J. A39025/00

2001 PA Super 118

DOROTHY T. AND ROBERT E. SCHINDLER,	:	IN THE SUPERIOR COURT OF PENNSYLVANIA
Appellants	:	
v.	:	
SOFAMOR, INC., SOFAMOR DANEK GROUP, INC., SOMEPIC TECHNOLOGIES, STUART PHARMACEUTICAL COMPANY,	:	
Appellees	:	No. 893 EDA 2000

Appeal from the Order dated February 15, 2000 in the Court of Common Pleas of Philadelphia County, Civil Division, at No. 1788, December Term, 1994.

BEFORE: STEVENS, LALLY-GREEN, and OLSZEWSKI, JJ.

OPINION BY LALLY-GREEN, J.: Filed: April 23, 2001

¶ 1 Appellants, Dorothy T. and Robert E. Schindler, appeal from the order dated February 15, 2000, granting judgment notwithstanding the verdict (JNOV) in favor of Appellee Stuart Pharmaceutical Company (Stuart). We affirm.

¶ 2 On December 15, 1994, Appellants filed a complaint against Stuart and other parties.[1] The complaint alleged that Stuart distributed a defectively-designed spinal fixation rod that broke after it was surgically

[1] The complaint also named Sofamor, Inc., Sofamor Danek Group, Inc. (collectively, "Sofamor") and Somepic Technologies. Somepic was never served with the complaint, and is not a party to this litigation. The trial court granted summary judgment in favor of Sofamor on October 20, 1998. Appellants do not challenge the grant of summary judgment.

implanted in Mrs. Schindler's spine.[2] The case proceeded to a four-day trial in December 1998. The trial court summarized the evidence as follows.

> In January 1963, Plaintiff, Dorothy Schindler, was diagnosed with scoliosis, which is a curvature of the spine. Between 1963 and 1988, Mrs. Schindler was treated by a chiropractor. In 1988, Mrs. Schindler began to experience intense leg and back pain and went to see Richard A. Balderston, M.D., an orthopedic surgeon. Dr. Balderston informed Mrs. Schindler that her spine had curved to 74 degrees and that she would need back surgery in order to improve.
>
> In November 1988, Mrs. Schindler underwent posterior and anterior fusion surgery. A Cotrel-Dubosset ("CD") spinal fixation device was placed in Mrs. Schindler's spine. The device consists of a series of hooks and rods which are used to stabilize and align the spine until fusion occurs. In January 1989, an x-ray revealed that one of the hooks implanted in Mrs. Schindler's spine had not set properly. Surgery was performed to repair the hook. After the surgeries, Mrs. Schindler's curve was reduced by 30 degrees and she became asymptomatic. Between 1989 and 1993, Mrs. Schindler testified that she felt good and that her activities resumed with no problems. In February 1993, while attending an exhibition baseball game, Mrs. Schindler experienced sharp lower back pain and was unable to walk out of the stadium. After that date, Mrs. Schindler began to experience pain and numbness in her legs and back.
>
> Mrs. Schindler saw Dr. Balderston again in July 1993. An examination revealed that Mrs. Schindler's spine had not fused at the T11-T12 and T8-T9 sites. At this point of non-fusion, an x-ray revealed that one of the CD rods implanted in Mrs. Schindler's

[2] The complaint also alleged negligence and breach of express and implied warranties. Before trial, Appellants voluntarily dismissed all claims except for strict products liability/design defect.

> spine had fractured. Dr. Balderston informed Mrs. Schindler that she would have to undergo surgery to repair the rod. Surgery was performed in September 1993. The CD rods were removed and three new rods were placed in Mrs. Schindler's back. . . .
>
> Plaintiffs claimed that the knurled surface of the CD Rod was a design defect, which caused it to prematurely fracture.

Trial Court Opinion, 2/15/2000, at 2-3 (citations omitted). Specifically, Appellants claimed that the CD Rod was not fit for its intended use because it broke before the spine had fused.

