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# ARTICLES

## COMPARING MEDICAL PROVIDERS: A FIRST LOOK AT THE NEW ERA OF MEDICAL STATISTICS

Aaron D. Twerski\* and Neil B. Cohen\*\*

### INTRODUCTION

The right of a patient to informed choice is relatively new. Thirty years ago, the major tort law treatises made no mention of it whatsoever.<sup>1</sup> Much has transpired during the past three decades. Courts have widely recognized an affirmative obligation on the part of medical care providers to share information with patients regarding the risks accompanying recommended medical procedures and the availability of different alternative procedures.<sup>2</sup> As medical information has become more sophisticated,

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<sup>1</sup> The leading torts hornbook, WILLIAM L. PROSSER, *THE LAW OF TORTS* (2d ed. 1955) made no reference whatsoever to a cause of action for informed consent. Other writers at the time expressed no sentiment in favor of such a cause of action. See, e.g., Harry Kalven Jr., *A Special Corner of Civil Liberties: A Legal View I*, 31 N.Y.U. L. REV. 1223, 1224 (1956); Morris Ploscowe, *The Place of Law in Medico-Moral Problems: A Legal View II*, 31 N.Y.U. L. REV. 1238, 1240 (1956).

<sup>2</sup> The earliest case recognizing informed consent was *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, 317 P.2d 170, 181 (Cal. Dist. Ct. App. 1957). The literature dealing with the informed consent doctrine is staggering in volume. A good review of the contours of the law can be found in PAUL S. APPELBAUM ET AL., *INFORMED CONSENT* chs. 3, 6 (1987); W. PAGE KEETON ET AL., *PROSSER AND KEETON ON THE LAW OF TORTS* § 32, at 189-92 (5th ed. 1984) [hereinafter PROSSER & KEETON]; Jay Katz, *Informed Consent-A Fairy Tale: Law's Vision*, 39 U. PITT. L. REV. 137 (1977); Marjorie Maguire Shultz, *From Informed Consent to Patient Choice: A New Protected Interest*, 95 YALE L.J. 219, 239-29

the data available to medical providers have become more exact and refined.<sup>3</sup> The duty to provide information may require more than a simple sharing of visceral concerns about the wisdom of undertaking a given therapeutic procedure. Physicians may have a responsibility to identify and correlate risk factors and to communicate the results to patients as a predicate to fulfilling their obligation to inform.

Running parallel to the development of more sophisticated data concerning risks of various therapeutic procedures has been the development of statistical models that compare the success rates of medical providers, such as hospitals and doctors, in performing various procedures.<sup>4</sup> The theoretical basis for drawing such comparisons is quite elementary. Just as one controls for various other risk factors in assessing the likelihood of success of a given therapeutic intervention, so one should be able to identify whether a hospital or a physician adds to or detracts from that likelihood. The major stumbling block standing in the way of comparing medical providers is the wide variation in the mixes of patients whom they service. It is fully understandable, for example, that more seriously ill patients will demonstrate poorer outcomes than will patients with healthier profiles and that some providers treat a higher percentage of such patients than do others. A good statistical model must account for all important variables and must be based on sufficient clinical experience to be meaningful.

In 1990 the New York State Department of Health published a study dealing with adult open heart surgery at various hospitals in the state of New York.<sup>5</sup> The study was notable in

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(1985); Eleanor S. Glass, *Restructuring Informed Consent: Legal Therapy For the Doctor-Patient Relationship*, 79 YALE L.J. 1533 (1970). For a succinct analysis of the law, providing a state-by-state compilation of the differing rules, see 3 PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, *MAKING HEALTH CARE DECISIONS: THE ETHICAL AND LEGAL IMPLICATIONS OF INFORMED CONSENT IN THE PATIENT-PRACTITIONER RELATIONSHIP* app. L at 193, 206-45 (1982) [hereinafter *MAKING HEALTH CARE DECISIONS*].

<sup>3</sup> See *infra* notes 5-8.

<sup>4</sup> *Id.* See also Harris Meyer, *Informed Consent Key in Emerging Suits*, AM. MED. NEWS, July 27, 1992 ("An example is proposed legislation moving through Congress that would require fertility treatment centers to disclose their individual in vitro success rates.").

<sup>5</sup> Edward L. Hannan et al., *Adult Open Heart Surgery in New York State, An Analysis of Risk Factors and Hospital Mortality Rates*, 254 JAMA 2768 (1990).

that it controlled for twenty different surgical risk factors that might affect the outcome of the surgery. The results revealed substantial differences in success rates among the hospitals studied. The performance of several hospitals gave cause for concern because their mortality rates on a risk-adjusted basis exceeded what could be attributed to normal statistical variation.<sup>6</sup> A similar statistical analysis was undertaken of surgeons performing open-heart surgery.<sup>7</sup> Once again, statistically significant variation of considerable magnitude was evident. Although the ground-breaking study was limited to open-heart surgery, similar studies have been or will be undertaken for a variety of other frequently performed surgical procedures.<sup>8</sup>

In the foreseeable future we should see a sharp increase in both the number and the sophistication of such comparative statistical studies. The most strident critics of such studies do not quarrel with the basic concepts. Rather, they argue that the studies are too crude and insufficiently developed to allow for meaningful conclusions.<sup>9</sup> Yet greater sophistication in the statistical modeling is only a matter of time. Now or in the near future both the medical and legal communities will have to address whether, and to what extent, these statistical studies may be utilized in their respective disciplines. Physicians and hospitals may wish to use these studies for peer review; insurers may wish to utilize them for rate-setting purposes; and attorneys may wish to use them in medical malpractice actions, including both traditional negligence and informed consent claims.

An exploration of all of the issues arising from comparative medical statistics would require the input of multiple disciplines. The goal of this Note is more modest. We intend to identify the problems that will be encountered if attorneys seek to use this new genre of statistical data in two strands of tradi-

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<sup>6</sup> *Id.* Table 5 at 2772.

<sup>7</sup> These statistics were published in *Newsday*. See David Zinman, *Heart Surgeons Rated; State Reveals Patient Mortality Records*, *Newsday*, December 18, 1991, at 3.

