NOTES

Duty to Warn Extended to Bystander in Close Contact with Polio Vaccinee

In *Givens v. Lederle*,[1] the U.S. Court of Appeals for the Fifth Circuit held that a warning to administering physicians concerning the possible dangers of an oral polio vaccine was inadequate and that such inadequacy was the proximate cause of poliomyelitis contracted by a bystander who was in close contact with the vaccinee.[2]

Plaintiff Sherry Givens took her daughter, Wendy, to a pediatrician, Dr. LaRue, who administered the oral Sabin polio vaccine[3] to Wendy on November 8, 1971.[4] In the package containing the vaccine an insert describing the dosage contained the following statement:

> Paralytic disease following the ingestion of live polio virus vaccines has been reported in individuals receiving the vaccine, and in some instances, in persons who were in close contact with subjects who had been given live oral polio virus vaccine. Fortunately, such occurrences are rare, and it could not be definitely established that any such case was due to the vaccine strain and was not coincidental with infection due to naturally occurring poliomyelitis, or other enteroviruses.[5]

Subsequent administration of the vaccine followed on December 8, 1971, and on January 11, 1972. On January 20, 1972, plaintiff Sherry Givens developed polio; she suffered partial paralysis to the upper part of her body and total paralysis to the lower. She had never received a polio vaccine.[6] Mrs. Givens and her husband filed suit in the U.S. District Court for the Middle District of Florida alleging breach of warranties for fitness and marketability and negligence in marketing.[7] A first trial ended in a jury

1. 556 F.2d 1341 (5th Cir. 1977). Majority opinion by Circuit Judge Thornberry.

2. *Id.* at 1345.

3. The Sabin oral vaccine, developed in the late 1950's, introduces live but attenuated polio virus into the recipient's system. An attenuated virus is one that laboratory processes have rendered incapable of producing disease, but which retains sufficient strength to cause the production of antibodies to resist and destroy an attacking wild or virulent polio virus in the vaccinee's alimentary tract. It is licensed for sale only as a prescription drug and its manufacture is permitted only by license. *See* 42 U.S.C.A. §262(a) (1974).

4. All facts are from the court's opinion, 556 F.2d at 1343.

5. *Id.*

6. This includes the Salk vaccine, which is a "killed virus" vaccine administered by innoculation.

7. This action was treated as a consolidated products liability case, and the principles of strict tort liability as set forth in §402A of the Restatement (Second) of Torts (1965) were

verdict for the manufacturer, Lederle. The court granted a motion for a new trial, and a second trial ended in a plaintiff's verdict.[8] On appeal, Lederle insisted that the trial court erred in not granting directed verdicts in both cases and in granting the new trial motion. On cross-appeal the Givenses asked for a new trial on the issue of damages awarded to the husband.[9]

A drug manufacturer's duty to warn substantially differs between drugs sold over-the-counter and prescription drugs. While pharmaceutical companies are required to warn consumers of inherent dangers in the former, with prescription drugs they are required only to warn the prescribing physician. The Fifth Circuit squarely established this principle in *Reyes v. Wyeth Laboratories,*[10] and current authority from other jurisdictions agrees with this principle.[11] The rationale behind this "prescription drug exception" is that a physician is in a better position to "balance the risks" between the possible adverse affects of the drug and the drug's utility to the patient.[12]

In *Davis v. Wyeth Laboratories, Inc.,*[13] the Court of Appeals for the Ninth Circuit, in a landmark decision, held that the manufacturer of a live virus polio vaccine had an affirmative duty to warn the consumer of the drug's dangers, or to make adequate provision for his being warned, when the vaccine was administered in mass innoculations. The court reasoned that when there is no physician-intermediary to balance the risks between adverse effects and benefits, the ultimate consumer must be given an opportunity, via a warning to him, to decide whether to take the drug.

---

applied, despite the fact that plaintiff did not allege strict liability. Florida courts first adopted the principles of strict liability in Royal v. Black & Decker, 205 So. 2d 307 (Fla. App. 1968). In so doing, the Florida courts recognized that the difference between the theories of tort and contract is largely one of terminology. *See* Greeno v. Clark Equip. Co., 237 F. Supp. 427, 429 (N.D. Ind. 1965). For an informative view on the impact of strict liability, see Carmichael, *Strict Liability in Tort—An Explosion in Products Liability Law,* 20 DRAKE L. REV. 529 (1971).

