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ESSAYS

AN EYE FOR AN EYE: FORESIGHT ON REMEDIES FOR LASIK SURGERY'S PROBLEMS

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I. INTRODUCTION

Laser eye surgery is remarkable. Never before in American medical history have 3 million people each year responded to massive advertising by paying for an innovative, elective surgery. Never before have surgeons competed so vigorously on price; and never has a surgery been so skillfully isolated from liability lawsuits. If LASIK eye surgery becomes the Mass Tort of 2025, will Americans regret accepting it as the benign 20/20 solution of today?

The first decisions in a series of liability suits against LASIK surgeons have been reported, with one plaintiff receiving a $4 million verdict.[1] Yet, the procedure is too new for a body of reported appellate precedent, so this review must be a forward-looking prediction of future judicial behaviors. This article examines the conundrum that an injured LASIK patient, whose vision deteriorates several years after the surgery, may be unable to find a viable defendant, thus leaving the customer without an effective remedy.

II. UNDERSTANDING THE CONTEXT

What is LASIK Surgery?

Open your eyes, read a newspaper, watch a television, see a billboard, and elective surgery advertising hits your eye. From thousands of dollars down to hundreds, the competition to sell this mass volume elective surgical procedure has driven down prices. The specific service that was to be provided to an estimated 3,135,000 patients in 2002 is LASIK.[2] LASIK is the acronym for "laser in-situ keratomileusis," a form of computer software-guided cutting of the cornea in the eye using

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1. *See* Diana Digges, *$4M Award Over Laser-Eye Surgery Breaks New Ground*, LAW. WKLY. USA, May 27, 2002, at 24.

2. The author thanks Spectrum Consulting and the media department of the American Academy of Ophthalmology for providing their January 2001 estimates, SPECTRUM CONSULTING ASSOCIATES, 2001 REVISED ESTIMATE OF THE U.S. PRK/LASIK MARKET & ESTIMATES OF PRK/LASIK BREAKDOWN.

laser light beams. LASIK and other eye surgery procedures[3] flatten the central curvature of the cornea of the eye, with a flap of skin peeled back in order to effectively alter the ability of the eye to see without external spectacles or contact lenses. A Pennsylvania court summarized the mechanics of the LASIK process in a succinct summary:

> During the LASIK procedure, after the surface of the eye has been anesthetized by eyedrops, a microkeratome is used to create a flap in the outer layer of the cornea which is folded back to allow an excimer laser access to the exposed corneal surface. Computer-controlled laser beams then remove thin layers of corneal tissue to reshape the curvature of the cornea so that visual images will focus directly onto the retina, thereby improving visual acuity. The corneal flap is returned to its original position without utilizing sutures, and a protective "bandage" contact lens is applied to prevent the eyelid from rubbing against the eye surface as the outer layer of cells regrow and the flap re-adheres.[4]

Measurement of the eye and setting the correct parameters into the computer-controlled laser equipment appear to be the principal determinants of surgical success. An experienced surgeon can perform many surgeries in the same day by using the staff of an outpatient surgery facility to prepare the patient. Though the equipment is constantly being improved, the computer controls depend on the accuracy of the data being fed into the system by a skilled surgeon during the pre-surgical evaluation of the patient.

The reader may choose to read more of the technical details of the surgery elsewhere.[5] This paper will deal with LASIK, but some of the issues are relevant to other processes. Relative to older forms of such refractive surgery, LASIK does not appear to produce greater glare or halo effects during the early stages after surgery.[6] However, the long-term consequences of LASIK are still unknown.

Is LASIK Surgery Safe?

As with any surgery penetrating through body tissue, cells are affected by the cutting of corneal tissue. The eye cells heal differently with

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3. In addition to those who purchase LASIK procedures, approximately 163,000 others will purchase photorefractive keratectomy (PRK), another form of eye surgery designed to improve vision. *Id.*

4. Oven v. Pascucci, 46 Pa. D. & C.4th 506, 509 n.1 (Pa. Com. Pl. 2000).

5. A useful reference about LASIK safety is the FDA LASIK, *at* http://www.fda.gov/cdrh/LASIK/ (last visited Jan. 13, 2003).

6. Peter Hersh et al., *Photorefractive Keratectomy Versus Laser In Situ Keratomileusis*, 107 OPHTHALMOLOGY 925, 931 (May 2000).

different patients whose personal health and other characteristics will affect recovery. In the event that slowly-developing cellular changes in the cornea may cloud the vision of LASIK patients in future years, we simply do not know how a LASIK procedure's adverse effects will manifest themselves. An experience base of five or more years may be needed to follow the progress of patients whose corneal cellular changes are manifested by slow blurring of the vision or the appearance of nighttime glare effects that hinder their ability to drive. This poses the same causation challenge that lawyers experience in other medical delayed-effects situations: the manifestation of eye deterioration attributable to the cutting of cells may be hard to differentiate from deterioration attributable to the effects of normal aging or of unrelated eye problems. For the short term, LASIK appears to be safe, with a small number of adverse effects, as discussed later in this article.

Why Is LASIK Different from Other Surgical Procedures?

Surgery is typically a drastic interventional response to a medical emergency or to the failure of an organ or bone system. Any surgery carries risks, especially the in-patient surgery that involves the risk of hospital-related infections. The development of skilled surgical techniques involving micro-surgical interventions has made American surgical capabilities well respected around the world.

But not all surgical interventions respond to health necessities. Persons who find contact lenses annoying or spectacles inconvenient are being pressed to "try the safe and affordable alternative: LASIK."[7] Americans are willing to pay for various types of elective surgery for anatomical flaws and cosmetic defects. Because the word "cosmetic surgery" draws angry rebukes from eye surgeons, the LASIK processes can at best be called "improvements on nature," rather than the classic use of surgery for a needed remediation of injuries. The wave of 3,300,000 annual LASIK procedures in the United States may be the greatest volume of surgical procedures ever voluntarily undertaken by consumers in the history of medicine.[8]

The sales target for expanding LASIK is thirty-five percent of the 180 million Americans who may need vision care.[9] Of course, such a goal is ambitious, and it amplifies the concern that even a small percentage

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7. Of course, the wording of the advertisements vary with the particular sales approach offered. The emphasis remains on cosmetic appearance benefits, the easier alternatives to glasses, and the affordability of the surgery.