<sup>8</sup> See, e.g., Michael S. Zdeb & Vito M. Legrillo, *Cesarean Childbirth in New York State: Trends and Directions*, *BIRTH*, Dec. 1989, at 203; NEW YORK STATE DEPARTMENT OF HEALTH, BUREAU OF BIostatistics, *CESAREAN CHILDBIRTH IN NEW YORK STATE* (Nov. 1987). The authors are informed that statistical studies similar to those already done for adult open-heart surgery are being planned for some neurological and urological surgical procedures.

<sup>9</sup> See Jesse Green, *Problems in the Use of Outcome Statistics to Compare Health Care Providers*, 58 *BROOK. L. REV.* 55 (1992).

tional medical malpractice litigation—negligence and the failure to obtain informed consent.

## I. THE NEW INFORMATION ERA

### A. *Risk Information Highly Correlated to Patient Risk Factors*

Until recently, physicians dealt with risk information in a highly subjective fashion. For example, an obese patient with a history of diabetes was considered to be at greater risk for coronary bypass surgery than a patient without these conditions. In assessing the risks of surgery as against continued use of medicinal therapy, a physician would make an impressionistic judgment about the wisdom of surgical intervention and relay that judgment and the reasoning underlying it to the patient. It is doubtful that such imprecise decision making will suffice much longer.<sup>10</sup> Today it is possible to determine risk factors that take into account not only general information about outcomes from the procedure, but also much information about the patient.<sup>11</sup> Thus, physicians will have at their fingertips statistical data to inform them of the risks associated with a given surgical procedure for patients with a given profile.

Of course, to make an appropriate treatment decision, a provider must evaluate how a patient would fare with alternative medical interventions. When the provider has statistical risk

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<sup>10</sup> The many risk factors identified and controlled for in the New York State study show the greater precision with which risk analysis may now be done. See *supra* note 7 and accompanying text. The study factors included: age; race; gender; payer; preoperation (a cardiac or great-vessel procedure performed during any previous admission); ejection fraction; previous myocardial infarction; morbid obesity (1.5 times ideal weight); hypertension history (requiring therapy); preoperative intra-aortic balloon pump; dialysis dependency; disasters (acute structural defect, renal failure, cariogenic shock, gunshot); intractable congestive heart failure (CHF), New York Heart Association functional class IV, symptoms of CHF at rest; diabetes requiring medication; <90 degrees narrowing of left main trunk; percutaneous transluminal coronary anoplasty "crash"; cardiac catheterization "crash"; unstable angina; chronic obstructive pulmonary disease resulting in functional disability hospitalization or forced expiratory volume in 1 second <75 degrees of predicted or requiring bronchoduator therapy; and type of operation (coronary artery bypass graft, valve, coronary artery bypass graft plus valve, other).

<sup>11</sup> Dr. Gerald T. O'Connor, Chairman of Medical Research, Department of Medicine, Dartmouth-Hitchcock Medical Center, address at the Brooklyn Law School Symposium: Comparing Medical Providers, January 9, 1992, related that surgeons at the medical center are already armed with pocket computers which allow them to assess multiple risks depending on a given patient profile (on file with *Brooklyn Law Review*).

information as to one form of medical intervention, but no such information as to alternative treatments, a simple comparison of risks is impossible. Thus, in such cases, which are likely to be the norm for quite some time, medical decision making will not consist solely of evaluating statistical data. Moreover, non-quantifiable "human elements" will always be part of the mix.

Even with these limitations, however, the medical profession will be unable to escape using available statistical information. At the very least, providers who do not consider such information in their decision making will be required to explain why. In addition, it is likely that providers, as part of their duty to provide informed choice, will be called upon to share risk information with patients.

Notwithstanding the rather common sense quality of these observations, one must be cautious in concluding that the failure to use and communicate such risk data will be determinative in medical malpractice cases. Where the plaintiff alleges that the doctor was negligent for choosing a given surgical procedure in light of the *patient's* risk profile, it is likely that a physician will have considered many of the factors in her own impressionistic judgment to recommend the procedure. If the doctor's rationale was sufficient to overcome her own *ex ante* internal evaluation of the risk factors, it is likely to be equally convincing in the context of *ex post* external review at trial in which the statistical information is considered. Admittedly, the statistical information has a focused quality and may be somewhat difficult to overcome. Nonetheless, unless the doctor's impressionistic evaluation is substantially off the mark, it is unlikely that the statistical data, even though more precise, will convince a jury that the doctor's risk valuation was negligent.<sup>12</sup>

However, in informed consent cases, the failure of providers to develop and communicate relevant statistical information to patients may take on greater significance. An injured plaintiff who suffers an undesired result from a surgical intervention can be expected to argue that, if he or she had been told the probability of an adverse outcome given the particular patient's profile, the plaintiff would have refused the surgery. Formidable

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<sup>12</sup> The analysis, however, is dramatically different when the statistical information concerns risks associated with the particular provider. See *infra* notes 38-49 and accompanying text.

barriers, however, stand in the way of this argument. Even when a doctor fails entirely to inform a patient of risks attendant to a surgical or other invasive procedure, a plaintiff faces a difficult causation problem.<sup>13</sup> As long as the doctor's advice is sound and non-negligent, it will be difficult to convince a jury that the patient would have discounted the doctor's recommendation and declined to undergo treatment.<sup>14</sup> After all, most reasonable patients follow the advice of their reasonable doctors.<sup>15</sup> Furthermore, since the doctor will have, in this case, shared with the patient her impressionistic assessment of the risks, the argument would have to be that the provider's failure to provide the statistical information to the patient *caused* the patient to acquiesce to the medical procedure.<sup>16</sup>

In short, causation problems are likely to loom very large in attempts to establish that a provider's failure to utilize statistical information concerning patient-specific risks "caused" a patient to submit to medical intervention. In a different forum the authors have asserted that the causation argument seriously undermines the goal of patient autonomy.<sup>17</sup> We have also argued that it is extremely difficult to determine after the fact how any individual patient's decision making would have played out.<sup>18</sup>

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<sup>13</sup> See, e.g., *Cobbs v. Grant*, 502 P.2d 1, 11-12 (Cal. 1972); *Reikes v. Martin*, 471 So.2d 385, 392-93 (Miss. 1985); *Scott v. Bradford*, 606 P.2d 554, 558-59 (Okla. 1979).

