

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

KAREN J. GREGG and	:	CIVIL ACTION
MICHAEL W. GREGG,	:	
Plaintiffs,	:	NO. 95-4630
	:	
v.	:	
	:	
DANIEL M. KANE, M.D.	:	
STEPHEN L. TROKEL, M.D.,	:	
VISX, INC., and WILLS EYE	:	
HOSPITAL,	:	
Defendants.	:	

M E M O R A N D U M

BUCKWALTER, J.

September 5, 1997

There are a total of seven motions for summary judgment filed by the four defendants. In the attached order, I have denied all of the motions. While I do not customarily write a memorandum when denying motions such as this, I thought it might be helpful to counsel if I would outline my reasons in this rather complex case.

I. Defendant Dr. Daniel M. Kane's Motions

Daniel M. Kane is the doctor who performed the excimer laser surgery. He has filed two motions for summary judgment, one on plaintiffs' claims for negligence and lack of informed consent, and the other on plaintiffs' claim for punitive damages.

At the very least the following evidence adduced by plaintiffs is sufficient to send all of the claims against Kane to a jury:

1. Plaintiffs' expert has opined that Kane deviated from the proper standard of care by operating on Mrs. Gregg's right eye, when she depended on that eye to work, drive and read.

2. The protocol governing the clinical trial that Mrs. Gregg was enrolled in prohibited operations on fellow eyes, yet Dr. Kane performed surgery on both of Mrs. Gregg's eyes, and even told her that VISX (the laser manufacturer) would not approve the surgery on her right eye unless her left eye was done first.

3. Under the protocol, no more than one-third of a patient's corneal thickness was to be removed in surgery. However, the evidence clearly shows that Kane removed 40% of Gregg's corneal thickness in her right eye.

4. The protocol required the surgeon to test the laser machine's ablation (cutting mechanism) before surgery was performed. It is unclear whether this test was to be performed once a day or prior to each surgery. Kane only performed the test once a day. Giving the plaintiffs the benefit of all favorable inferences, this could be seen as a departure from the proper standard of care.

5. Kane appears to have given plaintiffs an informed consent form for low myopia surgery, despite the fact that Mrs. Gregg had very high myopia. Thus, at the very least, the form could be seen as inadequate in that it did not disclose all of the possible risks. In addition, Mrs. Gregg testified that, as

to the surgery Kane performed on her left eye in December 1992,¹ the form she signed was not the same as the form she read, in other words, that Kane switched the consent forms. When it came time for surgery on her right eye in July 1993 (the surgery that resulted in the damages at issue in this case), Gregg merely signed a form that was opened to the signature page and that she believed was the same form used in the earlier surgery. Again, giving plaintiffs the benefit of all favorable inferences, this conduct by Kane could be seen as intentionally misleading.

6. The informed consent form stated that only a "minute" amount of Mrs. Gregg's cornea would be removed. But, as indicated above, Kane removed 40% of the cornea, an amount which could hardly be considered "minute." Kane testified that he explained to Mrs. Gregg that he was going to remove 40%, but he arguably misled her by not pointing out that such a percentage was not minute.

7. Kane testified that he was aware that the greater the myopia, the greater the risks inherent in the laser surgery. Yet Mrs. Gregg only recalls Kane telling her that she might have a temporary problem with glare around lights, not that there were

1. Kane argues that there can be no claims stemming from the December 1992 operation because this surgery occurred two years and seven months prior to the filing of the Complaint, and the statute of limitations on a negligence claim is only two years. However, as plaintiffs point out, the two operations can be viewed as part of one whole surgical procedure, because Kane made surgery on the left eye a condition precedent to surgery on the right eye. While there is no "continuous treatment rule" in Pennsylvania that tolls the statute of limitations in a medical malpractice case until the end of treatment, ongoing treatment can be considered in determining what investigation of the defendant's conduct the reasonably diligent plaintiff would have made. Greenberg v. McCabe, 453 F. Supp. 765, 772 (E.D. Pa. 1978), aff'd, 594 F.2d 854 (3d Cir. 1979).

other more serious risks. Again, the evidence suggests that Kane may have intentionally misled Mrs. Gregg.

II. Defendant Dr. Stephen L. Trokel's Motion

Dr. Trokel is defendant VISX's medical consultant. He argues that he should be dismissed from this case because he was not in a physician-patient relationship with Mrs. Gregg and therefore did not owe her a duty of care.