8. SPECTRUM CONSULTING ESTIMATES, *supra* note 2

9. *Id.*

of damaged eyes might mean that tens of thousands lose their optimal eyesight as a result of flawed surgery. The market's size is great and the potential downside for a fraction of that population could produce substantial damages. One symptom of the fluid nature of change in this marketplace is the way in which the manufacturers earn their profits: new eye lasers, once approved, are leased to surgeons in return for a per-surgery fee, with new equipment emerging continually in a hot, competitive climate.

III. THE REGULATORY CONTEXT

FDA's Twelve-Month Norm

A traditional question arises again: how much of a database of safety experience should society demand before a new technology is "safe enough" for use on humans? The Food and Drug Administration (FDA) has statutory jurisdiction over medical devices.[10] The FDA has used this authority to specifically approve numerous laser devices for surgical use on the eye.[11] So, it would then seem that the consumer expects to be fully protected by prior government approval before the LASIK device enters the competitive marketplace.

But, the human clinical studies of comparative surgical results, needed for FDA approval of a new laser eye device, are only required to study patients in the small test sample for twelve months post-surgery. Some studies go to twenty-four months, continuing after the approval of the new device.[12] The laser device maker must supply extensive information about the machine from which the FDA can evaluate the safety and efficacy of the design, and these "premarket approval applications" can be voluminous.[13] But the experience base is relatively short and cannot be expected to catch long-term deterioration effects on the eye, if such effects occur. This does not mean LASIK is going to be found to have a higher risk than we now expect—we just do not know. If ill effects do not arise among the three million customers per year, then a definitive risk conclusion can be made at some future date.

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10. 21 U.S.C. § 321(h) (1999).

11. *Id.* § 360E(c) (2000); 21 C.F.R. § 814.20 (2000).

12. FDA, Checklist of Information Usually Submitted in an Investigational Device Exemption for Refractive Surgical Lasers (Oct. 10, 1996), *at* http://www.fda.gov/cdrh/ode/2093.html (last visited Sept. 12, 2002).

13. *See* FDA-CENTER FOR DEVICES & RADIOLOGICAL HEALTH, CHECKLIST FOR FILING DECISION FOR PMAS (2001), *available at* http://www.fda.gov/cdrh/ode/checklist/pma.html (last visited Jan. 13, 2003).

A review of the FDA website's summaries of product safety for the approval of new laser devices[14] consistently shows that manufacturers submit, and the FDA grants approval based upon, twelve months' experience with the new laser devices. The FDA examines both the adverse events reported during the twelve month post-surgery follow-up and the complications from surgery reported by the surgeons. The FDA's Office of Device Evaluation in the Center for Devices & Radiological Health then makes a decision about the product's acceptability.[15]

The protection of LASIK surgery patients by the regulatory intermediary, the FDA Office of Device Evaluation, is premised on experiences of up to twelve months post-surgery. By its own public admission, the post-approval examination of medical devices "is not working well."[16] The FDA requires device sponsors to report the number of patients who seek a second LASIK procedure to improve vision after the first surgical results were inadequate, but "no laser company has presented enough evidence for the FDA to make conclusions about the safety or effectiveness of enhancement surgery."[17] Possibly, vision effects may be manifested after a longer period, as reports slowly arrive that demonstrate evolving patterns of experience with clouding of vision as cells change. Such effects might be noticeable after several years have passed: for example, when a patient changes eye doctors and complains about the results promised by an earlier eye surgeon who sold a LASIK procedure as the ideal solution for that person's desires.

In the liability claims context, the time of reported effects becomes significant. Corneal surgery of various types has a long history, but LASIK's laser/computer interface combined with mass marketing is a relatively recent novelty. A few warning flags are visible in the medical literature,[18] but no one can reliably predict the percentage of ten or twenty-year post-surgical experiences that will be adverse for LASIK patients. It may be that LASIK produces no adverse long-term effects.

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14. *See, e.g.* FDA, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH CONSUMER INFORMATION: RECENTLY APPROVED DEVICES, CDRH CONSUMER INFORMATION RECENTLY APPROVED DEVICES *at* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/mda/mda-list.cfm?list=1 (last visited Sept. 21, 2002).

15. *See* FDA, CHECKLIST OF INFORMATION USUALLY SUBMITTED IN AN INVESTIGATIONAL DEVICE EXEMPTION FOR REFRACTIVE SURGICAL LASERS § 3.2.6 (Oct. 10 1996).

16. FDA. PERFORMANCE PLAN 2002 § 2.6.1 PROGRAM DESCRIPTION, CONTEXT AND SUMMARY OF PERFORMANCE (2002), *at* http://www.fda.gov/opc/fy03plan/part2_med.html.

17. FDA, CENTER FOR DEVICES & RADIOLOGICAL HEALTH, LASIK EYE SURGERY: WHAT SHOULD I EXPECT BEFORE, DURING AND AFTER SURGERY?, *at* www.fda.gov/cdrh/lasik/expect.htm (last updated Oct. 1, 2002).

18. *See infra* Part V.

On the other hand, LASIK might cause a more rapid and serious cellular degeneration than other causes. The nexus of uncertainties regarding cellular change, rates of deterioration, the value of a twelve month pre-approval study as a predictor, and patient intolerance of vision problems, make for an intriguing challenge to the would-be tort plaintiff.

How are the Surgeons Regulated?

The FDA has no jurisdiction over physicians such as the surgeons who use the laser equipment.[19] The FDA requires adequate labeling for proper use by physicians[20] but cannot police the physicians themselves. Surgeons' performance is left to the state medical boards[21] and to the private malpractice system.[22]

The FDA tracks post-approval rates of injury under its Medwatch program of voluntary adverse effect reports on medical devices,[23] as explained on the FDA's Center for Devices website.[24] The surgeon who finds a malfunctioning LASIK device could file a report online with the Medwatch system but is not required to do so. Congress responded to complaints by manufacturers and hospitals, severely restricting the FDA's medical device user reporting authority[25] in the 1997 amendments to the device statutes.[26]

IV. THE LIABILITY CONTEXT

Identifying Causes of Action

At the rate at which LASIK surgery is being sold to new patients, even a small percentage of vision loss claims—a fraction of the millions of cases—could produce a significant volume of potential tort suits. This is a statistical certainty, since the smaller occurrence of adverse eye

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19. Sigma-Tau Pharms. Inc. v Schwetz, 288 F.3d 141, 145 (4th Cir. 2002).