<sup>14</sup> We do not mean to imply that the causation test gives a doctor any sense of assurance that a case of informed consent cannot be successfully established. For the most part causation is a fact-sensitive question that almost always goes to the jury. Nonetheless, the causation hurdle is a difficult one for plaintiffs to overcome.

<sup>15</sup> See Leonard L. Riskin, *Informed Consent: Looking for the Action*, 1975 U. ILL. L. REV. 580, 589-90; Schultz, *supra* note 2, at 249-50.

<sup>16</sup> It is only the failure to communicate the additionally desired information that is tortious. If the plaintiff would have made the same decision with or without the additional information, then causation has not been established. See *supra* note 11. Once again the analysis is dramatically different if the statistical information concerns risks associated with the particular provider. See *infra* notes 40-51 and accompanying text.

<sup>17</sup> See Aaron D. Twerski & Neil B. Cohen, *Informed Decision-Making and the Law of Torts: The Myth of Justiciable Causation*, 1988 U. ILL. L. REV., 607, 614-15. See also Richard A. Epstein, *Medical Malpractice: The Case for Contract*, 1 AM. B. FOUND. RES. J. 87, 121 n.72 (1976); Joseph Goldstein, *For Harold Laswell: Some Reflections on Human Dignity, Entrapment, Informed Consent, and the Plea Bargain*, 84 YALE L. J. 683, 691 (1975); Jay Katz, *THE SILENT WORLD OF DOCTOR AND PATIENT* 79-80 (1984); Koopersmith, *Informed Consent: The Problem of Causation*, 3 MED. & LAW 231, 233-36 (1984); David E. Seidelson, *Lack of Informed Consent in Medical Malpractice and Product Liability Cases: The Burden of Presenting Evidence*, 14 HOFSTRA L. REV. 621, 623-24 (1986).

<sup>18</sup> See Twerski & Cohen, *supra* note 17, at 626-48.

These arguments notwithstanding, causation continues to play a significant role in medical malpractice cases and would likely make it difficult for a plaintiff to prevail before a jury on the sole ground that statistical information was not adequately considered. However, when one uses such statistical information to supplement an otherwise plausible malpractice or informed consent case, its role changes considerably. Statistics may provide graphic and highly focused information that is very convincing to a jury. If, in explaining a surgical procedure to a patient, a given risk was understated by a doctor, the plaintiff's claim that the risk should have been given more prominence would be much enhanced by pointing to the statistical frequency of the ultimate harm suffered. Contrasting a soft warning against the starkness of hard statistics may serve to bolster the plaintiff's argument that the physician failed to communicate adequate information.

In conclusion, the increasing availability of patient-specific statistical information does not raise—as does provider-specific information—new ideological issues in negligent malpractice or informed consent causes of action. Nevertheless, advocates are expected to make use of the statistical data, or the failure to develop such data, to strengthen their positions in litigation.

### B. *Provider-Specific Information*

The 1990 New York State Department of Health study broke new ground.<sup>19</sup> It was the first study to use detailed clinical information from an entire state to identify significant risk factors, including the identity of the physician and hospital, with respect to a specific surgical procedure. As a result, patients are able to evaluate a medical health provider as an independent risk factor for the first time.

This new source of provider-specific information has potential relevance for actions alleging medical negligence and lack of informed consent. If such statistical information signals that a particular physician or hospital experiences bad results comparatively frequently when undertaking a given procedure, the conduct of the provider in deciding to perform the procedure may

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<sup>19</sup> See *supra* note 5.



be negligent in the first instance.<sup>20</sup> However, the very nature of this information makes the analysis much more difficult than in a typical negligence case.<sup>21</sup>

An even more intriguing question concerns the role of provider-specific data in an action predicated on informed consent. Patients who suffer adverse results from a procedure may well argue that the medical provider had an obligation to disclose her success rates for that procedure to enable the patient to decide

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<sup>20</sup> Moreover, the physician may face disciplinary action and administrative sanctions as well. Pursuant to N.Y. PUB. HEALTH LAW § 230(1) (McKinney Supp. 1992), the New York State Department of Health is authorized to institute disciplinary proceedings against physicians for instances of professional misconduct, as defined by N.Y. EDUC. LAW § 6530 (McKinney Supp. 1992). Professional misconduct is defined as either "[p]racticing the profession with negligence on more than one occasion" N.Y. EDUC. LAW § 6530(3) (McKinney Supp. 1992) or "... accepting and performing professional responsibilities which the [physician] knows or has reason to know that he or she is not competent to perform." *Id.* § 6530(24).

Several crucial issues arise with respect to these definitions of professional misconduct and the proliferation of medical provider statistics. First, how substantial a difference must there be between a negligent provider and a reasonable provider for liability to attach in an administrative proceeding? This is crucial because once the Department of Health determines what level of risk is acceptable for a given procedure, plaintiffs who sue physicians for negligently undertaking a procedure will come into court armed with the Department of Health's administrative rulings.

That, in turn, leads to the second question: is an administrative ruling sanctioning a physician determinative of the negligence issue in a suit for damages? That is, will the administrative ruling establish negligence as a matter of law, create a rebuttable presumption of negligence for the jury to accept or reject, or will it be considered simply evidence of the physician's negligence?

Whether the administrative sanction resulted from the physician's treating the plaintiff whose injury was the subject of the administrative inquiry; or whether the physician was sanctioned for performing a procedure on someone other than the plaintiff, a finding that a physician's performance statistics are unacceptable to the state Department of Health is likely to be of considerable importance in the ensuing negligence litigation. An administrative determination setting the standard of acceptable performance based on prior performance statistics is not fact-sensitive to the particular provider and thus arguably becomes the standard of care for the tort case. Thus, there may be no need to relitigate the negligence issue. Of course, the physician may wish to introduce evidence that in *this* procedure, her conduct was reasonable. See *infra* note 38.

