O/a 6-20-88

IN THE SUPREME COURT OF FLORIDA

YOLANDA FELIX, as Personal Representation of the ESTATE OF KEVIN FELIX-BAPTISTE,

Petitioner,

vs.

Case No. 71,633

HOFFMANN-LaROCHE INC., ROCHE BIOMEDICAL LABORATORIES, INC., BINDLEY-WESTERN INDUSTRIES, INC., GRAY DRUG STORES, INC. OF MIAMI, GRAY DRUG STORES, INC., THE SHERWIN WILLIAMS COMPANY, and LESTER M. WACHMAN,

Respondents.
_____/

WILLIAM F. CHILDERS and HOLLY CHILDERS, as Joint Personal Representatives of the ESTATE OF WILLIAM GILES CHILDERS,

Petitioners,

vs.

Case No. 71,634

HOFFMANN-LaROCHE INC., ROCHE BIOMEDICAL LABORATORIES, INC., BINDLEY-WESTERN INDUSTRIES, INC., THE KROGER COMPANY, SUPER-X DRUG STORES OF FLORIDA, INC., and SUPER-X DRUGS CORPORATION,

Respondents.
_____/

AMICUS CURIAE BRIEF OF G.D. SEARLE & CO. IN SUPPORT OF RESPONDENTS

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STATEMENT OF CASE AND FACTS

Amicus G.D. Searle & Co. adopts the respondents' statement of the case and facts.

SUMMARY OF ARGUMENT

Prescription drugs are by their nature "unavoidably unsafe" or they would be sold over-the-counter. The very organisms and chemicals that present the unwanted risks in prescription pharmaceuticals are those that provide the desired benefits; the latter cannot be had without the former. Unlike the risks that attend almost any other product, the risks that attend a particular pharmaceutical medicine cannot be reduced by adding a safety guard, changing the package, adding a warning, or obtaining incremental safety at the cost of a higher price, increased maintenance, less durability, or the like.

As the vast majority of courts, including those Florida courts which have addressed the question have recognized, research and manufacturing of useful and necessary drugs must not be deterred by fear of liability expanded beyond the duties imposed under Comment k to 402A of the Restatement (Second) of Torts. The analysis adopted by those courts makes sense and comports with sound public policy. Comment k strikes a balance between the competing interests in requiring the drug manufacturer to provide adequate warnings to the physician who acts as a "learned intermediary"

prescribing the drug for an individual patient. This Court should maintain that balance and adhere to the principles of comment k as they apply to all prescription drugs.

ARGUMENT

> The only duty of a prescription drug manufacturer is to provide adequate warnings to the medical community of the potential adverse side effects of the drug.

Having adopted Section 402(A) of the Restatement (Second) of Torts, Florida imposes strict liability upon manufacturers for unreasonably dangerous products which are sold with the knowledge that they are to be used by consumers without any inspection by them for defects and which have a defect that causes injury to human beings. West v. Caterpillar Tractor Company, Inc., 336 So.2d 80, 86 (Fla. 1976). At the same time, however, Florida has adopted comment k to Section 402(A) which establishes an exception to the strict liability doctrine where unavoidably unsafe products are involved. McLeod v. W. S. Merrell Co., 174 So.2d 736, 739 (Fla. 1965); E. R. Squibb & Sons v. Jordan, 254 So.2d 17, 20 n.1 (Fla. 1st DCA 1971); Russell v. Community Blood Bank, 185 So.2d 749, 754 (Fla. 2d DCA 1966), modified on other grounds, 196 So.2d 115 (Fla. 1967).

Comment k specifically characterizes prescription drugs as unavoidably unsafe products and provides that no strict liability is to be imposed where "proper warning" of those inherent risks is given:

> 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.

Thus, the very point of comment k is to prescribe the duty owed by prescription drug manufacturers to persons who use the product. The comment recognizes that, because of the important benefits of prescription drugs, "both the marketing and use of [such drugs] are fully justified," when the requisite warnings are given, "notwithstanding the unavoidable high degree of risk which they involve." Restatement (Second) of Torts, 402A, comment k (1965). When prescription drugs are accompanied by proper warnings to prescribing physicians, "such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk." Id.