8. The plaintiff's motion for a new trial was granted on the basis of the recent decision of *Reyes v. Wyeth Laboratories,* 498 F.2d 1264 (5th Cir. 1974), *cert. denied,* 419 U.S. 1096 (1974). In *Reyes,* the Court of Appeals had accepted the jury's finding of fact that the oral polio vaccine can produce a case of live polio. The trial judge in *Givens* realized that it was error to exclude records of prior vaccine-induced polio cases and granted the new trial on that basis.

9. *Id.* at 1343-1344. The trial court awarded $12,500 to the husband, an amount considered unconscionably low by the Givenses. The Fifth Circuit awarded Mr. Givens a new trial solely on the damage issue because the jury was not instructed on loss of the wife's services, comfort, society, and attention.

10. 498 F.2d 1264, 1276 (5th Cir. 1974), *cert. denied,* 419 U.S. 1096 (1974).

11. *See* O'Hare v. Merck & Co., 381 F.2d 286, 290-291 (8th Cir. 1967); Davis v. Wyeth Laboratories, Inc., 399 F.2d 121, 130 (9th Cir. 1968); Basko v. Sterling Drug, Inc., 416 F.2d 417, 426 (2d Cir. 1969); Singer v. Sterling Drug, Inc., 461 F.2d 288, 292 (7th Cir.), *cert. denied,* 409 U.S. 878 (1972); McCue v. Norwich Pharmacal Co., 453 F.2d 1033, 1035 (1st Cir. 1972).

12. 498 F.2d at 1276.

13. 399 F.2d 121 (9th Cir. 1968).

The plaintiff in *Davis* received the Sabin oral vaccine at a mass immunization clinic. He was thirty-nine years old and in apparent good health. Within thirty days he evidenced polio symptoms and shortly thereafter was paralyzed from the waist down. In granting recovery, the Ninth Circuit recognized that the vaccine was "an apparently useful and desirable product, attended with a known but apparently reasonable risk."[14] Therefore, according to comment *k* to §402A of the Restatement, it was not defective or unreasonably dangerous when accompanied by a proper warning. The court found that the manufacturer breached its duty to warn by not properly advertising the dangers to the recipients of the drug even though the bottles containing the dosages had inserts to that effect. The court suggested that "other means of communication such as advertisements, posters, releases to be read and signed by recipients of the vaccine, or oral warnings were clearly available and could easily have been undertaken or prescribed by appellee."[15]

This rationale was extended by the court in *Reyes* beyond mass innoculation administrations.[16] In *Reyes,* an eight-month-old infant contracted poliomyelitis two weeks after receiving the vaccine from a registered nurse at a county health department. The court chose not to distinguish the mass innoculation environment of *Davis,* concluding that: "Whether vaccine was received during a mass immunization or an on-going program, whether it was administered by nurse or pharmacist, it was, in both these cases, dispensed without the sort of individualized medical balancing of the risks to the vaccinee that is contemplated by the prescription drug exception."[17]

In *Givens,* the court found Lederle's argument that *Reyes* should be distinguished because there the vaccine was administered by a county health clinic unpersuasive, finding instead that the factual situation in *Reyes* actually supported plaintiff's position. Dr. LaRue testified that vaccine administration was no different in his office from what it would be in a public health clinic. This persuaded the court to decide that "[t]he administration of the vaccine by a public health nurse in *Reyes* is as close to the instant situation as it is to the *Davis* mass innoculation,"[18] and led the court to place an affirmative burden on Lederle to warn the consumer directly. Thus the *manner* rather than the *place* of administration was emphasized.[19]

---

14. RESTATEMENT (SECOND) OF TORTS §402A, comment *k* (1965), *quoted at* 399 F.2d at 127-128 n.10.

15. 399 F.2d at 125, 128-131.

16. 498 F.2d at 1277.

17. *Id.* at 1277.

18. 556 F.2d at 1344.

19. Alternatively, the court found that, even if the prescription drug exception were applicable, there was enough evidence to uphold the jury's verdict for plaintiffs. According to the court, the jury could have determined that the warning given to the administering physician could be read to mean that there was no risk to a bystander of contracting vaccine-induced polio, and thus the physician could have concluded that a warning was unnecessary. This

An overriding feature in *Davis, Reyes,* and again in *Givens* was the threshold question of whether the Sabin vaccine is capable of inducing polio. In *Reyes* the jury heard extensive testimony, both expert and documentary, regarding this question.[20] Jury response to special interrogatories indicated that the plaintiff contracted polio as a result of the vaccine, that there was a "medically cognizable risk" that the plaintiff could contract polio by taking the trivalent oral vaccine and that the failure to warn the victim's parents of the risk was the proximate cause of harm. The Fifth Circuit, in dicta, reaffirmed this fact-finding by adopting the report of the Surgeon General's Special Advisory Committee on Oral Poliomyelitis Vaccine, which concluded that it was "probable" that cases were produced by the vaccine. The report continued that there were, however, "no laboratory results available [which could] provide a definitive answer."[21]