Finally, what effect on subsequent administrative proceedings should a negligence verdict have against a physician? A jury could conclude that performance at a given risk level constitutes negligence where an administrative agency might opt for a higher threshold before sanctioning a physician. The goals of the common law tort system and regulatory adjudication need not be identical. The purpose of the administrative body is to protect citizens who come in contact with state licensed practitioners, while the civil justice system exists to provide remedies for actionable wrongs. See *In re DiMarcisico v. Ambach*, 48 N.Y. 576, 399 N.E.2d 1129, 424 N.Y.S.2d 107 (1979); *In re Morfesis v. Sobol*, 172 A.D.2d 897, 567 N.Y.S.2d 954 (3d Dep't 1991).

<sup>21</sup> See *infra* notes 21-37 and accompanying text.

whether to utilize that provider or an available alternate. Will the law recognize such a duty on the part of an individual provider? Need the provider offer data comparing her success rates with those of other providers? Can a plaintiff successfully establish that his injury was causally related to the failure of the provider to supply the desired information? The existing law of informed consent provides only limited guidance for an action based on the failure of a provider to tell a patient about provider-specific risk information. Moreover, this issue has not been addressed by the literature.

Therefore, this Note can do little more than explore the difficulties in establishing an independent cause of action based on provider-specific risk data. Notwithstanding these difficulties, we are quite certain, as the statistical validity of such data becomes firmly established, they will become an integral part of medical malpractice litigation. Whether standing alone or in combination with other more traditional types of proof, these statistical data will exert a powerful influence.

1. Negligence: Is It Actionable For A "Risky" Provider to Perform A Given Procedure?

To utilize now available provider-specific risk information most effectively, it is necessary first to create an "adjusted risk factor" for each provider. The creation of an "adjusted risk factor" for each provider, controlling for all known variables other than the identity of the provider, enables provider-specific information to be used in the most effective manner. The adjusted risk factor for each provider can then be compared with the adjusted risk factor of each other provider to reveal quickly the relative risk of utilizing one provider or the other for the specific procedure.

If a provider's adjusted risk factor is relatively high compared to those of other providers, can that, itself, ever be the basis for a malpractice claim in negligence? This question does not focus on the evidentiary relevance of the adjusted risk factor to determine whether a procedure was negligently performed.<sup>22</sup> Rather, the issue is whether the fact that a provider's adjusted

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<sup>22</sup> See Paul D. Rheingold, *The Admissibility of Evidence in Malpractice Cases: The Performance Record of Practitioners*, 58 BROOK. L. REV. 75 (1992).

risk factor for a particular procedure is poor can provide the basis for a negligence claim in the absence of proof that the procedure itself was poorly performed.

Our answer to this question is a qualified yes. The theory is that, in certain cases, a provider's decision to perform a procedure at which she is substantially worse than the relevant "market" is, itself, negligence apart from the question of whether the procedure was performed competently.<sup>23</sup> After all, the provider, by choosing to perform the procedure, has chosen to expose the patient to an unnecessarily high level of risk. If the performance of the procedure results in harm to the patient, the provider's decision to perform the procedure is a "but-for" cause of the harm.<sup>24</sup> Therefore, the provider, in proper circumstances, should be liable for the consequences of her improper decision.

To move from this initial generalization to a usable rule, several difficult pieces of analysis must be undertaken. First, it must be determined how "bad" a provider's risk factor must be for a decision to perform the procedure to be deemed negligent.

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<sup>23</sup> At first blush one might consider analogizing this situation to breach of licensing statutes. Most courts refuse to treat the failure to attain a license as relevant to the question of situational negligence. See Charles Gregory, *Breach of Criminal Licensing Statutes in Civil Litigation*, 36 CORNELL L. REV. 622 (1951). Presumably unlicensed personnel are less competent than those who possess a license. However, the analogy does not carry. The failure to obtain a license does not bear directly on an actor's competence. Many reasons, other than lack of competence, can be given for the failure to obtain a license. The case to be made out by provider-specific statistics goes directly to the competence of a provider to undertake a particular surgical procedure.

It is interesting that a leading case holding that breach of a licensing statute was inadmissible in a negligence action, *Brown v. Shyne*, 242 N.Y. 176, 151 N.E. 197 (1926), was overturned by a statute which provides that when one "not authorized to provide medicine . . . [was] a producing proximate or contributing cause of . . . injuries or death, the fact that such person practiced medicine without being so authorized shall be deemed prima facie evidence of negligence." N.Y. CIV. PRAC. L. & R. § 4504 (McKinney 1992).

Although under this statute an unlicensed practitioner could defend herself by demonstrating that her conduct was, in fact, non-negligent, under our proposal a comparatively risky provider whose decision to perform a medical procedure was negligent could defend herself only by showing that her conduct was non-causal, i.e., that the identical injury would have occurred even if an alternate provider had performed the procedure.

As a practical matter, however, in the case of an unlicensed practitioner, the only realistic method for the unlicensed actor to defend herself would be to convince the finder of fact that the same injury would have occurred if the procedure were performed by a licensed and fully competent practitioner.

<sup>24</sup> Of course, the harm might have occurred even if a "less risky" provider had performed the procedure. This, too, must be taken into account. See *infra* notes 32-37 and accompanying text.

A "reasonable provider" test should be used here.<sup>25</sup> A decision to perform a procedure despite one's high risk factor is, itself, negligent when a reasonable provider, knowing that risk factor and the distribution of risk factors of other providers, would not perform the procedure.

For a reasonable provider to decide not to perform the procedure, two elements must be present. First, the difference between the provider's risk factor and that of an alternative provider must be significant. That is, it must be sufficiently likely that the difference between the risk factors reflects a true difference in probable outcomes and not merely an illusion resulting from random factors in the data.<sup>26</sup> Second, the difference in the

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<sup>25</sup> One who holds himself out as a specialist is required to meet the standard of care of a reasonable specialist. See PROSSER & KEETON, *supra* note 2, § 32 at 191.