Comment k thus strikes a balance between the need to ensure that prescription drugs are used as safely as practicable and the equally pressing public health need to ensure the development and availability of such drugs. That balance requires that adequate warnings be given to the physicians who actually prescribe the drug for individual patients. Because the physician acts as a "learned intermediary" and exercises his informed judgment in prescribing a particular drug for the patient, the manufacturer is required to

provide an adequate warning only to the physician. When this is done, the marketing and use of the product is "fully justified." Id.

In short, comment k defines what is reasonable, as regards the marketing of prescription drugs. Indeed, the comment makes clear that imposing liability upon manufacturers who have provided the contemplated warnings to the physician would be unreasonable and would thwart the salutary objective of ensuring the development and availability of prescription drugs. See Collinsv. Ortho Pharmaceutical Corp., 231 Cal. Rptr. 396, 403 (Cal. App. Ct. 1986).

The Florida district courts which have been presented with the issue have each applied comment k where the adequacy of warnings provided with prescription drugs was at issue.1/ In the first of these cases, Buckner v. Allergan Pharmaceuticals, Inc., 400 So.2d 820 (Fla. 5th DCA 1981), pet. for rev. denied, 407 So.2d 1102 (Fla. 1981), the Fifth District Court of Appeal squarely held that a manufacturer of a prescription drug is not strictly liable in tort to a person who has used that drug if the manufacturer has provided the medical profession with adequate warnings of potential adverse reactions inherent in the use of that drug. As the Court declared:

> A manufacturer of a dangerous commodity, such as a drug, does have a duty to warn but when the commodity is a prescription drug we hold that his duty to warn is fulfilled by an adequate warning given to those members of the medical community lawfully authorized to prescribe, dispense and administer prescription drugs.

1/ Likewise, the Leon County Circuit Court has held that Comment k applies to a prescription IUD. Brock v. G.D. Searle & Co., No. 82-2953 (Fla. Cir. Ct. Oct. 26, 1987), appeal pending.

Id. at 822.

In so holding, the Buckner Court adopted the view expressed in Terhune v. A.H. Robins Co., 577 P.2d 975, 979 (Wash. 1978) that the principles of comment k rest on "the character of the medical profession, and the relationship which exists between the manufacturer, the physician and the patient." The Fifth District quoted with approval from Terhune as follows:

> if the product is properly labeled and carries the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved, the manufacturer may reasonably assume that the physician will exercise the informed judgment thereby gained in conjunction with his own independent learning, in the best interest of the patient.

Id. at 823 (quoting Terhune, 577 P.2d at 978).

Citing Buckner, the Fourth District has likewise held that the "manufacturer had a duty to warn the medical community with respect to any potential side effects from use of its product." Ricci v. Parke-Davis & Co., 491 So.2d 1182 (Fla. 4th DCA), review denied, 501 So.2d 1283 (Fla. 1986). Thereafter, citing Buckner and Ricci, the Third District held in one of the cases on appeal here, that "[i]f the warning given to the medical community is sufficient, then the drug manufacturer is not liable for injuries sustained by the physician's patients as a result of the side effects of the drugs." Felix v. Hoffmann-LaRoche, Inc., 513 So.2d 1319, 1320 (Fla. 3d DCA 1987), review granted, ____ So.2d ____ (Fla. 1988).

Numerous other courts have accepted the validity of the Restatement classification and have recognized that prescription drugs fall within the comment k exception. Indeed, as the Supreme Court of California recently observed: "with [a] few exceptions . . . , the courts which have adopted comment k have viewed all prescription drugs as coming within its scope." Brown v. Superior Court, 245 Cal. Rptr. 412, 422 (Cal. 1988); see also, id. at 424 n.11 ("we are of the view that [comment k] was intended to and should apply to all prescription drugs"). Thus, the courts have applied comment k to a wide variety of prescription drugs and medical devices.2_/

It is true that a few courts have declined to adopt comment k and the "learned intermediary" doctrine and have instead imposed a direct duty to warn the patient. See Odgers v. Ortho Pharmaceutical Corp., 609 F.Supp. 867, 878 (E.D. Mich. 1985); Stephensv. G. D. Searle & Co., 602 F.Supp. 379, 381 (E.D. Mich.