20. 21 U.S.C. § 352(f) (2000).

21. *See* Colo. State Bd. of Med. Exam'rs v. Roberts, 42 P.3d 70 (Colo. Ct. App. 2001).

22. *See, e.g., $1,750,000 Settlement in Suit Arising from LASIK Eye Surgery*, VERDICTS, SETTLEMENTS, & TACTICS, July 2002, at 297; *Misassembled LASIK Surgery Implement*, 45 ATLA L. REP. 328 (2002).

23. 21 C.F.R. pt. 803.

24. http://www.fda.gov/medwatch/articles.htm (last visited Jan. 13, 2003).

25. 21 U.S.C. § 360i(b) (2000).

26. The device user reporting section was partially repealed by Pub. L. No. 105-115, Title II, sec. 213(a)(1)(E), 111 Stat. 2347 (1997).

effects would become manifest slowly, as the several millions of LASIK recipients age during the years since their eyes were cut by the surgery.[27]

The classic tort negligence test requires a showing of foreseeability of the injury and fault by the responsible product manufacturer or physician. Modern strict liability imposes a compensation obligation on the manufacturer of a defective product regardless of fault[28] and leaves malpractice law to remedy the problems caused by the professional user of the device. Strict liability shifts the costs of injury to the designer and marketer of the product that caused the injury, without the need to show fault or even proof that the injury was foreseeable.[29]

However, strict liability is a policy that carries an important exception—it does not apply if the product offers a special societal benefit like a rabies vaccine or an important pharmaceutical to cure cancer.[30] These latter products were deemed by the creators of modern strict liability to be "unavoidably unsafe," and, thus, subject only to negligence law norms in order to prevent the advance of medical progress from being retarded by the costs of strict liability.[31]

The Third Restatement Shield

One of the controversial aspects of the 1997 adoption of the Third Restatement of Products Liability was the virtually complete shield from strict liability for prescription drugs and devices that have any beneficial effect for any class of patients.[32] The concept holds that with the existence of a class of patients that will benefit from the device, the device can be sold for all other classes as well and will be immune from the strict liability analysis.[33] For example, leprosy is rarely encountered among United States residents, but a drug that was beneficial to leprosy

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27. The rapid increases in volume of LASIK surgeries "adds to the importance of identifying even small risks associated with these elective procedures." David O. Mazur et al., *Retinal Detachment in Myopic Eyes After Laser in Situ Keratomileusis*, 129 AM. J. OPHTHALMOLOGY 823, 824 (June 2000).

28. RESTATEMENT (THIRD) OF PRODUCTS LIABILITY § 2 cmt. a (1997).

29. A product that is defective and unreasonably dangerous will be addressed with strict liability even if the designer was not negligent. RESTATEMENT (SECOND) OF TORTS § 402A (1965); *see also* RESTATEMENT (THIRD) OF PRODUCTS LIABILITY § 2 (1997).

30. RESTATEMENT (SECOND) OF TORTS § 402A, cmt. k (1965).

31. *Id.*

32. RESTATEMENT (THIRD) OF PRODUCTS LIABILITY § 6(c) (1997):

> A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.

33. *Id.* at cmt. b.

patients would not be vulnerable to challenges against its marketing for some other medical indication, such as cancer. The express predicate for this exclusion from strict liability was that the FDA "adequately review(s) new prescription drugs and devices, keeping unreasonably dangerous designs off the market."[34] If one believes the FDA achieves this goal, the Third Restatement makes sense.

Eye laser devices benefit from the protective shield that the Third Restatement seeks to apply to prescription-only products. Arguably, the availability of laser surgical devices benefits some patients whose eyes are medically impaired and for whom the corneal surgery has a therapeutic purpose. A contrary argument can be offered, however, that three million annual uses of a surgical tool for appearance and aesthetics far outweigh the smaller number of uses of these devices for cases of real medical necessity.

The Case of the Disappearing Defendants

In the event that even a small number of LASIK patients experience eye difficulties later, a small fraction out of three million customers each year is still a substantial population of potential plaintiffs. A significant concern for these plaintiffs is that tort law lags far behind laser technology. Lasers are improved each year, but liability systems lag behind, so no compensation for injury may be available to the LASIK customer at the time when a belated manifestation of injury to the eye is diagnosed. If vision clouding problems appear, there may be no financially responsible defendant available against whom a plaintiff can obtain sufficient recovery. This is a particular problem when the longer-term cellular effects of today's LASIK eye surgery manifest themselves years after the surgeon has been paid.

In part, this tort liability phenomenon of "no viable defendant to sue" reflects business practices that emphasize the very short term orientation of the coverage of malpractice insurance for ophthalmic surgeons. The malpractice insurance industry seems well protected by its preference for "claims-made" policy coverage, the dominant form of new coverage. Such coverage pays claims made during the years for which the insurance was in force. The coverage would not shield the individual surgeon when a claim about delayed corneal blurring effects is made long after the brief LASIK operation is over. This makes a difference for the plaintiff because the absence of an insurance carrier diminishes

34. *Id.*

the prospects that the plaintiff will ultimately receive damages after a favorable judgment.

V. THE MEDICAL CONTEXT

What Long-Term Issues Exist After LASIK Surgery?