¶ 3 Appellants presented the following evidence in support of this proposition. First, Mrs. Schindler testified that she was under the impression that the rod would be in her back for the rest of her life. N.T., 12/7/98, at 1.53.[3] Next, Dr. Ronald Rosenfeld, an orthopedic surgeon, testified that Mrs. Schindler's initial surgery took place in two phases. In the first phase, the discs between the vertebrae are scraped out and filled with bone; "the objective here is to obtain a solid fusion mass." ***Id.*** at 1.167. The second phase took place one week later. In this phase, the bone is scraped, the rods are inserted and tightened, then additional bone is laid on top of the first bony mass "in order to try to get the bone to create a solid bone fusion." ***Id.*** at 1.168.

[3] This evidence was introduced to illustrate Mrs. Schindler's state of mind, not for the truth of the underlying statement. N.T., 12/7/98, at 1.53.

¶ 4 On September 9, 1993, doctors discovered that a rod had broken and that the bone had not fused (a condition known as pseudoarthrosis) at that site.[4] ***Id.*** at 1.170. Pseudoarthrosis brought about increased movement and higher forces at the site of the broken rod. ***Id.*** at 1.214, 1.221. The broken rod allowed abnormal spinal movement, which caused further degeneration of the spine and the need for a fourth operation, which in turn brought about a chronic back condition. ***Id.*** at 1.181, 1.225-1.226. Dr. Rosenfeld further testified that a spine should fuse within a year after implantation, and preferably within six months. ***Id.*** at 1.226. When asked if the spine is not going to fuse at all if it has not fused within one year, Dr. Rosenfeld responded: "I don't know that that's an absolute. I don't have enough experience to answer that. But I would say if it doesn't fuse in a year the chances of it fusing in and of itself are much decreased and something should likely be done to encourage that spine to fuse." ***Id.*** Various options for encouraging the spine to fuse include externally-applied electronic bone stimulation and ultrasonic bone growth stimulators. ***Id.*** at 1.227. When asked if instrumentation will inevitably break if there is no

[4] Appellants' spinal instrumentation expert, Dr. Robert M. Rose, explained pseudoarthrosis as follows: "Well, if you have a fracture in the bone or some kind of gap which may have been created by the surgeon by an osteotomy, and what in general you want is for the fracture or the osteotomy to heal and to be replaced by fully calcified hard tissue, essentially new bone. In some cases that doesn't happen. With some procedures it may be pretty frequent. But if it doesn't happen, whatever tissue you get in there is now going to be flexible and at that point it's going to bend at that point [sic]. Well, if you put a load on it it will bend and that's why it's called a pseudoarthrosis. Essentially instead of getting hard bone bridging the gap and healing the fracture you get something soft." N.T., 12/8/98, at 2.58.

fusion, Dr. Rosenfeld responded: "Repeated stress forces on metal given an infinite amount of time will cause breakage. It's a question of the degree of force and the timeline." ***Id.*** at 1.227. Dr. Rosenfeld acknowledged that sometimes spines do not fuse, for reasons that are not clear. ***Id.*** at 1.198.

¶ 5 Dr. Robert M. Rose, Appellants' expert in engineering, metallurgy, orthopedic implants, and spinal instrumentation, testified that the rod was defective because of its knurled surface. In other words, the rod would not have failed if the surface had not been knurled. N.T., 12/8/98, at 2.24-2.25. The knurled surface concentrates the stresses in the metal, and the knurling process itself can also create stresses and peeling that ultimately lead to fractures. ***Id.*** at 2.36-2.38. According to Dr. Rose, the important factor in causing the metal to break was repeated stress on the knurled surface: "Now whether or not there was a pseudoarthrosis present does not change my conclusion that it would not have failed if the knurls were absent." ***Id.*** at 2.70. When asked on cross-examination whether "a proper fixation device serves its purpose if it aligns the spine for the time that it takes for fusion to occur," Dr. Rose responded: "That would be a successful limitation [sic], yes. If it keeps the spine aligned until fusion occurs then the surgeon has succeeded in his objective. I can't comment on the clinical results that would come of the fusion but, yes, the purpose of all that metal is to try to hold things together and hold them aligned until you can get fusion." ***Id.*** at 2.100; ***see also***, ***id.*** at 2.112 (the rod would not have served its purpose if

it fails before fusion occurs). The knurls were placed on the rod for improved holding power. ***Id.*** at 2.102. However, Dr. Rose testified that "most probably" the CD Rod system could be redesigned to use smooth rods. ***Id.*** at 2.111.