<sup>26</sup> Whenever one seeks to draw inferences from sample information, there is a risk that what appears to be a difference between two actors may reflect nothing more than differences which could be expected from repeated samplings from the same actor. For example, if Coin A and Coin B were each flipped 10 times and heads turned up six times for Coin A and four times for Coin B, the data could be read to suggest that Coin A comes up heads 60% of the time, while Coin B comes up heads only 40% of the time. Should one conclude that Coin A is a more "pro-heads" coin than Coin B? Of course not. The difference between six heads out of ten and four heads out of ten could easily result from chance. If, however, each coin were flipped 10,000 times, with Coin A coming up heads 6,000 times and Coin B coming up heads 4,000 times, the analysis would be quite different. Once again, the data suggest that Coin A is a 60% heads coin and Coin B a 40% heads coin. This time, however, one would likely conclude that Coin A is more "pro-heads" than Coin B. Why? Because the difference between 6,000 heads out of 10,000 flips and 4,000 heads out of 10,000 flips is quite unlikely to occur by chance if the coins are identical.

Since we can never "know" whether an observed difference is real or merely a random occurrence, any standard of significance that we choose to apply for deciding whether a difference is significant will result in errors in some cases. If the standard is high, i.e., if we demand very stark differences before rejecting the hypothesis that they result merely from chance variations, we will have very few cases in which we incorrectly state that a given provider's risk factor is higher than that of an alternate provider. On the other hand, there will likely be quite a few cases in which the provider in question truly is riskier, but where the difference is not stark enough to meet the standard; and, therefore, we do not conclude that the provider is riskier than the alternate provider. If the standard of significance is relatively low, however, there will be fewer cases in which we incorrectly fail to conclude that a real difference exists, but more cases where we conclude that there is a real difference when, in fact, there is none.

How to balance the risks of these two types of errors is the key decision in determining a significance test. The choice of the appropriate significance test has long intrigued courts and commentators. See *DeLuca v. Merrell Dow Pharmaceutical*, 911 F.2d 941 (3d Cir. 1990); Constantine Kokkoris, Comment, *DeLuca v. Merrell Dow Pharmaceuticals, Inc.: Statistical Significance and the Novel Scientific Technique*, 58 BROOK. L. REV. 219 (1992). See generally Neil B. Cohen, *Conceptualizing Proof and Calculating Probabilities: A Response to Professor Kaye*, 73 CORNELL L. REV. 78 (1987); Neil B. Cohen, *Confi-*

risk factors must be substantial. The difference must be large enough to justify a determination that, even after taking into account the dislocation and additional expense and effort involved for the patient in identifying and arranging with an alternate "provider," the extra benefit to the patient of utilizing the alternate provider is meaningful.<sup>27</sup>

Who is the mythical "alternative provider" with whom providers must compare their risk factors? Is it the best provider available? The "average provider"? The next best provider? There is no clearly correct answer. We would ask providers to compare their risk factors with those of marginal substitutes that are readily available under similar economic conditions in the same market. These substitutes need not be superior providers, or even average ones. So long as a substitute who is substantially less risky is easily available to the patient, a provider ought to pause before deciding to perform the procedure herself.

If a provider with a high adjusted risk factor performs a procedure that a reasonable provider in that position would not perform, knowing the risk factor and the distribution of risk factors of other providers, it is fair to conclude that performing the procedure is negligent. This is so whether one uses an efficiency concept of negligence<sup>28</sup> or a community standards

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*dence in Probability: Burdens of Persuasion in a World of Imperfect Knowledge*, 60 N.Y.U. L. REV. 385 (1985).

<sup>27</sup> It is important to distinguish the magnitude of the difference from its statistical significance. Statistical significance provides us with confidence that the observed difference is not the result of random fluctuations in the data. Yet the difference in performance level from one doctor to another may not be great. Even if one is quite sure that a small difference exists, the difference in the performance level may be too minute to justify the conclusion that the doctor's decision to perform the surgery was negligent.

<sup>28</sup> The leading tort decision expressing the efficiency concept is *United States v. Carroll Towing Co.*, 159 F.2d 169 (2d Cir. 1947). In that case Judge Learned Hand took the position that whether an actor's injury-causing conduct was negligent depended on three variables: (1) the probability that injury would result from the actor's conduct; (2) the gravity of the harm that could be expected to result should injury occur; and (3) the burden of taking precautions that would have avoided or minimized the injury. Hand suggested that the test could be reduced to algebraic terms: "[I]f the probability be called P; the injury L [loss]; and the burden B [i.e., the burden of precaution to have avoided the loss]; liability depends upon whether B is less than L multiplied by P: i.e., whether  $B < PL$ ." *Id.* at 173.

A quarter of a century passed before Professor (now Judge) Richard Posner pointed out that the Hand negligence tort formula was in lock-step with an economic test of negligence. In a landmark article expressing the "law and economics" perspective on the

concept.<sup>29</sup> It is certainly inefficient for a provider to perform a procedure with a lower net expected benefit than another provider who, even after taking into account the transaction costs of identifying the substitute provider, yields a higher net expected benefit. Similarly, a provider who performs procedures that consistently have significantly worse outcomes than those of an alternate provider, for whatever reason, can easily be said to be performing below the community standard.