The plaintiff in *Givens* did not receive the vaccine by ingestion or otherwise; yet, the court, in relying on the *Reyes* finding, failed to recognize that in *Reyes* there was no evidence of contraction by any means other than live ingestion. The conflicting testimony[22] regarding the possibility of contraction by a third party in *Givens* was granted little significance, however, since Lederle warned of the remote possibility that someone in close contact with the vaccinee could develop paralytic disease. In so doing, the *Givens* court appeared to adopt the unprecedented principle that a warning issued, no matter how adequate, is a binding admission as to the inherent dangers of a product, notwithstanding evidence to the contrary.

The major extension of *Reyes* by the *Givens* court is one which may be welcomed by future plaintiffs who suffer from the effects of any widely-dispensed prescription drug, the dispensation of which may not require an individualized medical judgment, even though the drug is dispensed in a physician's office. Carried to its logical extreme, the holding in *Givens* could impose almost insurmountable burdens upon manufacturers of drugs generally administered by physicians to "all comers." In addition, the court failed to delineate the extent of a manufacturer's duty to warn bystanders in such situations. While the child's parent in this case is conceivably the consumer to be warned, one must seriously question the outcome had the plaintiff been a more distant relative, household guest,

---

holding was based in part on Dr. LaRue's testimony that because of the "nebulous" nature of the warning given by Lederle, he did not feel that his warning Mrs. Givens was necessary.

20. This evidence included testimony by medical and epidemological experts and documents detailing confirmed and suspected polio cases.

21. 498 F.2d at 1297, *quoting,* PUBLIC HEALTH SERVICE, REPORT OF THE SPECIAL ADVISORY COMMITTEE ON ORAL POLIOMYELITIS VACCINE TO THE SURGEON GENERAL 4 (1965). In Appendix B of the opinion, emphasis was also placed on an HEW report from the Center for Disease Control which indicated that "for the year 1964, 20 of the 56 reported cases could be associated with vaccine ingestion." 498 F.2d at 1297 n.63.

22. At trial Dr. Albert Sabin, the creator of the Sabin vaccine, testified that it could not cause polio. 556 F.2d at 1344.

or someone else who was in close contact with the vaccinee. The fact remains that the court did not limit future warnings to parents, guardians, those who accompany the vacinee to the doctor's office, or even those who are in the vacinee's household. The question is left for future determination, which leaves manufacturers in the unenviable position of second-guessing the courts. Manufacturers are also faced with the task of disseminating this information through as yet unprescribed channels of communication, which conceivably could extend from one poster in each doctor's office to subjective notification through written releases.[23] Simply stated, the court failed to identify adequately the person to be warned, while compounding the dilemma by failing to define the content, breadth, and scope of the warning required. The manufacturer is additionally burdened by the court's reliance upon a warning issued as a binding admission as to the dangerousness of the product.

Judge Thornberry, author of the *Givens* opinion, set forth a principle of recovery in *Helene Curtis Industries, Inc. v. Pruitt*[24] which has apparently woven its way into the *Givens* decision. The principle amounts to a policy consideration which is based on a balancing of the need for recovery against the need for "viable enterprises."[25] Its basic consideration amounts to answering the question of "who best bears the risk of loss?" The answer to the question is at the heart of the theory of strict liability. The bottom line answer in *Reyes* was that the cost should be borne by the manufacturer and passed on to the public in the form of price increases.[26] Although *Givens* is silent on the applicability of this principle, the appeal of requiring that a large drug manufacturer, as opposed to a paralytic plaintiff, bear the loss undoubtedly influenced the court's decision. If the court had articulated this basis, which has support in case law,[27] for its opinion it could have avoided the confusion the opinion created on the issues of how and to whom a warning should be issued.

The "prescription drug exception" is thus severely restricted, not due to its own inadequacy, but because of the unavailability of appropriate defendants. The practical effect of the decision in *Givens* is that manufacturers of any widely-dispensed prescription drug are under an affirmative duty to warn not only the prescribing physician, but also those patients who take the drug, as well as third-party bystanders who may suffer effects of the drug by contact with the patient.

WILLIAM E. MOORE, JR.

23. See note 15, *supra*, and accompanying text.
24. 385 F.2d 841 (5th Cir. 1968).
25. *Id.* at 862.
26. 498 F.2d at 1294.
27. *Id.* n.57; 385 F.2d at 862.