LASIK is widely performed worldwide "despite the absence of thorough data on the healing response and long term complications at the tissue level. Clinically visible complications . . . are relatively well known, but the underlying cell biology of these phenomena is less well understood."[35] One study found a loss of cells in a layer of the eye beginning six months after surgery, but the cause of this diminution is unknown and requires further research.[36] Corneal haze of several types "may degrade the retinal image" and more research is needed about its clinical impact.[37] These concerns are more long-term; issues concerning the flap of corneal tissue cut in the eye are among the near-term concerns of eye surgeons, as illustrated in American Academy of Ophthalmology publications.[38]

A frequently cited challenge for surgeons is "irregular astigmatism." When the same eye has been subjected to multiple laser surgeries to improve on conditions initially reported by the patient after surgery, "corneal stability in the long-term is still a worrying factor," and in individuals with a major degree of irregular astigmatism, loss of visual acuity is permanent and symptomatic.[39] Not all irregular astigmatism can be corrected; careful patient selection is often recommended.[40] The LASIK technique is too new for surgeons to understand the natural history of future effects of "central islands" on the cornea, which cause numerous detrimental effects.[41] For the estimated 165,000 photorefractive keratectomy (PRK) procedures done annually, "visually debilitating corneal haze may persist in approximately 5% of all PRK

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35. Minna Vesaluoma et al., *Corneal Stromal Changes Induced by Myopic LASIK*, 41 INVESTIGATIVE OPHTHALMOLOGY & VISUAL SCI. 369, 373 (Feb. 2000).

36. *Id.* at 375.

37. Hersh, *supra* note 6, at 932.

38. *See, e.g.*, *My LASIK Flap Management Technique*, EYE WORLD (Aug. 2002), *at* http://www.eyeworld.org/aug02/0802p43.html (last visited Sept. 12, 2002).

39. Jorge L. Alio et al., *Selective Zonal Ablations with Excimer Laser for Correction of Irregular Astigmatism Induced by Refractive Surgery*, 107 OPHTHALMOLOGY 662, 670 (April 2000).

40. *Id.* at 670.

41. Yi-Yu Tsai & Jane-Ming Lin, *Natural History of Central Islands After Laser In Situ Keratomileusis*, 26 J. CATARACT & REFRACTIVE SURGERY 853 (June 2000).

patients."[42] Enhanced cellular reflections from high numbers of wound healing keratocytes are an important contributor to haze, and drugs may be useful to aid clarity of vision after PRK.[43] Night vision deficiencies are "one of the main challenges" to improving laser eye surgery.[44] Corneal scarring and keratectasia, or dilation of the eye, were a particular issue with patients who had multiple LASIK surgeries, with cautions for surgeons about third and fourth retreatments of the same eye.[45] A Utah researcher/surgeon noted the "paucity of peer review literature" to substantiate LASIK's safety and efficacy and expected in a 1998 article that better computer software would reduce the percentage of patients who required retreatment—which was then at about thirty percent.[46] We simply do not yet know enough.

VI. THE LITIGATION CONTEXT

Are Long-Term Effects Actionable?

If a patient is dissatisfied with the resulting vision after LASIK, a second surgical procedure may be offered, but the literature cautions about more serious consequences with each successive cutting of the eye tissue.[47] Corneal perforation is rare, but other potential complications include ingrowth of the epithelial layer, infection, severing of the flap of skin cut in the cornea, wrinkling of the flap, and corneal astigmatism.[48] The longer-term effect of the surgery on cellular changes in the complex tissues of the eye is being studied, but time will tell whether the current favorable view of the surgery is altered by future studies showing eventual degradation in vision in a LASIK population compared to an uncut-cornea "control group." As of now, evidence is unavailable. There are indications that the collective profitability for surgeons performing the procedure may inhibit other doctors from rendering

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42. Torben Moller-Pedersen et al., *Stromal Wound Healing Explains Refractive Instability and Haze Development After Photorefractive Keratectomy*, 107 OPHTHALMOLOGY 1235, 1236 (July 2000).

43. *Id.* at 1243.

44. Mihai Pop & Yves Payette, *Photorefractive Keratectomy Versus Laser in Situ Keratomileusis*, 107 OPHTHALMOLOGY 251, 256 (February 2000).

45. *See* Simon P. Holland et al., *Avoiding Serious Corneal Complications of Laser Assisted in Situ Keratomileusis and Photorefractive Keratectomy*, 107 OPHTHALMOLOGY 640, 651 (April 2000).

46. Thomas Clinch, Discussion, commenting on Howard Gimbel et al., *Incidence and Management of Intraoperative and Early Postoperative Complications in 1000 Consecutive Laser In Situ Keratomileusis Cases*, 105 OPHTHALMOLOGY 1839, 1847 (Oct. 1998).

47. *See id.* at 1847.

48. Yuichi Hori et al., *Medical Treatment of Operative Corneal Perforation Caused by Laser in Situ Keratomileusis*, 117 ARCHIVES OF OPHTHALMOLOGY 1422 (Oct. 1999).

critical second opinions about LASIK.[49] Regardless, the cases that have reached litigation have involved a variety of vision impairments, including disabling impairments for persons who need excellent night vision, such as pilots.[50]

Whether the individual's impaired vision effects are worth litigating is a matter of judgment for the patient and counsel. The contingent fee system makes the plaintiff's counsel somewhat reluctant to challenge multiple defendants on a cause of action that does not yet have substantial case law illuminating the duty and liability of the manufacturer and surgeon. The population of persons paying for this elective surgery tends to be somewhat more affluent than average patients, and for some of them, perhaps a later experience of complications will stimulate the search for legal relief on a fee-paid hourly basis. Counseling such a client to initiate damages litigation involves a number of considerations, including the unavailability of insurance carriers for claims that are made several years after the surgery.

The causes of action would include defects in LASIK equipment design, defects in the knife-like microkeratome used to slice the cornea, failure to adequately communicate risks to the patient, failure to adequately warn of the long-term effects observed in the LASIK medical literature, and, perhaps, claims of breach of express warranty that the procedure is "safe" for the eye of the patient. The bold and attractive promises being made in LASIK advertising by eye surgery marketing corporations, some of whom are publicly traded entities,[51] may give rise to express warranty claims[52] as well as claims against the individual surgeon or the surgeon's corporate entity as conventional malpractice claims.[53] Safety advances in the design of machines for laser eye surgery

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49. Posting of letter *No One Wins Unless Everyone Wins* by Marguerite B. McDonald, Chief Medical Director, Eyeworld, on LasikInfoCenter website (1999) (copy on file with the University of Cincinnati Law Review) ("We are only starting to ride the enormous growth curve of LASIK in this country. There will be more than enough surgeries for everyone to benefit if we keep our heads by sharing information openly and honestly and by *resisting the temptation to criticize the work of our colleagues when we are offering a second opinion to a patient with a suboptimal result.*").