¶ 6 The jury found in favor of Appellants and awarded $1,585,000.00. On December 21, 1998, Stuart filed post-trial motions seeking JNOV and/or a new trial. On February 15, 2000, the trial court granted JNOV. The court ruled as a matter of law that the rod was not unreasonably dangerous. Specifically, the court found that the rod was safe for its intended use:

> The rod's surface was knurled, or grooved. The knurling provided improved holding power and was not decorative. Plaintiffs claimed that the knurled surface of the rod caused it to prematurely break. Plaintiff's expert opined that smooth metallic surfaces last longer than <u>any</u> metallic surfaces which have been altered. Thus, Plaintiffs claimed that the knurled surface was a design defect.
>
> An examination of the record clearly reveals that the CD Rod was not unreasonably dangerous for its intended use. The intended use of the rod was to stabilize the spine until fusion occurred. If fusion is to occur in an individual, it will occur within one year of surgery. The rod was never intended to last indefinitely in the absence of fusion. The testimony at trial established that all implants will eventually fracture in the event of non-fusion.
>
> Mrs. Schindler's surgery took place in January 1989 and fusion should have occurred by January 1990. Therefore, the CD Rod had served its intended purpose if it stabilized Mrs. Schindler's spine within the one year following her January 1989 surgery. Plaintiffs do not claim that the rod failed to align Mrs. Schindler's spine in the year following the

> surgery. The rod did not break until July 1993, four and a half years after the surgery and three and a half years after the point that fusion should have occurred. The CD Rod fulfilled its intended use in providing stabilization for an additional three and a half years past its intended use.

Trial Court Opinion, 2/15/2000, at 5 (citations omitted). This appeal followed.[5]

¶ 7 Appellants raise three issues on appeal:

> 1. Does a review of the testimony under the correct standard demonstrate that the back rod was unsafe for its intended use?
>
> 2. Did the lower court violate the proper standard of review when it granted a judgment notwithstanding the verdict on the basis of testimony that was contradicted?
>
> 3. Did the lower court err as a matter of law when it considered on a motion for judgment notwithstanding the verdict whether or not the back rod was unreasonably dangerous?

---

[5] Preliminarily, we must address Appellants' claim that the issue of intended use is waived because Stuart raised it for the first time in post-trial motions. Under our Rules of Civil Procedure,

> Post-Trial relief may not be granted unless the grounds therefor, (1) if then available, were raised in pre-trial proceedings or by motion, objection . . . or other appropriate method at trial; and (2) are specified in the motion. . . . Grounds not specified are deemed waived unless leave is granted upon cause shown to specify additional grounds.

Pa.R.Civ.P. 227.1(b)(1), (b)(2), 42 Pa.C.S.A. Here, Stuart did raise the issue of whether the CD Rod was safe for its intended use several times before trial was complete. ***See***, Stuart's Motion for Summary Judgment, R.R. 28a (CD Rod broke "long after the purpose of the instrument had been fulfilled"); ***Id.*** at 36a (rod did not break prematurely even though it broke before fusion); Oral Argument in Support of Motion for Summary Judgment, N.T., 12/1/98, at 10-11 (Appellants failed to present evidence that CD Rod broke prematurely); Oral Argument on Motion for Compulsory Nonsuit, N.T., 12/9/98, at 3.22 (Appellants "have not identified any purpose that this device was to serve beyond an alignment of the spine for a period of time adequate to achieve fusion"). Thus, the issue is not waived.

Appellants' Brief at 3.

¶ 8 Appellants' three issues are closely interrelated; as such, we will address them together. Appellants argue that the trial court misapplied the standard for awarding JNOV because the court did not construe all factual inferences in favor of Appellants. They reason as follows. First, they presented evidence that the purpose of the CD Rod was to stabilize the spine until fusion took place. Next, it is undisputed that the CD Rod broke before fusion took place. Finally, they presented expert testimony that the CD Rod did not fulfill its intended purpose because it broke before fusion took place. According to Appellants, this evidence was sufficient from which a jury could (and did) find that the CD Rod was unfit for its intended purpose. Appellants further argue that the trial court erred by disregarding this evidence and concluding as a matter of law that that the CD Rod **was** fit for its intended purpose because the rod stayed in place for over one year, even though fusion did not take place.