2_/ See, e.g., McKee v. Moore, 648 P.2d 21, 24 (Okla. 1982) (manufacturer's duty "is satisfied if an adequate warning is given to the prescribing physician"); Leibowitz v. Ortho Pharmaceutical Corp., 224 Pa. Super. 418, 307 A.2d 449, 457-58 (1973) (birth control pills); Seley v. G. D. Searle & Co., 67 Ohio St. 2d 192, 423 N.E.2d 831, 836 (1981) (birth control pills); Phelps v. Sherwood Medical Indus., 836 F.2d 296, 303 (7th Cir. 1987) (heart catheter); Brooks v. Medtronic, Inc., 750 F.2d 1227, 1230-31 (4th Cir. 1984) (pacemaker); Dalke v. Upjohn Co., 555 F.2d 245, 247-48 (9th Cir. 1977) (tetracycline-based prescription drug); Basko v. Sterling Drug, Inc., 416 F.2d 417, 426 (2d Cir. 1969) (Aralen and Triquin); Perfetti v. McGhan Medical, 99 N.M. 645, 662 P.2d 646 (Ct. App. 1983) (mammary prosthesis); Racer v. Utterman, 629 S.W.2d 387 (Mo. Ct. App. 1981) (surgical drape). Indeed, the Supreme Court of Alabama recently extended comment k to a professional drycleaning solvent, reasoning that the product "no matter how carefully manufactured or used, can conceivably cause physical injury." Purvis v. PPG Indus., Inc., 502 So.2d 714, 718 (Ala. 1987).

1985); Lukaszewicz v. Ortho Pharmaceutical Corp., 510 F.Supp. 961, 965 (E.D. Wis. 1981); MacDonald v. Ortho Pharmaceuticals Corp., 394 Mass. 131, 475 N.E.2d 65, 69-70, cert. denied, 474 U.S. 920 (1985). Those decisions, which involve birth control pills, not only represent the minority view, they have been rejected by other courts.

The reasoning in Odgers and Stephens -- both decided by district courts within the Sixth Circuit -- was implicitly rejected by the Sixth Circuit in Beyette v. Ortho Pharmaceutical Corp., 823 F.2d 990 (6th Cir. 1987), when it held that "[a] manufacturer of a pharmaceutical product has a duty to warn the medical profession, not the patient, of any risks inherent in the use of the product which the manufacturer knows or should know to exist." Id. at 992. Likewise, the precedential value of Lukaszewicz -- a district court decision in the Seventh Circuit -- has been seriously weakened by that Circuit's later decision in Phelps v. Sherwood Medical Industries, 836 F.2d 296 (7th Cir. 1987), holding that the manufacturer's duty to warn of the risks involved in using a heart catheter ran only to the physician, not to the patient. Id. at 303. Finally, the MacDonald decision was expressly repudiated in Dupre v. G. D. Searle & Co., Prod. Liab. Rep. (CCH) 11,426 (D.N.H. Apr. 28, 1987), discussed infra at pp.7-8, as well as in Kociemba v. G. D. Searle & Co., No. 3-85-1599 (D. Minn. Feb. 1, 1988).

These courts, like the Florida courts, have recognized that a physician with specialized training and experience is in the best position to advise individual patients of the potential risks present in prescription medical products. The physician serves as a "learned intermediary" between the manufacturer and the patient and makes his medical judgment as to whether a drug should be prescribed for that particular patient. As the Buckner court put it, "[it] is [the physician's] duty to inform himself of the qualities and characteristics of those products which he prescribes for or administers to or uses on this patients and to exercise an independent judgment, taking into account his knowledge of the patient as well as the product." 400 So.2d at 823. See also, Swayze v. McNeil Laboratories, Inc., 807 F.2d 464, 468 (5th Cir. 1987) (refusing to require drug manufacturer to warn patients of possible risks from using drug where to do so would "intrude . . . into . . . doctor-patient relationship").

As a matter of law, then, the duty of a manufacturer of prescription drugs is fulfilled by providing an adequate warning to the patient's prescribing physician and there is no duty to warn the patient directly. As the California Supreme Court declared in Brown v. Superior Court, "[i]t is well established that a manufacturer fulfills its duty to warn if it provides adequate warning to the physician." 245 Cal. Rptr. at 419 n.9. Similarly, in Buckner, the Fifth District specifically rejected the argument that the manufacturer of prescription drugs was required to warn the ultimate consumer of the drug's "dangerous potentialities."

400 So.2d at 822-23. That court made no distinctions among types of prescription drugs but instead, as the courts subsequently did in Ricci and Felix, adhered to the straightforward rule that the warnings must be provided to the physician prescribing the drug. Id.