50. *See* Digges, *supra* note 1, at 24.

51. Attractive websites offering "safe" surgery include http://www.sightsolutions.com/index-dhtml.htm (last visited Feb. 21, 2003) (no claim is made that this site or others creates an express warranty; it is used for illustrative purposes only).

52. Conceptually, eye surgery is a service rather than "goods," so the conventional treatment of express warranties under Uniform Commercial Code section 2-313 is available only by analogy.

53. Laser eye surgery is a source of malpractice claims that have successfully asserted "conscious disregard for the rights and safety" of eye patients. *See* Siuda v. Howard, No. C-000656, 2002-Ohio-2292, 2002 WL 946188, at *11 (Ct. App. May 10, 2002). Websites critical of LASIK present more reports of verdicts and settlements. *See generally* www.lasikdisaster.com (last visited Jan. 2003); http://members.tripod.com/~lasik_facts (last visited Jan. 2003).

may have reduced the adverse effects that would have been seen with the earliest LASIK equipment, though an insufficient time has passed to form reliable statistical projections. An elaborate publicity campaign against criticism of LASIK has been launched by a trade group, funded by manufacturers using a national public relations firm.[54]

Plaintiffs confront numerous barriers, including the Daubert standard,[55] which allows equipment makers and surgeons to exclude the testimony of a critic of the LASIK device's use if that critic had not passed the scrutiny of pre-trial screenings. A climate for product design liability regarding inadequacy of pre-market testing of the machines may exist when future claims are brought. The makers of the expensive laser equipment are rapidly altering and upgrading their machines and software as the marketplace demands rapid responses to competitors' innovations.

What Barriers to Recovery Exist?

The first barrier to recovery will be time: if the now-reasonable balance of risk data and effectiveness were to shift against LASIK after five to ten more years of experience, the patient with blurred eyes must establish a causal connection to his or her present condition. The complexity of medical proof of causation would be formidable because many post-surgery events might have triggered the harm.

Time also affects the viability of a damages claim by the impact of the statute of limitations on the ability of a plaintiff to sue for an effect that became evident long after the laser surgery was completed. A cause of action would arise either when the surgery was performed or when the plaintiff discovered the connection between the surgery and the plaintiff's presently deficient vision. Plaintiffs could claim that they sued within a reasonable period after discovering that a tort had been committed, this "discovery rule" in torts would halt the tolling of the statute of limitations.[56] But, the degree to which any belated discovery of blurred vision can be tied to knowledge of the surgery-injury connection will be very fact-specific. This is not an easy issue for the plaintiff to reopen, several years after surgery. State medical

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54. Ellen Dean Smith, *New Campaign Aims to Tell the Truth About Laser Surgery*, EYE WORLD, *at* http://www.eyeworld.org/june02/0602p13.html (last visited Jan. 13, 2003).

55. Daubert v. Merrell Dow Pharms., 509 U.S. 579, 592-93 (1993). This doctrine is followed in seventeen states. *See* Joseph Eaton, *Survival of the Fryest*, 30 PROD. SAFETY & LIAB. REP. (BNA) 333 (Apr. 15, 2002).

56. *See, e.g.*, Kubrick v. United States, 444 U.S. 111 (1979) (requiring actions to be initiated within a reasonable time after discovery of the malpractice).

malpractice procedures form an additional barrier against the potential plaintiff's recovery.[57]

Effects of the Malpractice Crisis

The second barrier will be a likely absence of malpractice insurance as a force for settlement. An immediately observable injury tied to malpractice can produce a sizeable claim and a large settlement, as demonstrated in a recent Colorado case.[58] But, LASIK's cellular effect on the eye, if it occurs in a patient, will take time to develop.

Timing is everything when insurance coverage is at stake, and here it will be central to the plaintiff's attorney selecting the right contingent fee case to accept. There has been a significant rise in the use of "claims-made" malpractice policy forms, under which most medical malpractice carriers decline to pay claims that have not been presented to the insurer during the contract term or within a short "tail" thereafter.[59] This type of surgical malpractice policy contrasts with the "occurrence" policy covering the acts of the surgeon during the entire policy period, even if the claim is made after expiration of the policy years.[60]

The severe lack of profitability is driving some insurance carriers out of the medical malpractice insurance market. Aggregate 2001 industry statistics[61] show that about $10 billion was spent on health care malpractice insurance mechanisms in 2001, of which $5,586,584,000 was in insurance premiums. Loss ratios rose to 74.4% in 2000 from 54.3% in 1997. It is estimated that the malpractice insurance carriers' combined ratios of loss and expense exceeded 133% of the insurance carrier's income from premiums at the same time that income from

57. These statutes place procedural restrictions upon the malpractice plaintiff and reduce the potential damage awards.

58. Colo. State Bd. of Med. Exam'rs v. Roberts, 42 P.3d 70 (Colo. Ct. App. 2001).

59. A major professional liability insurer explains the distinction: "A 'claims made' policy protects the policyholder against claims or incidents that are reported while the policy is in force, or during an 'extended reporting period.' The negligent act, error or omission must have also occurred during the specific time frame set by the policy." AMERICAN INTERNATIONAL GROUP, INC., FREQUENTLY ASKED QUESTIONS, *at* http://www.aigdirect.com/small_business/customer_service/faq_index.cfm?PageID=fq020#top (last visited Jan. 13, 2003).

60. Experts in malpractice coverage estimate ninety percent of malpractice coverage is on a claims-made basis and assume that "in the next five years or so occurrence [policies] will all but disappear." E-mail from Jim Kelley, Coverage, Inc., to James O'Reilly, Visiting Professor of Law, University of Cincinnati College of Law (October 29, 2002 10:43:00 EST) (on file with the University of Cincinnati Law Review).

