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Stradley Ronon Stevens & Young, LLP
2600 One Commerce Square
Philadelphia, Pennsylvania 19103
215 564 8000 Telephone
215 564 8120 Facsimile
www.stradley.com

With offices in:
Harrisburg, Pa.
Malvern, Pa.
Wilmington, Del.
Cherry Hill, N.J.
Washington, D.C.

Assumption of Risk and Pharmaceuticals

The doctrine of assumption of risk has a long and checkered history in Pennsylvania. While a minority of the Pennsylvania Supreme Court has repeatedly sought to abolish it, and numerous courts of this state have expressed their confusion as to the continued viability of the doctrine under Pennsylvania law, assumption of risk remains a complete bar to recovery in Pennsylvania. In McMurdie v. Wyeth, No. 1386 Dec.Term 2002, 2005 WL 465952 (C.C.P. Phila. Cty. Feb. 23, 2005), Philadelphia Common Pleas Judge Mark I. Bernstein applied the doctrine of assumption of risk to bar a plaintiff in a pharmaceutical products liability action from recovering against a manufacturer, where she had been warned of the potential harm that she ultimately suffered. While breaking no new legal ground, Judge Bernstein's opinion indicates a willingness to apply this black sheep of the tort family in a way that may afford greater protection for drug makers who provide sufficient warnings to patients thus made subjectively aware of the dangers associated with a drug.

The History of Assumption of Risk

Assumption of risk has been around in Pennsylvania, in one form or another, for well over a hundred years. Analytically, it can be thought of as a form of contributory negligence – that is, a plaintiff who voluntarily chooses to take the risk that he will suffer a particular injury, and who in fact suffers that injury, cannot later complain that he should be compensated for the harm he has suffered. The basic idea behind the doctrine of assumption of risk is that it is unfair to permit a plaintiff to point the finger of blame at another where he has voluntarily and knowingly proceeded in the face of an obvious and known danger. Assumption of risk does not require a showing that the potential tortfeasor is without fault, but rather excuses a defendant's fault on account of the plaintiff's decision to voluntarily encounter it. Nor is it plaintiff's negligence that bars his recovery under the doctrine of assumption of risk, differentiating this tort doctrine from that of contributory negligence; rather, it is his decision to proceed in the face of a known risk. In sum, assumption of risk embodies the concept that someone who decides to take his chances can't later complain when he gets hurt.

In 1981, a plurality of the Pennsylvania Supreme Court in Rutter v. Northeastern Beaver County School Dist., 437 A.2d 1198, 1206 (Pa. 1981), noted that "there is a serious question as to whether the doctrine of assumption of risk . . . should be permitted longer to survive." The plurality concluded that "we think that it should not." Id. Applying a form of assumption-of-risk analysis itself, the Rutter court concluded that "the difficulties of using the term 'assumption of risk' outweigh the benefits. The issues should be limited to negligence and contributory negligence." Id. at 1209. Thus, except in a

few narrow situations, assumption of risk was purportedly abolished. Id. The dissents in Rutter, while admitting to the doctrinal overlap of assumption of risk and contributory negligence, lamented the passing of "a necessary and viable component of tort law." Id. at 1212 (Nix, J., dissenting).

Two years later, however, the Superior Court in Fish v. Gosnell, 463 A.2d 1042 (Pa. Super. 1983), continued to address assumption of risk as a viable doctrine under Pennsylvania law. While ultimately holding that assumption of risk did not apply to the case at bar, the Fish court noted that "assumption of risk and comparative negligence may sometimes overlap because certain conduct may exhibit all the elements of both. However, assumption of risk as a separate defense has a distinct character." Id. at 1048. The Supreme Court too continued to apply the doctrine of assumption of risk despite the holding of the Rutter plurality. See Carrender v. Fitterer, 469 A.2d 120 (Pa. 1983). That assumption of risk remained viable in Pennsylvania was echoed by the Superior Court in other decisions, where it made the statement, for example, that "the doctrine of assumption of the risk is available as a defense in Pennsylvania," and furthermore observed that "the [plurality] opinion in Rutter was not joined in by a majority of the justices and therefore is not binding precedent." Malinder v. Jenkins Elevator & Machine Co., 414 A.2d 509, 512-13 (Pa. Super. 1988).