Recent decisions underscore the logic and forcefulness of this rule. For instance, in Dupre v. G. D. Searle & Co., supra, the defendant drug manufacturer filed a motion in limine raising the threshold legal issue of the scope of its duty to warn of dangers inherent in the use of the Cu-7. Faced with a choice of law between MacDonald v. Ortho Pharmaceutical, supra, or the New Hampshire "learned intermediary" rule, the court found the latter to be both the majority rule and "the sounder rule of law." Id. at 32,072. Indeed, the court cited with approval the dissenting opinion in MacDonald; the dissenting judge had pointedly observed there that:

> Doctors, unlike printed warnings, can tailor to the needs and abilities of an individual patient the information that that patient needs in order to make an informed decision whether to use a particular drug. Manufacturers are not in position to give adequate advice directly to those consumers whose medical histories and physical conditions, perhaps unknown to the consumers, make them peculiarly susceptible to risk.

MacDonald, 475 N.E.2d at 74.

The California Supreme Court recently made the same point in a somewhat different fashion by declaring:

> [w]hile the 'ordinary consumer' may have a reasonable expectation that a product such as a machine he purchases will operate safely when used as intended, a patient's expectations

> regarding the effects of such a drug are those related to him by his physician, to whom the manufacturer directs the warnings regarding the drug's properties.

Brown, 245 Cal. Rptr. at 419. For this reason, it is the adequacy of the warning from the perspective of a medical doctor that must be determined.

In adopting comment k for prescription drugs, the California Supreme Court further emphasized that "the broader public interest in the availability of drugs at an affordable price must be considered in deciding the appropriate standard of liability for injuries resulting from their use."3/ Id. at 420. Pointing to a "host of examples of products which have greatly increased in price or have been withdrawn or withheld from the market because of the fear that their producers would be held liable for large judgments," Id. at 420-21, the court observed that "[t]here is no doubt that, from the public's standpoint, these are unfortunate consequences." Id. at 421. The court accordingly adopted the comment k negligence standard for evaluating the physician warnings, concluding that "the imposition of a harsher test for liability would not further the public interest in the development and availability of these important products." Id.

In Kearl v. Lederle Laboratories, 218 Cal. Rptr. 453 (Cal. App. Ct. 1985), the court specifically rejected the argument that society might be willing to forego the speedy marketing of medical

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3/ This was an explicit concern of the authors of comment k. 38American Law Institute (ALI) Proc. 19, 90-98 (1961). Dean Prosser, the Reporter for the Restatement, recommended that the special problems posed by such medicines should be dealt with in the comments accompanying section 402A and that was done.

products (or sacrifice availability of such products altogether) in return for greater accountability of drug manufacturers. The court found that strict liability for defective design should not be imposed on manufacturers of unavoidably unsafe products such as prescription drugs and medical devices:

> Although this may be an appropriate trade off when we are considering designs of appliances, cars, hand tools, or food, it might not be appropriate with regard to some special products that are extremely beneficial to society and yet pose an inherent and substantial risk that is unavoidable at the time of distribution.

Id. at 459.4_/

This view was echoed by the California Supreme Court in Brown, where that court also concluded that the public interest would not be served by imposing strict liability upon prescription drug manufacturers. The court compared prescription drugs with construction equipment, lawnmowers, and perfume and declared:

> In the latter cases, the product is used to make work easier or to provide pleasure, while in the former it may be necessary to alleviate pain and suffering or to sustain life. Moreover, unlike other important medical products (wheelchairs, for example), harm to some users from prescription drugs is unavoidable. Because of these distinctions, the broader public interest in the availability of drugs at an affordable price must be

4_/ The California Supreme Court went even further than Kearl when it adopted comment k in its entirety in Brownv. Superior Court, supra. Thus, although Kearl was affirmed in part by the California Supreme Court, it was overruled to the extent that it held that comment k should not be applied unless the trial court first determined that the drug is "unavoidably unsafe." Brown, 245 Cal. Rptr. at 424. The Brown Court held that comment k applies as a matter of law to all properly prepared prescription drugs accompanied by warnings of dangers "known or reasonably scientifically knowable" at the time of distribution. Id.

> considered in deciding the appropriate standard of liability for injuries resulting from their use.

Brown, 245 Cal. Rptr. at 420.