61. The statistics are taken from A.M. Best reports and other sources, and were presented to the 2002 Annual Meeting of the American Bar Association by malpractice insurance experts. Theresa W. Bourdon, Address at the 2002 Annual Meeting of the ABA, Tort and Insurance Practice Session (Aug. 10, 2002).

investments was diminished by stock market declines. St. Paul Insurance Company quit the medical malpractice insurance market when its losses became too severe: in 2001, the major malpractice carrier lost $940,000,000 on medical malpractice coverage and halted all future policy renewals or new policies.[62]

If an adverse eye effect is only manifested some years after the surgery, the physician's carrier will decline coverage because the patient's vision deterioration claim was not presented to the carrier during the contract period of the "claims made" policy. The plaintiff is able to continue the suit against the corporate or individual entity that performed the service, but the likelihood of a major settlement payment diminishes without the presence of an insurance carrier at the negotiating table.

Once the plaintiff's lawyer learns that no insurance coverage exists for the belated claim, the corporate structure of the eye surgeon becomes very important to the plaintiff's recovery efforts.[63] The corporate structures used to protect the surgeon's own assets in an LLC or professional corporation may have been dissolved by the year when litigation begins. The surgeon is quite likely to have imprinted the corporation's name on the documents to protect the surgeon's personal assets. Propensity of the LASIK surgeon's competitors to cut prices[64] and to reduce overhead leaves less residual cash for an insurance or loss reserve within the surgeon's LLC. In short, there may be no viable defendant left by the time the plaintiff determines that LASIK caused the vision problems.

Effects of Consent

Consent forms present the third barrier to the plaintiff. The attractive models in the LASIK advertisement and the terrific price claims for throwing away one's glasses will inevitably receive more visible space in advertisements for LASIK than the comparable visuals receive in prescription drug advertisements. That is because the surgical consent forms that contain the warnings only need to be presented at the time

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62. THE ST. PAUL COMPANIES, INC., NEWS, (Dec. 12, 2001) ("The St. Paul Announces Fourth-Quarter Actions to Improve Profitability and Business Positioning," press release of St. Paul Companies), *at* http://www2.stpaul.com/spc/corp/spcnews.nsf/6d54d5b37c9943cc86256a64006cba96/c007bc65cf4993c686256b200049c504?OpenDocument (last visited Feb. 21, 2003).

63. Oven v. Pascucci, 46 Pa. D. & C.4th 506 (Pa. Com. Pl. 2000) (eye laser litigation against corporate provider of the surgical service).

64. For example, in September 2002, a company called Lasik*Plus* advertised laser vision correction for only $299 per eye. *Genuine LasikPlus Laser Vision Correction: Now Only $299 Per Eye*, CIN. ENQUIRER, Sept. 13, 2002, at D7 (on file with the University of Cincinnati Law Review).

the buyer pays for the service. The FDA has jurisdiction over the advertisements for a prescription medical device and, although the FDA requires that warnings be stated for prescription drug ads made to consumers, it does not require the same communication about risks in LASIK advertising.[65]

The drafting of a surgical consent form is an art, at which defense counsel should excel. Surgeons have listened carefully to their defense counsel. If a LASIK surgeon is sued, the defense will argue that an ironclad consent form was executed by the plaintiff. The consent forms for laser eye surgery may be an extreme readability test for people who have selected one among several competing vendors for cheaper, faster and more efficient service for their eyes. The savvy surgical staff always has "one more form" to hand the patient to be signed. The person who has elected to get the surgery has probably signed the credit card receipt before signing all the other forms, including the surgical consent forms. The buyer of high volume elective surgery may be unaware that among the routine paperwork, the customer is signing away future rights by failing to focus on the consent forms. Breaking through this barrier to attack the failure to adequately warn will be a major inhibitor upon the willingness of the plaintiff's bar to take these cases on a contingent fee basis.

Effects of Preemption Defenses

The reader may expect that, even if the surgeon escapes liability, the device manufacturer is still an available defendant for a compensation claim. Alas, preemption of state tort recoveries by federal statutes is the fourth barrier to be faced by an injured customer. The United States Constitution permits Congress to govern interstate commerce.[66] Congress responded to a concern about medical device safety by regulating the interstate sale of medical devices.[67] At the time the specific authority to approve new medical devices was delegated to the FDA, Congress answered the device manufacturers' pleas by prohibiting the states from adopting "requirements" for medical devices that differed from federal "requirements."[68] In the 1976 Medical Device

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65. 21 U.S.C. § 352(r) (2000) literally covers advertising for "restricted" devices, but in practice the broader class of prescription devices have been within FDA's advertising controls; *see also* 21 C.F.R. § 801.109.

66. U.S. CONST. art. I, § 8, cl.3.

67. 21 U.S.C. § 321(h) (2000). The LASIK machinery is classified as a medical device under federal regulations. *See* 21 C.F.R. § 886.4390 (2000).

68. 21 U.S.C. § 360k(a)(1) (1999).

Amendments, Congress preempted states from imposing medical device requirements that are in addition to or different from federal medical device approval requirements.[69]

In two cases, the United States Supreme Court has interpreted the device legislation to shield virtually all manufacturers of innovative medical devices. The injured LASIK patient's compensation claim against a LASIK device maker is likely to be barred by the Supreme Court's interpretation of the Food Drug & Cosmetic Act[70] to prevent state verdicts asserting design defect claims against FDA-approved medical devices.[71] The plaintiff in a LASIK case against a manufacturer must overcome the legacy of the device industry's landmark victory in the 1996 Supreme Court decision *Lohr v. Medtronic, Inc.*[72] when combined with both the industry's successful effort to win 1997 amendments to the FDCA[73] and the 2001 Supreme Court industry victory in *Buckman Co. v. Plaintiff's Legal Committee.*[74] These efforts have collectively slammed the door on most causes of action for defective design of a medical device.[75] Suing the LASIK equipment supplier will be unlikely to succeed if the claim is related to design; claims of inadequate warning might also be blocked both by the FDA's specific product labeling approval[76] and by the patient consent forms, considering the breadth of wording in the pre-surgery consent documents that are routinely signed by LASIK patients.