¶ 9 Our standard of review regarding the grant or denial of JNOV is as follows:

> [T]here are two bases upon which a judgment n.o.v. can be entered: one, the movant is entitled to judgment as a matter of law, and/or two, the evidence was such that no two reasonable minds could disagree that the outcome should have been rendered in favor of the movant. With the first, a court reviews the record and concludes that even with all factual inferences decided adverse to the

> movant the law nonetheless requires a verdict in his favor, whereas with the second, the court reviews the evidentiary record and concludes that the evidence was such that a verdict for the movant was beyond peradventure.
>
> ***Moure v. Raeuchle***, 529 Pa. 394, 402-403, 604 A.2d 1003, 1007 (1992) (citations omitted).

Davis v. Berwind Corp., 690 A.2d 186, 189 (Pa. 1997).

¶ 10 We will now review the substantive law of products liability/design defect cases, with a particular emphasis on the proper role of the judge and the jury in such a case.

> Court control of jury action in products liability cases is more extensive than in an ordinary negligence action. ***Dambacher by Dambacher v. Mallis***, 336 Pa. Super. 22, 47, 485 A.2d 408, 422 (1983). In ***Azzarello v. Black Bros. Co., Inc.***, 480 Pa. 547, 558, 391 A.2d 1020, 1026 (1978), the Supreme Court held that **it is a judicial function to decide whether, under the plaintiff's version of the facts, recovery would be justified**; and only after this judicial determination is made is the cause submitted to the jury to determine whether the facts of the case support the averrants [sic] of the complaint. ***Id.*** at 558, 391 A.2d at 1026.
>
> In products liability cases, § 402A of the Restatement (Second) of Torts has been adopted as the law of this Commonwealth, ***Webb. v. Zern***, 422 Pa. 424, 220 A.2d 853 (1966), and to prevail, the plaintiff must prove (1) that the product was defective, (2) that the defect existed when it left the hands of the defendant, and (3) that the defect caused the harm. ***Ellis v. Chicago Bridge & Iron Co.***, 376 Pa. Super. 220, 235, 545 A.2d 906, 909 (1988).n1 The threshold inquiry in all products liability cases is whether there is a defect. ***Dambacher***, ***supra*** at 52, 485 A.2d at 425. This threshold can be crossed in one of two ways: either

by proving a breakdown in the machine or a component thereof, traditionally known as a manufacturing defect; or in cases where there is no breakdown, by proving that the design of the machine results in an unreasonably dangerous product, traditionally known as a design defect. ***See Ellis v. Chicago Bridge & Iron Co., supra***. The latter is the issue that is before us in this case.

- - - - - - - - - - Footnotes- - - - - - - - - - - - - - - - - -

n1 § 402A reads in full as follows:

"(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 a 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."

Restatement (Second) of Torts, § 402A (1965).

- - - - - - - - - - - - - -End Footnotes- - - - - - - - - - -

The question of whether a product is unreasonably dangerous is a question of law. ***Azzarello***, ***supra*** at 556, 391 A.2d at 1026. In

answering this question a court is essentially making a social policy determination and acting as both a social philosopher and a risk-utility economic analyst. ***Fitzpatrick v. Madonna***, 424 Pa. Super. 473, 476, 623 A.2d 322, 324 (1993). In ***Dambacher***, *supra*, this Court identified certain factors to consider in making this determination:

> The gravity of the danger posed by the challenged design; the likelihood that such danger would occur; the mechanical feasibility of a safer design; and the adverse consequences to the product and to the consumer that would result from a safer design. (citation omitted).

Id. at 50 n.5, 485 A.2d at 423 n.5.

The Court also cited to additional factors, which included:

> (1) The usefulness and desirability of the product - its utility to the user and to the public as a whole. (2) The safety aspects of a product - the likelihood that it will cause injury, and the probable seriousness of the injury. (3) The availability of a substitute product which would meet the same need and not be as unsafe. (4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility. (5) The user's ability to avoid danger by the exercise of care in the use of the product. (6) The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions. (7) The feasibility on the part of the manufacturer, of spreading the loss of

> setting the price of the product or carrying liability insurance.

Riley v. Warren Mfg., 688 A.2d 221, 224-225 (Pa. Super. 1997) (emphasis added, footnote omitted).