Two points must be clearly understood. First, we do not suggest that the providers at the bottom of a "success rate" list are *per se* negligent in deciding to perform their procedures. Such a suggestion would be logically and practically incoherent. Every rank order list has a bottom. If the legal system impels a provider at the bottom of the list to refrain from performing a procedure, the next lowest provider will now be at the bottom and similarly be impelled to abstain from performing the specific procedure. This vicious cycle would result in driving all providers but the single best from each field. Rather, it must be

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subject, Posner argued that the Hand formula stood for the following proposition:

Discounting (multiplying) the cost of an accident if it occurs by the probability of occurrence yields a measure of the economic benefit to be anticipated from incurring the costs necessary to prevent the accident. The cost of prevention is what Hand meant by the burden of taking precautions against the accident. It may be the cost of installing safety equipment or otherwise making the activity safer, or the benefit foregone by curtailing or eliminating the activity. If the cost of safety measures or of curtailment-whichever cost is lower-exceeds the benefit in accident avoidance to be gained by incurring that cost, society would be better off, in economic terms, to forgo accident prevention. A rule making the enterprise liable for the accidents that occur in such cases cannot be justified on the ground that it will induce the enterprise to increase the safety of its operations. When the cost of accidents is less than the cost of prevention, a rational profit-maximizing enterprise will pay tort judgments to the accident victims rather than incur the larger cost of avoiding liability. Furthermore, overall economic value or welfare would be diminished rather than increased by incurring a higher accident-prevention cost in order to avoid a lower accident cost. If, on the other hand, the benefits in accident avoidance exceed the costs of prevention, society is better off if those costs are incurred and the accident averted, and so in this case the enterprise is made liable, in the expectation that self-interest will lead it to adopt the precautions in order to avoid a greater cost in tort judgments.

Richard A. Posner, *Theory of Negligence*, 1 J. LEGAL STUD. 29, 32 (1972).

<sup>29</sup> Generally, medical custom sets the standard of care in traditional malpractice litigation. See Allan H. McCoid, *The Care Required of Medical Practitioners*, 12 VAND. L. REV. 549 (1959); Richard N. Pearson, *The Role of Custom in Medical Malpractice Cases*, 51 IND. L.J. 528 (1976).

emphasized that a provider at the bottom of the list who continues to perform the procedure in question is negligent only if the gap between that provider's risk factor and that of the alternative provider is such that a reasonable provider would refrain. Most often, this will not be the case. The difference between that provider's risk factor and that of an alternate provider may not be significant,<sup>30</sup> or, if significant, it may not be substantial.<sup>31</sup>

Second, if a provider's risk factor is substantially higher than that of an alternative provider, and the difference is statistically significant, it is negligent for the provider to perform the procedure even if it cannot be said that the provider generally performs the procedure "poorly." It is negligent to expose the patient to higher risks than necessary.

For example, imagine an ambulance dispatcher who has two ambulances at his disposal. The first ambulance is a well-maintained 1988 model with equipment that was state-of-the-art at the time of manufacture. The second ambulance is a 1992 model equipped with sophisticated new devices to revive patients in cardiac arrest; these new devices, which substantially increase the probability of a patient's survival, were not available in 1988. If the dispatcher receives a call reporting a patient in cardiac arrest, which ambulance should be sent? There is no doubt that, if both ambulances are available, the 1992 model ought to be dispatched. Why? Because the patient will have a higher probability of survival. This conclusion does not depend on any pejorative judgment as to the quality of the well-maintained 1988 model; in other contexts it is a fine machine. But it would be the wrong machine to send on this mission. The analogy to choosing between medical providers could not be closer.

If a provider negligently decides to perform a particular procedure, and the procedure results in injury to the patient, does the negligent act of the provider have enough of a causal link to the patient's injury to justify liability? At first blush, it would appear that there is a "but-for" causal connection between the decision and the injury. After all, if the provider had not performed the ill-considered procedure, the injury in question would not have resulted.

Further reflection reveals that the causation issue is more

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<sup>30</sup> See *supra* note 26.

<sup>31</sup> See *supra* text accompanying note 27.

complicated. The likely outcome of the procedure had it been performed by an alternate provider must be considered. It is possible that an adverse outcome might have occurred even if the procedure had been performed by a provider with a lower risk factor. Should this possibility affect the existence of liability or the measure of damages? The answer to this question triggers difficult analytical issues of both fact and law. In determining what would have happened to the patient if another provider had performed the procedure, the fact finder's task is not the typical fact reconstruction task of determining what actually happened—the other provider did *not* perform the procedure. Rather, the fact finder must determine what *would have* happened if an alternate provider had performed the procedure.<sup>32</sup> Moreover, the fact finder's determination will certainly be a probabilistic statement rather than a simple yes or no answer.<sup>33</sup>

How should the legal system compare the injury that *did* occur following the negligent act of performing the procedure with the injury that *might or might not have* occurred if an alternate provider had performed the procedure? On closer analysis, the answer to this probabilistic causation question depends on the relative risks associated with the two providers.<sup>34</sup> To see

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<sup>32</sup> The literature discussing the cause-in-fact requirement is voluminous. See, e.g., HERBERT L. A. HART and TONY HONORE, *CAUSATION IN THE LAW* (2d ed. 1985); ARNO C. BECHT & FRANK W. MILLER, *THE TEST OF FACTUAL CAUSATION IN NEGLIGENCE AND STRICT LIABILITY CASES* (1961); Wex S. Malone, *Ruminations on Cause-in-Fact*, 9 STAN. L. REV. 60 (1956); Leon Green, *The Causal Relation Issue in Negligence Law*, 60 MICH. L. REV. 543 (1962).

<sup>33</sup> A provider might legitimately argue in defense that despite the fact that she subjected a patient to greater than necessary risk by undertaking the procedure in question, the identical result would have taken place even had an alternate, less risky provider performed the procedure. While such proof is likely to be difficult to come by, we would clearly allow the defense to break the causal chain. See *infra* text accompanying notes 39-40.

<sup>34</sup> An extensive body of literature has developed dealing with the issue of probabilistic causation. See, e.g., Bert Black & David E. Lilienfeld, *Epidemiological Proof in Toxic Tort Litigation*, 52 FORDHAM L. REV. 732 (1984); Christopher L. Callahan, *Establishment of Causation in Toxic Tort Litigation*, 23 ARIZ. ST. L.J. 605 (1991); Richard Delgado, *Beyond Sindell: Relaxation of Cause-In-Fact Rules for Indeterminate Plaintiffs*, 70 CALIF. L. REV. 881 (1982); Michael Dore, *A Commentary on the Use of Epidemiological Evidence in Demonstrating Cause-In-Fact*, 7 HARV. ENV. L. REV. 429 (1993); Nancy Lee Firak, *The Developing Policy Characteristics of Cause-In-Fact: Alternative Forms of Liability, Epidemiological Proof and Trans-Scientific Issues*, 63 TEMP. L. REV. 311 (1990); Steve Gold, *Causation in Toxic Torts: Burdens of Proof, Standards of Persuasion, and Statistical Evidence*, 96 YALE L.J. 376 (1986); Leonard R. Jaffee, *Of Probativity and Probability: Statistics, Scientific Evidence, and the Calculus of Chance at Trial*,



how the relative risks affect the analysis, imagine two rather extreme situations.