Courts and commentators have explicitly recognized the important public policies underlying comment k in assuring that the public will be protected from illness and disease, and they have accordingly expressed concern about the escalating product liability judgments on pharmaceutical manufacturers. For example, the court in McCreery v. Eli Lilly & Co., 87 Cal. App. 3d 77, 86-87, 150 Cal. Rptr. 730, 736 (1978), observed that: "[comment k] implicitly recognizes the social policy behind the development of new pharmaceutical preparations." The court went further and warned:

> [t]he social and economic benefits from mobilizing the industry's resources in the war against disease and in reducing the costs of medical care are potentially enormous. The development of new drugs in the last three decades has already resulted in great social benefits. The potential gains from further advances remain large. To risk such gains is unwise. Our major objective should be to encourage a continued high level of industry investment in pharmaceutical R & D [research and development]. (Citations omitted.)

Id.

Similarly, the Ad Hoc Commission on Vaccine Injury Compensation, which was sponsored by the American Medical Association and included representatives of the federal government's Centers for Disease Control, specifically endorsed comment k as the appropriate product liability system for vaccines:

> Our society has maintained this standard [comment k] for vaccines because of the tremendous benefits flowing to a society free of those diseases for which vaccines are available. Maintenance of this standard recognizes that (1) vaccines cannot be made absolutely safe for all persons, and (2) some persons who are, in fact, injured by a vaccine with no attributable negligence may not have a civil remedy.

Report of the Ad Hoc Commission on Vaccine Injury Compensation at 4, reprinted in Vaccine Injury Compensation: Hearings Before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, 98th Cong., 2d Sess. 152 (Sept.10, 1984). The American Medical Association's House of Delegates adopted the Commission's report in June 1984. Id. at 137.

Similarly, in the edition of his treatise published shortly before his death, Dean Prosser explained the need for special product liability treatment of pharmaceutical manufacturers by citing the examples of "two of the greatest medical boons to the human race, penicillin and cortisone, both [of which] have their dangerous side effects." W. Prosser, Handbook of the Law of Torts 99, at 661 (4th ed. 1971). Had liability for such side effects been imposed on manufacturers, he stated, the companies "might well have been deterred from producing and selling these medicines." Id. Accord Note, Mass Immunization Cases: Drug Manufacturers' Liability for Failure to Warn, 29 Vand. L. Rev. 235, 261 (1976) ("basic research may be stifled if the drug companies determine that the risks in marketing a new drug are too great to justify the

expenditure necessary to develop and produce the drug"). See also, Calabresi & Hirschoff, Toward a Test for Strict Liability in Tort, 81 Yale L.J. 1055, 1063 n.24 (1972).

Perhaps the most poignant description of the problem was presented by Dr. Martin H. Smith, who testified before a congressional subcommittee on behalf of the American Academy of Pediatrics -- the physicians who must deal with the tragedy that results from the unavailability of childhood vaccines. After noting that over three million children are born in the United States each year, he stated:

> [I]n some areas of the country [the diptheria, tetanus toxids, pertussis vaccine] has been unobtainable at any price. This situation, we believe, is directly attributable to the deteriorating liability situation and speaks to the fact that the tort process has not served us well in these instances. . . .
>
> If there is even one more departure from the vaccine production market place, there will be millions of children who will go unprotected against totally preventable and dangerous childhood diseases. At the present time we are sitting on an explosive situation and it could have a short fuse. As pediatricians, we are not only concerned with the children who are injured; we must remain strong advocates of those millions of children who are protected by virtue of their participation in this essential program.

Vaccine Injury Compensation: Hearings before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, 98th Cong. 2d Sess. 122 (Sept. 10, 1984).

CONCLUSION

In light of the compelling public interest in the research and development of new medicines and medical devices, this Court should affirm the Third District Court of Appeal holding to the extent that it limited a drug manufacturer's duty to warn to the medical profession. Comment k to 402A, Restatement (Second) of Torts, is the appropriate standard of liability to impose upon manufacturers of prescription drugs, and should be applied as a matter of law to such drugs apart from any case-by-case risk/benefit analysis.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by Federal Express to Jeffrey P. Kaiser, Esq., 15476 NW 77th Court, Suite 315, Miami Lakes, FL 33016 and Mercer Clarke, Esq., 100 Chopin Plaza, Suite 2400, Miami, FL 33131 this 6th day of June, 1988.

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