¶ 11 "In a defective design case, the question is whether the product should have been designed more safely for its intended use." ***Putt v. Yates-American Mach. Co.***, 722 A.2d 217, 221 (Pa. Super. 1998) (citation omitted), *appeal denied*, 737 A.2d 743 (Pa. 1999). "The initial issue, therefore, is a question of law whose resolution depends upon social policy." ***Fitzpatrick***, 623 A.2d at 324, *citing*, ***Azzarello***, 391 A.2d at 1026; ***see also***, ***Surace v. Caterpillar, Inc.***, 111 F.3d 1039, 1049 n. 10 (3rd Cir. Pa. 1997) (trial court's duty is to determine "whether the evidence is sufficient, for purposes of the threshold risk-utility analysis, **to conclude as a matter of law that the product was not unreasonably dangerous**, **not whether the evidence creates a material fact for the jury**") (emphasis added). "When a judicial determination has been made that recovery would be justified, a 'jury may find a defect where the product left the supplier's control lacking any element necessary to make it safe for its intended use or possessing any feature that renders it unsafe for the intended use.'" ***Fitzpatrick***, 623 A.2d at 324, *quoting*, ***Azzarello***, 391 A.2d at 1027.

¶ 12 As noted above, the issue of whether a product is unreasonably dangerous is a question of law. ***Riley***, 688 A.2d at 224-225. Generally, even where the trial court is required to accept a party's averments of fact

and reasonable inferences therefrom as true, it is not bound by a party's legal conclusions or unwarranted factual inferences. ***See***, ***Jacobini v. V. & O. Press Co.***, 588 A.2d 476, 479 (Pa. 1991) (affirming directed verdict for defendant where plaintiff presented expert opinion that a certain type of warning was required on the product, but such a warning would not have averted the specific type of injury suffered by the plaintiff); ***Mackowick v. Westinghouse Elec. Corp.***, 575 A.2d 100, 103 (Pa. 1990) (rejecting claim that electrical capacitor was defective because it failed to warn trained electrician about the dangers of arcing, even though plaintiff claimed he was unaware that arcing could take place without touching the unit itself); ***Dauphin Deposit Bank & Trust Co. v. Toyota Motor Corp.***, 596 A.2d 845, 850-851 (Pa. Super. 1991) (granting demurrer on plaintiff's claim that alcohol manufacturer was required to provide warnings about the dangers of drunk driving; court decided as a matter of law that these dangers are obvious to the public and that no warnings are required, despite plaintiff's evidence to the contrary).

¶ 13 In short, trial courts and this Court have the power to reject design defect claims as a matter of law, even where the plaintiff presents evidence tending to show that the product is defective. ***See***, ***Jacobini***, 588 A.2d at 479; ***Riley***, 688 A.2d at 225-226 (affirming directed verdict in favor of manufacturer of bulk-feed trailer even though plaintiff presented eight alternative designs and expert testimony that trailer was defective because

it lacked a guard on the discharge tube); ***Fitzpatrick***, 623 A.2d at 326 (granting JNOV on appeal in favor of manufacturer of outboard motor even though plaintiff presented expert testimony that motor was defective for failing to encase propeller in a shield); ***Jordon v. K-Mart Corp.***, 611 A.2d 1328, 1331 (Pa. Super. 1992) (affirming summary judgment in favor of seller of plastic toboggan, even though plaintiffs were prepared to present expert evidence that product was defective because it had "molded runners that rendered the sled unsteerable" and "because it "lacked independent steering or braking mechanisms.")

¶ 14 Determining the product's intended purpose is critical to the court's legal conclusions about whether the product can be deemed defective. ***Riley***, 688 A.2d at 224-225. The court will necessarily make different conclusions about the risk-utility of a product depending on whether the court construes the intended purpose of a product broadly or narrowly. If the trial court is properly to discharge its duty as a social philosopher and a risk-utility economic analyst, the court must be afforded some measure of latitude to determine the intended purpose of a product. It follows that the intended use of a product is a conclusion of law, to be decided by the trial court. In other words, the trial court is not bound by any party's legal conclusions as to the intended purpose of a product, even if those conclusions are couched as averments of fact or presented as expert

evidence.[6] To hold otherwise would force trial courts (and reviewing courts) to accept unrealistic, generalized, or distorted views of a product's purpose simply because they are presented as factual evidence.[7]

