCTS LIABILITY—DOCTRINE OF UNAVOIDABLY UNSAFE PRODUCTS APPLIED TO MANUFACTURER OF POLIO VACCINE.** *Cunningham v. Charles Pfizer & Co.*, 532 P.2d 1377 (Okla. 1974).

In *Cunningham v. Charles Pfizer & Co.*<sup>1</sup> plaintiff Cunningham had contracted polio as a result of ingesting Sabin oral polio vaccine at a mass immunization clinic. Although a physician was present at each distribution center to answer questions, the vaccine was dispensed without individual consultation. Both the manufacturer and the society sponsoring the program were aware of the relationship between ingestion of the vaccine and the onset of polio,<sup>2</sup> however, this relationship was not disclosed to those vaccinated in the program.

The court held that the theory of strict liability was properly applied to the case, that the manufacturer had a duty to warn the plaintiff of the dangers involved in taking the vaccine and that the evidence was sufficient to establish that the plaintiff had contracted polio as a result of taking the vaccine. However, the case was remanded to determine if the manufacturer's failure to provide an adequate warning was the proximate cause of the plaintiff's injuries.

The case presented a factual situation to which Oklahoma's newly adopted doctrine of Manufacturers' Products Liability<sup>3</sup> was found to be applicable. The issues upon which the outcome would turn were two-fold.<sup>4</sup> First, whether the product, the vaccine, could properly be found to be "defective;" and second, whether the alleged defective product was the proximate cause of the plaintiff's injuries.

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1. 532 P.2d 1377 (Okla. 1974).

2. At the time plaintiff herein took the vaccine defendant was aware of a report of the special advisory committee on oral poliomyelitis vaccine dated December 18, 1962. This report indicated the committee had considered 23 cases of polio associated with administration of Type I vaccine [the type administered to plaintiff] causation, six were inconclusive and ten were not compatible with vaccine causation.

*Id.* at 1380.

3. *Kirkland v. General Motors Corp.*, 521 P.2d 1353 (1974). See generally McNichols, *The Kirkland v. General Motors Manufacturers' Products Liability Doctrine—What's In a Name?*, 27 OKLA. L. REV. 347 (1974).

4. There were also two minor issues present in the case: Whether the doctrine of Manufacturers' Products Liability was applicable to the case and whether the evidence was sufficient to establish defendant's product as the cause in fact of the plaintiff's injuries. The court answered both of these questions in the affirmative. 532 P.2d at 1380.

According to section 402A of the *Restatement (Second) of Torts* (1965) which identifies the standard for products liability, the sale of a defective product "unreasonably dangerous"<sup>5</sup> to the user subjects the seller to liability.<sup>6</sup> Although the word "defective" is nowhere defined, comment *k* cautions that "unavoidably unsafe" products are not to be regarded as defective merely because there is a risk inherent in their use.<sup>7</sup> To qualify for this "exception"<sup>8</sup> the product must be incapable in the present state of human knowledge of being made safe for its intended use and it must be accompanied by a warning regarding the dangers involved in its use.<sup>9</sup>

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5. RESTATEMENT (SECOND) OF TORTS § 402A (1965). Comment *i* provides in part:

*Unreasonably dangerous.* The rule stated in this Section applies only where the defective condition of the product makes it unreasonably dangerous to the user or consumer. . . . 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. Good whiskey is not unreasonably dangerous merely because it will make some people drunk, and is especially dangerous to alcoholics; but bad whiskey, containing a dangerous amount of fusel oil, is unreasonably dangerous.

6. RESTATEMENT (SECOND) OF TORTS § 402A (1965) provides:

Special Liability of Seller of Product for Physical Harm to User or Consumer

(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.

7. *Id.* 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. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. . . . 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.

8. The concept of viewing Comment *k* as an exception derives from *Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 425 (2d Cir. 1969).

9. A warning of the dangers is necessary to permit the buyer to exercise his freedom of choice in deciding whether the product is of sufficient merit to warrant risking whatever dangers are involved. *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121, 129 (9th Cir. 1968). See generally Noel, *Products Defective Because of Inadequate Direction or Warnings*, 23 Sw. L.J. 256 (1969).

The most complete discussion of the application of the *Restatement's* exception for unavoidably unsafe products is found in *Reyes v. Wyeth Laboratories*<sup>10</sup> which arose upon facts very similar to those of *Cunningham*.<sup>11</sup> According to *Reyes*, a product qualifies for the exception only if it is not *unreasonably dangerous per se* and it is not *unreasonably dangerous as marketed*.<sup>12</sup>

A product is considered unreasonably dangerous per se if it is "so dangerous that a reasonable man would not sell [it] if he knew the risk involved . . . ." <sup>13</sup> and the potential harmful effects of the product outweigh the legitimate public interest in making it available.<sup>14</sup> A product is considered unreasonably dangerous as marketed if the manufacturer fails to provide an adequate warning of the dangers accompanying the use of his product.<sup>15</sup>

Finding a product to be unreasonably dangerous per se renders the product "defective" as used in the doctrine of Manufacturers' Products Liability and the manufacturer will be held to strict liability for any injuries which are proximately caused by the product. Even if the product is not unreasonably dangerous per se, failure to provide an adequate warning of the attending dangers will itself render the product

10. 498 F.2d 1264 (5th Cir. 1974).