EXAMPLE 1—Assume first that the provider in question had a 10% risk of adverse outcome from a particular procedure, while the risk associated with an alternate provider was zero; that is, an alternate provider would never have an adverse outcome from the procedure. Assume further that, based on this risk information, it was negligent for the provider in question to perform the procedure. This case is quite simple. Each time the provider in question performs the procedure with an adverse outcome, it can be said with certainty that the adverse outcome resulted from the negligent decision of the provider to perform the procedure. Therefore, the provider should be liable for the full damages associated with the adverse outcome.

EXAMPLE 2—At the other extreme, assume that for a particular procedure utilized only for gravely ill patients, the provider in question has a 70% risk of adverse outcome, while the risk associated with an alternate provider is 55%. Assume further that, based on this risk information, it was negligent for the provider in question to perform the procedure. Although the provider is negligent, one cannot say that the negligence *certainly* caused the adverse outcome. Of course, the legal system does not demand certainty. In a civil lawsuit, all that is typically required is that the plaintiff demonstrate his case by a preponderance of the evidence. Probablistically, this translates into a requirement that the plaintiff demonstrate that it is more likely than not that the facts supporting liability are present—i.e., the plaintiff must show that the probability is greater than 0.5.<sup>35</sup> In this hypothetical situation, since the doctor's negligence caused only a slight increase in the likelihood of an adverse outcome, it cannot be said that the provider, more likely than not, brought about the

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46 U. PITT. L. REV. 925 (1985); Joseph H. King, Jr., *Causation, Valuation and Chance in Personal Injury Torts Involving Preexisting Conditions and Future Consequences*, 90 YALE L.J. 1353 (1981); Saul Levmore, *Probablistic Recoveries, Restitution, and Recurring Wrongs*, 19 J. LEG. STUD. 691 (1990); Glen O. Robinson, *Probablistic Causation and Compensation for Tortious Risk*, 14 J. LEG. STUD. 779 (1985); David Rosenberg, *The Causal Connection in Mass Exposure Cases: A "Public Law" Vision of the Tort System*, 97 HARV. L. REV. 849 (1984); Richard W. Wright, *Causation, Responsibility, Risk, Probability, Naked Statistics, and Proof: Pruning the Bramble Bush by Clarifying the Concepts*, 73 IOWA L. REV. 1001 (1988); Laura L. Gonsakves, Note, *Probability of Causation in Radiation Tort Litigation*, 24 TULSA L.J. 479 (1989).

<sup>35</sup> See generally Cohen, *supra* note 26.

adverse results. Rather, it is more likely than not that the patient would have suffered the same adverse result even if an alternate provider had performed the procedure.

Should the negligent provider prevail because of the patient's inability to state with high enough probabilistic certainty that the negligence brought about the adverse result? Certainly a rule that the negligent provider should always prevail in a case like Example 2 will result in fewer fact finding errors than a rule that the negligent provider always loses. After all, the risk factors suggest that for every 70 adverse outcomes that would result from procedures performed by the provider in question, 55 would have occurred anyway if the procedure were performed by the typical provider. Yet to hold the negligent providers not liable is to immunize them for the effects of their negligence. For every 100 procedures performed by a typical provider, the risk factors suggest that there would be 45 favorable outcomes and 55 adverse outcomes. For every 100 procedures performed by the provider in question, however, the risk factors suggest that there would be 15 additional cases with an adverse outcome and, correspondingly, 15 fewer cases with favorable outcomes.

How should the legal system account for the 15 additional adverse results flowing from the provider's negligent decision to perform the procedure even though, in any particular case, it is less likely than not that adverse results resulted from that decision? The legal system does not deal well with questions of this sort, and there is no obvious solution that comports with notions of accuracy and individual justice. We would, with some reluctance, follow the lead of the concurring opinion in *Herskovitz v. Group Health Cooperative of Puget Sound*,<sup>36</sup> awarding the patient a partial recovery based on the decreased chance of a successful procedure brought about by the provider's negligence. The trend toward proportional recovery in "lost chance" cases has generated considerable momentum and provides a real option for resolving intractable causation cases when traditional standards cannot be met and may be inapposite.<sup>37</sup>

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<sup>36</sup> 664 P.2d 474, 479 (Wash. 1983) (Pearson J., concurring).

<sup>37</sup> In *Herskovitz* plaintiff-decedent contended that the failure of a physician to timely diagnose lung cancer reduced his chance of recovery from 39% (Stage 1 tumor) to 25% (Stage 2 tumor). The concurring opinion by Judge Pearson, relying on Joseph H. King, *Causation, Valuation and Chance in Personal Injury Torts Involving Preexisting Conditions and Future Consequences*, 90 YALE L.J. 1353 (1981), suggested that plaintiff

The proportional recovery would work as follows: of every 100 patients treated by the provider in question, 70 would have an adverse outcome. Fifty-five of those 70 would have suffered the adverse outcome even if the procedure had been performed by the alternate provider, while 15 of the adverse outcomes can be said to have resulted from the increased risk associated with the provider in question. Thus, if all 70 unfortunate patients sued the provider, the provider's total liability should be for 15 adverse outcomes. Accordingly, each patient should receive a recovery that represents 15/70 of his total injury.<sup>38</sup>

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be granted the proportion of his damages recovery reflecting the percentage of lost chance created by the physician's negligence. *Accord* Broody v. United States, 706 F. Supp. 1548, 1564-67 (D. Kan. 1989); Mays v. United States, 608 F. Supp. 1476, 1482 n.1 (D. Colo. 1985); DeBurharte v. Louvar, 393 N.W.2d 131, 139 (Iowa 1986); Falcon v. Memorial Hospital, 462 N.W.2d 44, 56-57 (Mich. 1990); Aasheim v. Humberger, 695 P.2d 824 (Mont. 1985) (citing with approval the doctrine of proportional causation, but not clearly adopting proportional recovery); Perez v. Las Vegas Medical Center, 805 P.2d 589, 592 (Nev. 1991); Scafidi v. Seiler, 574 A.2d 398, 406-07 (N.J. 1990); McKellips v. Saint Francis Hospital, 741 P.2d 467, 476 (Okla. 1987).