¶ 15 One recent decision of this Court illustrates this principle. In ***Weiner v. American Honda Motor Co.***, 718 A.2d 305 (Pa. Super. 1998), the driver of a two-door Acura Integra hatchback was transporting a 54-inch, 180-pound canister of pressurized nitrous oxide. To fit the canister in the car, he lowered the folding rear seats. After the driver struck a guardrail, the canister slid forward into the driver's seat, causing serious injuries to the driver. The driver filed suit against Honda, claiming that the Acura was defectively designed because it lacked protective devices to prevent the

---

[6] One federal court has noted the dangers of taking a "weighted view of the evidence" when deciding whether a product is unreasonably dangerous. ***See***, ***Surace***, 111 F.3d at 1048 n.9 (trial court's decision is "a legal determination which should probably not be predicated upon a weighted view of the evidence. The Pennsylvania Supreme Court might want to revisit this aspect of the matter if and when it definitively comes to grips with the issues we have identified in this opinion.")

[7] The determination of whether a product is unreasonably dangerous is analytically similar to the determination of whether the defendant owes a duty to the plaintiff in a negligence action. In the case of a design defect, "[i]t must be understood that the words, 'unreasonably dangerous' have no independent significance and **merely represent a label to be used where it is determined that the risk of loss should be placed upon the supplier**. . . . While a lay finder of fact is obviously competent in resolving a dispute as to the condition of a product, an entirely different question is presented where a decision as to whether that condition justifies placing liability upon the supplier must be made." ***Azzarello***, 391 A.2d at 1024 (emphasis added). Similarly, "[i]n determining the existence of a duty of care, it must be remembered that **the concept of duty amounts to no more than the sum total of those considerations of policy which led the law to say that the particular plaintiff is entitled to protection from the harm suffered**." ***Campo v. St. Luke's Hosp.***, 755 A.2d 20, 24 (Pa. Super. 2000)(citations and internal quotation marks omitted, emphasis added) (granting JNOV on the basis that the facts adduced at trial did not support the existence of a duty). It is undisputed that the trial court is not bound to accept a plaintiff's assertion that the defendant owes a duty under a given set of facts. ***See***, ***id.*** Similarly, the trial court is not bound to accept a plaintiff's assertions regarding the intended use of a product or the existence of a design defect.

cargo from sliding. The driver suggested that the hatchback was unfit for its intended purpose of hauling cargo because it could not safely haul all cargo that could fit within the car itself. The trial court rejected this position and granted summary judgment, holding that the purpose of a two-door hatchback was not to haul industrial equipment. ***Id.*** at 308. We agreed, and rejected the driver's broad suggestion of the intended use of the product:

> To find that the Acura was defective and unreasonably dangerous and hold Appellees strictly liable for all injuries sustained from shifting cargo upon impact simply because such cargo was capable of fitting inside the vehicle would run contrary to the purposes of § 402A, since it would effectively place Appellees in the position of being an insurer of safety with no consideration given to the intended use of the vehicle and its cargo area.

Id. at 309.

¶ 16 In the instant case, the trial court was charged with deciding whether, "under the plaintiff's version of the facts, recovery would be justified." ***Azzarello***, 391 A.2d at 1026. As noted above, Appellants' version of the facts is that the CD Rod was designed to stay in place until fusion took place, and that the rod did not do so. Appellants conclude that their version of the facts compels a legal finding that the CD Rod was not fit for its intended purpose. For the following reasons, we disagree.

¶ 17 This case hinges on the difference between averments of fact and conclusions of law. All parties agree that the CD Rod is designed to stabilize

the spine "until" fusion takes place. It is also undisputed that the rods generally do stay in place forever if fusion takes place.[8] Appellants would convert these statements of fact into a conclusion of law that the rod is defective if it breaks before fusion takes place. The unspoken assumption behind this statement is that fusion **always** takes place once a rod is inserted. Appellants would have the trial court accept this assumption as true, under the guise of construing all factual inferences in Appellant's favor.