Effects of Market Volatility

Finally, the medical device market is both global and volatile. Rapid changes in technology are altering the competitive landscape. Additionally, the manufacturers of LASIK devices are entering and leaving the market more rapidly than manufacturers in more conventional medical fields.[77] The marketplace of laser makers is

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69. *Id.*

70. *Id.* at § 360k (1999).

71. *See, e.g.*, Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996).

72. *Id.* (holding that 21 U.S.C. § 360k(a) preempted certain state tort claims).

73. Pub. L. No. 105-115, 111 Stat. 2296 (1997).

74. Buckman Co. v. Plaintiff's Legal Comm., 531 U.S. 341 (2001).

75. *See, e.g.*, Baker v. Medtronic, Inc., No. 2:99-CV-1355, 2002 WL 483013 (S.D. Ohio Mar. 28, 2002) (holding that preemption precludes virtually all state tort claims against medical device manufacturers).

76. The issue remains debatable for medical devices like LASIK equipment. Several courts have held that FDA clearance of a label does not preempt state tort cases for failure to adequately warn. *See, e.g.*, Webster v. Pacesetter, Inc., 171 F. Supp. 2d 1 (D.D.C.,2001) (medical device); Eve v. Sandoz Pharms. Corp., No. IP98-1429-C-Y/S, 2002 WL 181972 (S.D. Ind. Jan. 28, 2002) (drug).

77. Devices for laser eye surgery incur large development costs, making some companies vulnerable, with corporate survival consequences if the equipment does not achieve the desired results. *See* S.E.C. v.

rapidly evolving, with some of the makers of today's machines unlikely to be found in existence if cases arise several years hence, and others consolidating and merging assets, perhaps without retaining liabilities for past users of the equipment.

It may be that the maker of the machine used in a 2001 surgery has disappeared entirely or is not doing business in the United States by 2011, when the LASIK customer learns that his or her serious vision problem was triggered by cellular changes in the aftermath of the surgery. Piercing the corporate veil is a rarity[78] and the device makers will presumably have acted within the law in their merger or dissolution of the corporate structures.

Likewise, the physician who performs LASIK surgery as the agent of a corporation will seek to be shielded by the corporate form under state corporate laws, as occurred in a Pennsylvania LASIK negligence case.[79] The surgeon may attempt to structure the corporate shell as thinly as possible, so that the corporation or limited liability company can be terminated after a few years or will be insufficiently capitalized to pay judgments that arise from later-detected harms.

The result of this litany of disappearing defendants is that the eye surgery purchaser of 2003 may be unable to gain compensation in 2013, if and when serious eye problems can be diagnostically attributed to the surgery. The maker of the device is shielded; the surgeon is shielded or the surgeon's corporation is dissolved; and the malpractice carrier is excluded by a claims-made policy format. Clairvoyance is not required to recognize that LASIK's future problems would bring calls for a legislative solution to the absence of compensation or remedy.

VII. SOLUTIONS

Suggesting a Pooled Reserve Solution

A certain portion of those who claim a LASIK-induced eye deterioration will correctly attribute their harm to the surgery. Of course, for some injuries there is no compensation because an act of God or force of nature caused the harm: LASIK surgery, however, is the kind of expensive service for which the injured person will expect to be compensated should an unexpected harm occur. The adverse eye

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Schiffer, No. 97 Civ. 3853 (RO), 2001 WL 504860 (S.D.N.Y. May 11, 2001); *see also In re* VISX Sec. Litig., Nos. C-00-0649 CRB, C-00-0815 CM, 2001 WL 210481 (N.D. Cal. Feb. 27, 2001).

78. This piercing would mean that parent or related corporations and successors might be held liable for injuries alleged to have been the result of a prior dissolved corporation's actions.

79. Oven v. Pascucci, 46 Pa. D. & C.4th 506, 509 (Pa. Comm. Pl. 2000).

conditions will diminish occupational abilities for persons like airline pilots and will diminish the quality of life for all who depend on clear vision. Such harm would merit some form of compensation under tort law principles if the surgeon acted negligently, if the device the surgeon utilized was negligently designed, or if the plaintiff received inadequate warnings. But, the legal system involves the various limitations noted above, so tort law will deny compensation in most cases.

Nature abhors a vacuum—and modern media and politics seem to abhor a remediless injured person. Federal compensation for mass injury situations is requested by victims and their advocates in numerous situations. But the actual passage of federal relief legislation is very rare. Agent Orange compensation to military personnel who had served in Vietnam[80] and swine flu vaccine for persons who developed a rare adverse effect are among the rare few. Relief by federal cash assistance to persons who had elective surgery is quite unlikely in this instance.

The states can respond to future calls for compensation by requiring the insurance carriers who write surgical malpractice coverage to establish a sufficient reserve to be available for future claims. Perhaps in hindsight, such a reserve compensation pool should have been structured for asbestos and other chronic illnesses with belated onset. However, once the medical signs of future problems appeared for those products, the opportunity had passed. The later claims system has borne the higher transaction costs of that inactivity. A state insurance department imposing a surcharge on surgical malpractice policies could create the pool of funding, allowing for claims on the pool in future years to be adjudicated through the tort system, as it operates in the future. Claims for which a viable defendant or carrier exists would be required to be brought first against those viable parties.

What Loss-Reserve Structure Could Work?

In light of the probable unavailability of viable defendants for the compensation of longer-term LASIK injuries, as discussed above, this paper advocates the creation of a state-level statutory "risk reserve pool" to pay claims for which no other resources are available. The fund would be used as a limited compensation vehicle with a cap on individual benefits payable upon proof of the elements warranting compensation. Funding for the risk reserve would come from a required surcharge or supplemental coverage payment for the issuance of malpractice insurance covering physicians who perform elective, non-

80. 38 U.S.C. § 1116(a)(1) (1991).

emergency eye surgery. The payments into the risk reserve pool would be made by the surgeons or their corporate structure, perhaps in the form of a state surcharge of fifty dollars per non-therapeutically indicated[81] eye surgical operation performed. The pool would be held by the state insurance department in escrow as a funding source for any future claims for compensation. If the funds were not the subject of claims for ten years, which seems unlikely given the size of the patient population receiving LASIK surgery, then the fund would dissolve with the surcharges returned to those physicians who "contributed."