While Trokel clearly does not have a duty arising from the physician-patient relationship, plaintiffs have presented a convincing argument that Trokel may be liable under Section 324A of the Restatement of Torts. That Section provides as follows:

One who undertakes . . . to render services to another which he should recognize as necessary for the protection of a third person . . . is subject to liability to the third person for physical harm resulting from his failure to exercise reasonable care to protect his undertaking, if

(a) his failure to exercise reasonable care increases the risk of such harm, or

(b) he has undertaken to perform a duty owed by the other to the third person, or

(c) the harm is suffered because of reliance on the other or the third person upon the undertaking.

Restatement (Second) of Torts § 324A (1965). The essential provisions of this Section have been the law of Pennsylvania for many years. Cantwell v. Allegheny County, 483 A.2d 1350, 1353 (Pa. 1984).

Plaintiffs' evidence demonstrates that Trokel undertook to render the following services to the physicians at Wills Eye Hospital:

1. He was the medical monitor in the protocol in which plaintiffs allege Mrs. Gregg was misenrolled, and, in addition, the medical monitor of VISX's high myopia clinical study. Plaintiffs contend that he was negligent in recommending the expansion of trials for Mrs. Gregg's clinical group, despite knowing that there had been no signs of improvement among the patients in that group.

2. He spent at least one, and perhaps two, days at Wills lecturing physicians on the proper use of the laser.² In the course of these lectures, he specifically told the doctors not to test the laser machine's ablation before each operation (advice that apparently was followed by Kane, see supra).

3. He supplied the doctors at Wills with an informed consent form that he used at Columbia Presbyterian Hospital, where he works. This form was designed for low myopia, and it was the form Kane gave to Mrs. Gregg to review prior to her surgery (see supra).

Plaintiffs clearly have enough evidence to go to a jury on the first element of Section 324A liability, the undertaking to render services to another.

2. Trokel argues that he cannot be held liable because there is no evidence that he provided training specifically to Dr. Kane. But the evidence does show that Kane heard Trokel speak on at least one occasion, on the subject of high myopia.

In addition to this element, plaintiffs must also satisfy what is essentially the foreseeability requirement of 324A, that Trokel undertook to render services "which he should [have] recognize[d] as necessary for the protection of a third person" Cantwell, 483 A.2d at 1353-54 (quoting § 324A). Plaintiffs offer the following evidence in support of this requirement:

1. The complicated nature of the surgery itself, which plaintiffs contend should have made Trokel acutely aware of the importance of his role as medical advisor to VISX. Trokel himself testified that, in its initial stages, the clinical investigation was difficult and poorly understood by the physicians.

2. Trokel was aware of the risks of operating on high myopia patients prior to Mrs. Gregg's operation. He knew (or at least should have known) that laser surgery was far more predictable for patients with low myopia.

3. The doctors Trokel trained did not have extensive experience with laser surgery, and Trokel was aware of this fact.

4. Trokel was well aware that a person could be injured in the surgery if the proper procedures were not followed.

Again, this evidence is sufficient to send Trokel's case to a jury. (Indeed, the question of foreseeability is inherently one for a jury to decide.)

III. Defendant Wills Eye Hospital's Motion

The record reveals the following evidence against Wills, which taken together is enough to send plaintiffs' claims against it to a jury:

1. Wills' Institutional Review Board (IRB), the body which approved the protocol in which Mrs. Gregg was enrolled, was required by FDA regulations to make an independent risk assessment prior to its approval. See 21 C.F.R. § 56.111(a)(1)-(2) (1997).³ Yet neither the IRB statement granting unconditional approval nor the minutes of IRB meetings discussing the protocol contain any indication that such an assessment was done. Nor is there any other evidence that the IRB performed the independent risk assessment.

2. The Wills IRB only approved two VISX excimer laser protocols, the "PTK [photo therapeutic keratectomy] Phase III" clinical trial and the "moderate myopia" PRK [photo refractive keratectomy] protocol. Neither of these protocols allowed for high myopia surgery. In fact, pursuant to the moderate myopia clinical trial, Wills was only allowed to perform operations for patients with -6 to -8 diopters of myopia. Mrs. Gregg's myopia was -21 diopters, well beyond the approved range.

Mrs. Gregg was enrolled in the PTK protocol. When the IRB approved this protocol, Wills issued a press release with

3. Plaintiffs' Exhibit 90, located in Volume 3 of the Appendix to Plaintiffs' Combined Response, contains a copy of the FDA regulations applicable to this case.

VISX making clear that myopia operations were not permitted under it. Yet Gregg underwent a myopia operation, apparently under the auspices of the protocol. These departures from protocol guidelines could be seen as examples of negligent, or even reckless, conduct on behalf of Wills.