While thus generally, if uneasily, accepted as the law of the land following these decisions of the 1980s, the doctrine of assumption of risk was again taken up by the Pennsylvania Supreme Court in 1993 in Howell v. Clyde, 620 A.2d 1107 (Pa. 1993). Again speaking through a plurality, the Supreme Court, while doing away with some of the subcategories extant in the assumption-of-risk analysis, this time reaffirmed the applicability of assumption of risk as a complete bar to recovery in Pennsylvania. The form of assumption of risk adopted, however, bore some analytical modifications, such as the holding that assumption of risk was normally subsumed into the duty analysis, and thus was normally a question of law for the court and not a jury question. One dissenting justice in Howell expressed his regret that "until such time as this Court arrives at a clear-cut majority, we will continue to muddy the waters in the sensitive areas of both comparative negligence and assumption of risk." Id. at 1115 (Zappala, J., dissenting).

Again without the guidance of a majority of the Supreme Court, lower courts were faced in the wake of Howell with the task of deciding whether assumption of risk remained a viable defense. Again they decided that it was. The Superior Court's last definitive word on the issue was in 2000, in Staub v. Toy Factory, Inc., 749 A.2d 522 (Pa. Super. 2000), where it again tried to make sense of the numerous mixed messages coming from the Supreme Court. The Staub court, taking its lead from the Howell plurality, held that until the legislature or the Supreme Court unambiguously decided to do away with the doctrine, assumption of risk remained the law of the land and continued to operate to completely bar a tort plaintiff's recovery. Assumption of risk thus remains a viable defense in the Commonwealth today, though it is doubtful that we have heard the last word on this subject from the courts of Pennsylvania.

Application of Assumption of Risk in McMurdie

Plaintiff Geri McMurdie took the drug Pondimin, manufactured by Wyeth, in 1996 and 1997. Pondimin had been approved by the FDA only to treat "exogenous obesity" as a short term cure, namely, for a few weeks. It was conceded by the parties that McMurdie took the drug "off label," meaning that her doctor had prescribed it for a use not approved by the FDA. McMurdie took Pondimin for six months full well knowing that it was not approved for such long term use and moreover acknowledged a willingness to take it "for life," while conceding that the risks associated with long-term use were not known.

Pondimin had become very popular in Utah during the time that McMurdie, a Utah resident, took it. So popular, in fact, that it became a controlled substance under Utah law and the Utah legislature enacted an informed consent statute regulating prescription of Pondimin for weight control. This law required prescribing physicians to obtain a patient's informed consent, and further required that doctors discuss the possible risks associated with the drug with their patients, especially the fact that all long-term risks were not yet known.

McMurdie went to her doctor and specifically requested that she be put on Pondimin. Her physician initially refused

on account of her medical history and hypertension. Judge Bernstein noted that the doctor "undoubtedly explained to his patient his reasons for refusing to prescribe Pondimin." Once McMurdie got her blood pressure down, however, and again asked her doctor to put her on the drug, the physician prescribed Pondimin. In accordance with the Utah law, the doctor "discussed her individual risks," and, as a result, "plaintiff was well educated about those risks. McMurdie understood that the medication could seriously exacerbate her hypertension. She understood that because of her history of high blood pressure, use of Pondimin presented a serious risk of stroke or heart attacks. She knowingly and voluntarily assumed these risks." The consent form reiterated that the risks of long-term use had not been studied, and included increased heart rate, higher blood pressure, and heart attack among the known potential harms associated with Pondimin. The opinion summed up the evidence of McMurdie's awareness of the risks she was voluntarily assuming: "She knew that Pondimin carried a risk of side effects which would cause serious adverse heart conditions including heart attack and stroke. Equally importantly, her doctor explained, and she acknowledged, acceptance of unknown risks with long-term use."