¶ 18 The trial court chose not to do so, and implicitly rejected this assumption as unreasonable. Instead, the trial court took the additional step of asking two questions: (1) whether fusion occasionally does not take place at all, and (2) whether the CD Rod was designed to stay in place indefinitely in such a situation. In doing so, the trial court took into account the fact that occasionally the spine does not fuse (a condition known as pseudoarthrosis), and that if the spine does fuse, it will generally do so within one year. The trial court concluded that "the rod was never intended to last indefinitely in the absence of fusion," and that the rod served its purpose if it stabilized the spine for one year. Trial Court Opinion, 2/15/2000, at 5.

¶ 19 We see no error of law in this statement of the CD Rod's intended purpose. Appellants presented no evidence that the CD Rod was intended to

[8] Thus, Mrs. Schindler's expectation that the CD Rod would stay in place forever appears to be based on the reasonable (but incorrect) pre-surgery assumption that her spine would fuse properly and that pseudoarthrosis would not take place.

stabilize the spine indefinitely in the case of pseudoarthrosis. Rather, it would appear that if fusion does not take place within one year, physicians should take additional measures to encourage fusion, such as bone stimulation.[9] In other words, the goal of the CD Rod is to **facilitate** bone fusion, not to **substitute** for fusion in the event of pseudoarthrosis. Moreover, the mere fact that stabilization rods generally last forever in the event of fusion does not necessarily imply that they last forever in the event of non-fusion. Thus, even if a smooth CD Rod would have lasted forever, this fact is irrelevant because the rod was not intended to last forever in the event of pseudoarthrosis.[10] Based on the trial court's appropriately-limited statement of the CD Rod's purpose, and the undisputed fact that the CD Rod did indeed stabilize the spine for well over one year, we see no error in the court's conclusion that the product was not unreasonably dangerous as a matter of law. JNOV was therefore appropriate. ***See***, ***Davis***, 690 A.2d at 190-191 (affirming grant of JNOV on appeal where plaintiff's products liability/failure to warn claim was untenable as a matter of law); ***Fitzpatrick***, 623 A.2d at 326 (granting JNOV on appeal in favor of

[9] We do not, of course, express any opinion on the merits of a potential medical malpractice action based on Mrs. Schindler's surgeon's failure to detect the pseudoarthrosis and take aggressive measures to encourage fusion in the four and one-half years before the CD Rod broke.

[10] In this respect, the instant case is analogous to ***Weiner***, *supra*. In ***Weiner***, the plaintiff claimed that his Acura Integra was defective because it did not have restraints to secure industrial equipment in the back seat. Even assuming that restraints would have restrained the equipment in the event of an accident, the car was not defective for failing to have such restraints because the car was not designed to haul industrial equipment.

defendant because plaintiff's evidence did not support a legal conclusion that design defect existed).[11]

¶ 20 As a result of our disposition, we need not directly address Appellants' argument that the ten factors identified in ***Riley*** support a judgment in their favor as a matter of law, because Appellants' argument hinges on the assumption that the CD Rod was intended to last indefinitely in the absence of fusion. We also need not address Stuart's three alternative arguments in support of judgment as a matter of law, namely: (1) the merits of the ***Riley*** factors; (2) the application of the learned intermediary doctrine; and (3) the contention that strict liability does not apply to prescription medical devices.

¶ 21 Order affirmed.

¶ 22 Olszewski, J. : dissents.

[11] Appellants suggest that the trial court's "gatekeeping" standard for deciding whether a design defect case should proceed to a jury is different from the court's standard for granting JNOV after a jury has heard the case. Appellants' Brief at 39. We disagree. Regardless of the phase of the case (demurrer, summary judgment, compulsory nonsuit, or JNOV), the trial court's standard is substantially the same: accepting the plaintiff's evidence and reasonable inferences therefrom as true, can the product be deemed unsafe for its intended use as a matter of law?

Nevertheless, we are compelled to discuss the timing of the trial court's decision to enter judgment for Stuart as a matter of law. As noted above, Stuart presented the issue of intended use in a motion for summary judgment and in a motion for compulsory nonsuit. The trial court declined to rule in Stuart's favor until after trial was complete and Appellants were awarded a significant jury verdict. It is unfortunate that the trial court arrived at the proper legal result only after significant expenditures of time and effort by the litigants and the jury. Of course, we will not disturb a proper legal decision simply because it could have been entered earlier.