3. There are several examples of deficiencies in the Wills clinical site and its operating procedures that at least predate and even may have coincided with Mrs. Gregg's surgery. For example, by September 1992, Wills surgeons had performed 38 laser operations, yet at least as late as April 1992, the hospital did not even have an operator's manual for use of the laser. In addition, correspondence from VISX to Wills expressed concern about Wills' patient forms, complaining that they were late, required many corrections, and were filled with incomplete or illegible data. A VISX memo dated June 1992 stated that the Wills site needed significant support in the area of training of laser operators and physicians, and a July 1992 memo expressed concern that the site would not pass an FDA inspection. Finally, the laser was housed in a part of the hospital undergoing significant construction, and the laser's mirrors had to be replaced frequently because of the construction dust. No doubt an inference could be drawn from all of these examples that Wills was negligent in not properly maintaining its clinical site.

4. As to plaintiffs' claim for lack of informed consent, the FDA regulations make IRBs like the one at Wills responsible for insuring that informed consent will be sought

from all prospective subjects, in accordance with fairly detailed standards governing such consent. 21 C.F.R. § 56.111(a)(4) (1997). Given what occurred with respect to informed consent in Mrs. Gregg's case (see supra), Wills could be found liable for not fulfilling its FDA-mandated responsibilities.

IV. Defendant VISX, Inc.'s Motions

VISX has filed three separate motions, one on the issue of preemption, another challenging plaintiffs' negligence claim, and the third seeking summary judgment on plaintiffs' claim for punitive damages.

A. Preemption

VISX argues that plaintiffs' claims are preempted by Section 360k(a) of the Medical Device Amendments of 1976 ("MDA"). That section provides in pertinent part as follows:

[N]o state . . . may establish or continue in effect with respect to a device intended for human use any requirement --

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C.A. § 360k(a) (West Supp. 1997).

Construing this provision, the Supreme Court recently held that the MDA does not preempt state requirements that are

equal to, or substantially identical to, requirements imposed under federal law. Medtronic, Inc. v. Lohr, 116 S.Ct. 2240 (1996). The Court reasoned:

Nothing in § 360k denies [states] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. Even if it may be necessary as a matter of [state] law to prove that those violations were the result of negligent conduct, or that they created an unreasonable hazard for the users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader, than the federal requirement. While such a narrower requirement might be "different from" the federal rules in a literal sense, such a difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it duplicates the federal rule.

Id. at 2255. The court went on to delineate the factors that must be present for preemption to occur. First, the state requirement must be "with respect to" medical devices and "different from, or in addition to" the applicable federal requirement. Second, the state requirement must relate to the safety or effectiveness of the device in question. Third, the federal regulations must be "specific" to a "particular device." Id. at 2257.

VISX's motion is based in large part on the argument that the federal regulations at issue in this case are device-specific, and, therefore, preempt plaintiffs' tort claims.

However, the cases VISX cites tend to support the opposite conclusion. In Papike v. Tambrands, Inc., 107 F.3d 737 (9th Cir. 1997), the Ninth Circuit declared that "preemption is triggered by and `the scope of preemption is limited to instances where there are specific FDA requirements applicable to a particular device.'" Id. at 742 (quoting Anquiano v. E.I. du Pont De Nemours & Co., 44 F.3d 806, 809 (9th Cir. 1995)) (emphasis added). Thus, it held that a failure to warn claim against a tampon manufacturer was preempted because there was a specific tampon labeling regulation on point. Id. Similarly, the Third Circuit in Gile v. Optical Radiation Corp., 22 F.3d 540 (3d Cir.), cert. denied, 513 U.S. 965 (1994), held that a plaintiff's claims of negligence and products liability against the manufacturer of an intraocular lens ("IOL") were preempted by the MDA, where there were particular FDA regulations governing the development of IOLs. See id. at 542. These cases stand in sharp contrast to the case sub judice, where there are no FDA regulations specific to the excimer laser.

The case that best supports VISX's position is Martin v. Telectronics Pacing Sys., Inc., 105 F.3d 1090 (6th Cir. 1997). Martin involved the same FDA regulations that are at issue in this case, those governing "investigational devices" that have not yet received market approval. The Sixth Circuit held that these very regulations, while not specific to a particular product, have application and approval procedures that are "device specific." Id. at 1097. Martin, however, is

distinguishable from the case sub judice. The plaintiff in Martin brought various claims that the court held would impose greater requirements on the device in question than those imposed by the FDA. As such, they were preempted under Section 360k(a). Id. at 1099-1100.