In the event that a LASIK patient's post-operative eye problems are persistent or appear at a point in time set in state legislation, claims would be made against the pool only if normal channels of compensation were foreclosed and only if the surgical event proximately caused the harm to the eye. The long-term negative consequences of these elective eye surgeries might manifest themselves after the plaintiff has found that the conventional routes of compensation, against malpractice coverage of the surgeon or against the device maker, are no longer available. The insurance excise charge would produce the "insurer of last resort" in the state insurance fund.

Why a State Remedy?

Since these surgeries are elective purchases of a medical service,[82] they have no federal Medicare cost consequence. These elective surgeries are not paid for with federal funds, and are not usually provided as an employee benefit, so the federal rules that lead to ERISA preemption of state remedies are not likely to inhibit state legislators. At least one court has held that such surgery is not medically necessary but is elective.[83] The state primacy over such surgical activities will be manifested by state oversight of malpractice insurance terms and reserves[84]

81. A norm such as that used by Medicare for "medically necessary" surgical procedures would separate the aesthetic or convenience self-paid surgeries from those where eye surgery had been performed to respond to a medical need. "Under the Medicare Act, a physician's certification that the ambulance services provided are medically necessary is required before Medicare reimbursement is available." Howard Med., Inc. v Temple Univ. Hosp., No. 00-5977, 2002 WL 169380 at *4 (E.D. Pa. Feb. 1, 2002) (citing 42 U.S.C. § 1395n(a)(2)(2002)). Since this is not provided as an employee benefit, ERISA preemption is not likely to inhibit state responses.

82. Steven Z. v. Kimberley Z, No. CN00-7918, 2000 WL 1658620 (Del. Fam. Ct. 2000).

83. Stasack v. Capital Dist. Physicians' Health Plan Inc., 736 N.Y.S.2d 764 (A.D. 3 Dept. 2002).

84. Federal ERISA recognized the primacy of states in regulating insurance within the states, and these malpractice insurance reserve issues are properly within the realm of state insurance departments. 29 U.S.C. § 1144(b)(2)(A) (1991); UNUM Life Ins. Co. v Ward, 526 U.S. 358 (1999).

and by the medical licensure roles of the states.[85] The states that recognize a LASIK compensation issue would be free to employ their authority over insurance carrier policy conditions and loss reserves, as well as the state medical licensing powers over physicians practicing in this area of surgery.

Of course, how the proposed LASIK injury compensation system will work is yet to be determined. State legislators will first have to hear from a constituency supporting compensation in numbers that can outweigh the power of the medical lobby and the LASIK machine manufacturers' probable defensive alliances. If the experience with HMO legislation in Congress is any indication, many legislators will undoubtedly approach the task of drafting remedial legislation with a pro-patient approach.

The compromise legislation that ultimately passes may set a standard for recovery from the fund that requires exhaustion of other remedies before a claim can be made to the state fund. Simplified administrative hearings before an administrative agency physician or panel of physicians, attorneys and administrators might be convened. The hearing could be similar to a disability benefits hearing, without the transaction costs of adversarial litigation. Causation of the eye condition will be the major fact issue for the adjudicator or panel, as a delayed effect of damage to the eye could be causally attributed to the LASIK surgery only after close attention to the eye's present condition by an expert ophthalmologist employed as advisor to the panel. The plaintiff's expert would be expected to meet informal norms of qualification, less stringent than the constraints on expert testimony under the Daubert[86] test or other state-law tests of expert witness testimony. Proof of causation could be somewhat relaxed in claims against the fund, perhaps with a set of presumptions concerning the vision deterioration effects of eye surgery and of aging as causal factors, when the legislation establishing the compensation scheme is created.

The hearing could determine the current amount of eye impairment compared to an age-appropriate eye functions grid, fix the percentage of such current eye condition attributed to the LASIK surgery, and then determine whether another source exists from which benefits would be accessible to the claimant. Payments from the state fund would not be available unless the administrative official in the state department of insurance found sufficient credible evidence from competent medical evaluators that the vision conditions in the patient's eye had been

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85. *See, e.g.*, Colo. State Bd. of Med. Exam'rs v. Roberts, 42 P.3d 70 (Colo. Ct. App. 2001) (LASIK surgical malpractice led to state medical board disciplinary action).

86. Daubert v. Merrell Dow Pharms., 509 U.S. 579 (1993).

adversely affected by the results of the elective LASIK eye surgery and that the impairment of vision as of the time of a benefits application was causally attributable to the surgery. Awards could be set up to a maximum amount of compensation, perhaps $50,000. If there were a viable civil tort case to be brought, the compensation would not be pursued or might be deferred by the panel.

Certainly, proponents of the relief legislation will argue for statutory presumptions that eye surgery caused the compensable deterioration while opponents of the statute, including eye surgeons and their malpractice carriers, will argue that the person who bought the elective surgery should be left with the consequences. The degree of relaxation of such proof of causation would likely draw intense debate in the state legislatures. The factual issue of causation based on competing expert testimony regarding the source of the eye deterioration will pose a tough question for the civil jury. If normal aging of the claimant's eye tissue exacerbated the adverse effects of the laser slicing of the eye, the expert will need to opine about relative percentages of causation attributable to the effects of the surgery. The standard of proof in a case involving an older adult with other health problems may be especially difficult for the plaintiff.

VIII. CONCLUSION

New issues suggest new solutions. While laser eye surgery seems today to have few near-term problems, the massive numbers in the target population and the vagaries of human optical problems will pose concerns for trial lawyers. Barriers to recovery, when and if problems are found, will be a challenge to the remedial system of the future. State legislative action and insurance regulatory decisions to establish a risk-pool surcharge may be the optimal means to assure that future claims can be compensated. Plaintiffs' trial counsel will have a role in the creation of this future mechanism for relief, which will entail a focused and intelligent effort for governmental assurance of remedies.