11. In *Reyes* eight-month-old Anits Reyes was diagnosed as having paralytic poliomyelitis slightly more than two weeks after she had received a dose of oral polio vaccine manufactured by Wyeth Laboratories. Suit was filed by Anita's father against Wyeth Laboratories, alleging that the live polio virus in the vaccine had caused her polio and that Wyeth was liable for her injuries because it had failed to warn her parents of this danger. *Id.* at 1269.

12. *Id.* at 1273. This "per se as marketed" distinction had been suggested by Dean Keeton. See Keeton, *Products Liability—Inadequacy of Information*, 48 TEXAS L. REV. 399, 406 (1970); Keeton, *Products Liability and Meaning of Defect*, 5 ST. MARY'S L.J. 30, 38 (1973), noted in *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1273 n.15 (5th Cir. 1974).

13. 498 F.2d at 1273-74, quoting *Borel v. Fibreboard Paper Products Corp.*, 493 F.2d 1076, 1088 (5th Cir. 1973).

14. 498 F.2d at 1274.

Professor Wade suggests a rather more complex calculus, with no fewer than seven variables:

Factors involved in making this determination include, among others, the following: (1) the usefulness and desirability of the product, (2) the availability of other and safer products to meet the same need, (3) the likelihood of injury and its probable seriousness, (4) the obviousness of the danger, (5) common knowledge and normal public expectation of the danger (particularly for established products), (6) the avoidability of injury by care in use of the product (including the effect of instructions or warnings), and (7) the ability to eliminate the danger without seriously impairing the usefulness of the product or making it unduly expensive.

*Id.* at 1274 n.17. This approach was discussed in Wade, *Strict Tort Liability of Manufacturers*, 19 SW. L.J. 5, 17 (1965).

15. 498 F.2d at 1274-75.

defective.<sup>16</sup> However, where adequate warning has been given the mere fact that the product is accompanied by some inherent danger does not render it defective.

Thus, it is clear that a manufacturer of an unavoidably unsafe product has a duty to provide adequate warning as to the dangers inherent in his product. But to whom must this warning be given?

In the case of prescription drugs, a warning to the prescribing physician regarding the dangers of the drug is considered adequate, since the choice involved essentially calls for a judgment based upon medical knowledge and skill. Thus, a warning to the user or consumer would not be effective.<sup>17</sup>

However, when, as in *Cunningham*, a prescription drug is disseminated without the intercession of a physician the foundation for the rule concerning prescription drugs is absent. Under such circumstances in order to be adequate the warning must be given to the user or consumer.<sup>18</sup> As noted earlier, no such warning was given to *Cunningham*. Thus, the vaccine was found to be defective.

But if it is determined that a duty to warn existed and that a breach of this duty rendered the product defective, strict liability may be avoided if it can be shown that the defect was not the proximate cause of the injuries because the plaintiff would have taken the vaccine in spite of the fact that he had been adequately warned of its dangers.<sup>19</sup>

In resolving this issue *Cunningham* adopted an objective test—whether, considering all of the circumstances existing at the time, a reasonably prudent man given adequate warning would have taken the

16. *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974); *Alman Brothers Farms & Feed Mill, Inc. v. Diamond Laboratories, Inc.*, 437 F.2d 1295 (5th Cir. 1971); *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9th Cir. 1968); *Cunningham v. Charles Pfizer & Co.*, 532 P.2d 1377 (Okla. 1974); 2 L. FRUMER & M. FRIEDMAN, *PRODUCTS LIABILITY* § 16A(4)(e) (1975).

17. *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9th Cir. 1968); *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1967); *Magee v. Wyeth Laboratories, Inc.*, 214 Cal. App. 2d 340, 29 Cal. Rptr. 322 (Dist. Ct. App. 1963).

18. *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974); *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9th Cir. 1968); *Cunningham v. Charles Pfizer & Co.*, 532 P.2d 1377 (Okla. 1974). The general rule has been stated as follows in Noel, *Products Defective Because of Inadequate Directions or Warnings*, 23 Sw. L.J. 256, 281 (1969) (citation omitted): "The duty to warn runs to those the manufacturer should expect to use the chattel, or be endangered by its probable use, and the warning must be reasonably calculated to reach such persons, directly or indirectly." See 1 L. FRUMER & M. FRIEDMAN, *PRODUCTS LIABILITY* § 8.03(3) (1975); 2 F. HARPER & F. JAMES, *THE LAW OF TORTS* § 28.7, at 1548 (1956); *RESTATEMENT (SECOND) OF TORTS* § 388 (1965).

19. 532 P.2d at 1382.

vaccine.<sup>20</sup> For purposes of this test the plaintiff is entitled to a rebuttable presumption that he would have read the warning if it had been given and acted so as to minimize his risks.<sup>21</sup> The failure of the trial court to instruct the jury regarding this test was held to be fundamental error and the case was remanded for a new trial.

Oklahoma has taken a step forward by its adoption of the doctrine of unavoidably unsafe products. The doctrine makes provision for new and experimental products along with other unavoidably unsafe products by providing for their sale without the deterrent of strict liability. At the same time it protects the consuming public by requiring that adequate warning of the dangers be given. This requirement also serves to insure the individual's freedom of choice.

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20. *Id.*

21. This concept was adopted from *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1281 (5th Cir. 1974).