By contrast, plaintiffs claims against VISX are rooted primarily in VISX's alleged violations of FDA regulations. Thus, this case is similar to Green v. Dolsky, 685 A.2d 110 (Pa. 1996), cert. denied, 117 S.Ct. 1432 (1997), where the Pennsylvania Supreme Court held that a plaintiff's negligence claims against a manufacturer were not preempted because those claims "in essence, mirror[ed] FDA requirements" Id. at 117-18. See also Chambers v. Osteonics Corp., 109 F.3d 1243, 1248 (7th Cir. 1997) (plaintiff's negligent manufacturing claim not preempted where crux of claim was that manufacturer did not follow FDA requirements and procedures).

Because plaintiffs' claims are not "different from, or in addition to" the applicable FDA regulations, and because those regulations are not specific to the excimer laser in question, plaintiffs' claims are not preempted.

B. Negligence

VISX's motion for summary judgment on plaintiffs' negligence claim argues that plaintiffs' expert, Dr. Steinert, cannot opine to a reasonable degree of medical certainty that the

laser caused Mrs. Gregg's harm.⁴ Steinert's report does contain a sufficient degree of certainty so as to not grant this motion on this basis.

In addition to the evidence discussed in relation to the other defendants, some of which also goes to VISX's liability, the following evidence is sufficient to allow plaintiffs' negligence claim versus VISX to go to a jury:

1. The high myopia protocol that VISX submitted to the FDA is relatively scant, and does not discuss the significant risks of high myopia surgery. Yet VISX knew from the clinical trials it had conducted in 1991 and 1992 that high myopia surgery was far more risky than low myopia surgery.

2. Under the high myopia protocol, the highest myopia allowed in the patients was 20 diopters. Yet Mrs. Gregg had 21 diopters of myopia.

3. VISX's PTK protocols did not allow "fellow eyes" to be operated on. VISX claims that it changed this requirement when it wrote the FDA in July 1992. However, the letter contained only a brief and cryptic reference to "fellow eyes," which hardly met FDA requirements for altering a protocol. Further, the FDA's response to this letter did not even contain an acknowledgment of the "fellow eye" issue.

4. Defendant Trokel made the same argument in his motion.

4. In April 1994, the FDA notified VISX that it had not received any of VISX's progress reports for PTK Group II (Mrs. Gregg's subgroup) within at least the prior year, despite VISX's obligation to do so as a sponsor. One month later, VISX submitted such a report indicating that there had been no adverse events that would cause VISX to reevaluate its initial risk assessment. This report failed to acknowledge the problems with Mrs. Gregg's operation. Finally, in 1996, after repeated demands from the FDA, VISX admitted there had been at least 60 adverse incidents in PTK Group II.

C. Punitive Damages

Like the other defendants, VISX argues that its conduct cannot be seen as malicious or wanton, and asks that we dismiss plaintiffs' claim for punitive damages. While plaintiffs may not have a particularly strong case for punitive damages against VISX (or, perhaps, the other defendants), I believe that a jury could reasonably find that VISX acted in conscious disregard of a known risk, on the present state of the record.

An order follows.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

KAREN J. GREGG and	:	CIVIL ACTION
MICHAEL W. GREGG,	:	
Plaintiffs,	:	NO. 95-4630
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v.	:	
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DANIEL M. KANE, M.D.	:	
STEPHEN L. TROKEL, M.D.,	:	
VISX, INC., and WILLS EYE	:	
HOSPITAL,	:	
Defendants.	:	

O R D E R

AND NOW, this 5th day of September, 1997, upon consideration of the seven (7) summary judgment motions filed by the various defendants to this action, plaintiffs' Combined Response in Opposition (Docket No. 83), and the various replies to that Response filed by the defendants, it is hereby ORDERED that:

(1) Defendant Daniel M. Kane's Motion for Partial Summary Judgment on the Issue of Punitive Damages (Docket No. 73) is DENIED;

(2) Defendant Daniel M. Kane's Motion for Summary Judgment on Issues of Negligence and Informed Consent (Docket No. 77) is DENIED;

(3) Defendant Stephen L. Trokel's Motion for Summary Judgment (Docket No. 78) is DENIED;

(4) Defendant Wills Eye Hospital's Motion for Summary Judgment (Docket No. 79) is DENIED;

(5) Defendant VISX, Inc.'s Motion for Summary Judgment on Preemption (Docket No. 80) is DENIED;

(6) Defendant VISX, Inc.'s Motion for Partial Summary Judgment on Plaintiffs' Claims for Punitive Damages (Docket No. 81) is DENIED; and

(7) Defendant VISX, Inc.'s Motion for Summary Judgment on Plaintiffs' Claim of Negligence (Docket No. 82) is DENIED.

BY THE COURT:

RONALD L. BUCKWALTER, J.