Judge Bernstein noted that McMurdie may not have been negligent in choosing to take Pondimin off label – her potential negligence, however, was not part of the assumption of risk calculus (and moreover no defense of comparative negligence had been asserted by defendant Wyeth). Instead, it was McMurdie's subjective awareness that served to bar her recovery: She had stated at trial that "I believe the weight loss associated with the use of these medications will be beneficial to my health and this benefit outweighs the risks." The objective reasonableness of this view, Judge Bernstein noted, was irrelevant. "Plaintiff's right to make her own decision . . . weighing her unique risks and benefits is respected by the law," embodied in principles of "individual liberty and freedom of choice in medical care."

Having taken the drug with her eyes wide open as to the possible risks to her heart, however, McMurdie could not after the fact complain that Wyeth should be held liable for the particular heart ailment she eventually suffered, "valvular regurgitation": "Having knowingly chosen Pondimin's potential benefit against the known risk of serious heart injury including stroke; having knowingly chosen . . . Pondimin's potential benefit against the known risk of serious heart injury including heart attack; having knowingly chosen Pondimin's potential benefit when used 'off-label' for unapproved long-term use against 'unknown' risks, plaintiff may not seek compensation because she had not been specifically told of a risk of 'valvular regurgitation.'" This was thus a classic case where the plaintiff voluntarily assumed the risk of the class of harm she suffered, and the doctrine of assumption of risk wholly barred her claim against the drug maker under these circumstances. "Plaintiff affirmatively, explicitly, tacitly, and impliedly agreed to relieve the defendant of the significantly lesser risks which actually occurred." As a result, defendant Wyeth could not be held accountable for plaintiff McMurdie's injuries.

Conclusion

The scope of the holding in McMurdie is arguably quite narrow, and it by no means clears up any of the confusion that surrounds assumption of risk as a viable defense under Pennsylvania law. McMurdie's claim was barred by assumption of risk only where state law imposed a duty on doctors to obtain written consent from patients for whom they were prescribing the drug, which included the risk of unknown injuries. Moreover, there was no question on the facts of this case not only that McMurdie was subjectively aware of the risk of the harm that ultimately befell her, but moreover that she explicitly admitted to weighing these known and unknown risks against the potential benefits of taking Pondimin. However, Judge Bernstein's opinion can be seen as espousing a willingness to hold takers of prescription drugs accountable for their decision to proceed in the face of potential injuries a prescription pharmaceutical can cause. Where drug manufacturers make known the potential risks involved in taking their medications, and where patients are consequently made aware of the trade-offs that are implicit in choosing to take virtually any drug, from aspirin to Vioxx, McMurdie may signal a willingness to hold patients accountable for their decisions and allow drug makers to escape liability where patients are sufficiently made aware of the potential harm that may befall them.

STRADLEY RONON
ATTORNEYS AT LAW

Stradley Ronon Stevens & Young, LLP
2600 One Commerce Square
Philadelphia, PA 19103

STRADLEY RONON
ATTORNEYS AT LAW

PRODUCTS LIABILITY AND MASS TORT PRACTICE GROUP

Joseph J. McHale, *chair* . .jmchale@stradley.com 610-640-8007
Daniel T. Fitch . . . . . .dfitch@stradley.com 215-564-8063
Jeffrey D. Grossman . . . . .jgrossman@stradley.com . .215-564-8061
Patrick R. Kingsley . . . . . .pkingsley@stradley.com . . .215-564-8029
Jana M. Landon . . . . . .jlandon@stradley.com 215-564-8049
Jeffrey A. Lutsky . . . . . .jlutsky@stradley.com 215-564-8087
Michael D. O'Mara . . . . . .momara@stradley.com . . .610-640-5802
Ellen Rosen Rogoff . . . . . .erogoff@stradley.com 215-564-8058
Gina M. Stowe . . . . . .gstowe@stradley.com 610-640-7960
Andrew K. Stutzman . . . . .astutzman@stradley.com . .215-564-8008
Neal R. Troum . . . . . .ntroum@stradley.com 215-564-8028