For a discussion of the authors' views as to how lost chance percentages should be calculated, see *infra* text accompanying note 38. Other courts totally reject recovery for "lost chance." See, e.g., Gooding v. University Hospital Building, Inc. 445 So.2d 1015, 1020-21 (Fla. 1984); Fennell v. Southern Maryland Hospital, 580 A.2d 206, 211 (Md. 1990); Clayton v. Thompson, 475 So.2d 439, 445 (Miss. 1985); Pillsbury-Flood v. Portsmouth Hospital, 512 A.2d 1126, 1129 (N.H. 1986); Cooper v. Sisters of Charity of Cincinnati, 272 N.E.2d 97, 103 (Ohio 1971).

However, a significant number of courts recognize recovery for "lost chance" even when the likelihood that death or injury would have been avoided is under 50%. For the most part, it appears that once the "lost chance" is established, the courts leave the issue of recovery to jury discretion without instruction that damages are to be reduced by some fixed proportion. See e.g., Jones v. United States, 483 F. Supp. 581, 587-88 (N.D. Cal. 1980); Thompson v. Sun City Community Hospital, Inc., 688 P.2d 605-16 (Ariz. 1984); Sharp v. Kaiser Foundation Health Plan of Colorado, 710 P.2d 1153, 1156 (Colo. App. 1985); Jones v. Montefiore Hospital, 431 A.2d 920, 924 (Pa. 1981); Brown v. Kouziahis, 331 S.E.2d 440, 446 (Va. 1985); Thornton v. CAMC, Etc., 305 S.E.2d 316, 323-24 (W.Va. 1983); Ehlinger v. Sipes, 454 N.W.2d 754, 763 (Wis. 1990).

<sup>38</sup> The courts that have granted proportional recovery have opted for a slightly different and, we believe, inaccurate formula. Consider, for example, the following discussion in *McKellips*, 741 P.2d at 477:

To illustrate the method in a case where the jury determines from the statistical findings combined with the specific facts relevant to the patient the patient originally had a 40% chance of cure and the physician's negligence reduced the chance of cure to 25%, (40%-25%) 15% represents the patient's loss of survival. If the total amount of damages proved by the evidence is \$500,000, the damages caused by defendant is 15% x \$500,000 or \$75,000.

*Id.* at 477. Under the formula suggested in *McKellips* though, for every 100 patients treated by the negligent physician, 75 would have had adverse outcomes. Sixty patients would have died even if an alternate provider had performed the procedure; 15 extra

What about cases between the extremes? Consider the following two cases:

*Example 3*—Assume that for a particular procedure the provider in question has a 15% risk of adverse outcome, while the risk associated with an alternate provider is 10%. Assume further that, based on this risk information, it was negligent for the provider in question to perform the procedure. Finally, assume that performance of the procedure results in an adverse outcome for the patient. Is the provider in question liable for the damages associated with the adverse outcome?

At first glance, this case may seem easily distinguishable from Example 2. The provider in question negligently proceeded with the procedure and the adverse outcome resulted. Had an alternate provider performed the procedure, on the other hand, there would have been a 90% chance that the adverse outcome would not have occurred. It would seem, then, that it is more likely than not that the adverse outcome can be blamed on the risky provider's negligent decision.

Upon closer analysis, however, the negligence of the provider in question only raised the probability of suffering an adverse outcome from 10% to 15%. Therefore, of the 15 adverse outcomes that could be expected from every 100 procedures performed by the negligent provider, 10 could have been expected to result even with a non-negligent provider. Thus, the chances are only  $\frac{1}{3}$  that the adverse outcome resulted from the negligent decision to proceed.

How should the legal system respond? Once again, the authors would adopt an approach that would allow for proportional recovery.

*Example 4*—Assume that for a particular procedure the provider in question has a 15% risk of adverse outcome, while the risk associated with an alternate provider is 5%. Assume further that, based on this risk information, it was negligent for the provider in question to perform the procedure. Finally, assume that performance of the procedure results in an adverse outcome for the patient. Should the provider in question be liable for the damages associated with the adverse outcome?

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deaths are, therefore, attributable to the negligent physician. In our view, the patient is thus entitled to 15/75 or 20% of full damages rather than the 15% suggested by the *McKellips* court.

While superficially similar to Example 3, this example is actually quite different. In Example 3, only a minority of the adverse outcomes expected from procedures performed by the provider in question would result from the increased risk associated with that provider. In Example 4, on the other hand, of the 15 adverse outcomes that can be expected from every 100 procedures performed by the provider in question, only 5 would be expected from an alternate provider. In other words, two out of every three adverse outcomes occurring with the provider in question result from the increased risk associated with that provider. Thus, it is more likely than not that the adverse outcome in this particular case resulted from the decision of the provider in question to perform the procedure.

Does this mean that the provider is liable whenever an adverse outcome results from a provider's negligent decision to perform a procedure in a case such as Example 4? The temptation is to say yes. After all, in each case, it is more likely than not that the negligent decision "caused" the outcome and therefore, under the proof standard traditionally applicable in civil cases, the plaintiff would be entitled to full recovery. Yet if recovery is granted in all such cases, there will be, in the aggregate, overcompensation to patients and overpayment by providers. If the provider in Example 4 performed 100 such procedures, 15 adverse outcomes would be expected. For each of these 15 cases, it was more likely than not that the provider's negligence caused the adverse outcome. Yet in only 10 of the 15 cases did the provider's negligence actually *cause* the adverse outcome. If full recovery is given in all 15 cases, there will be overcompensation and overpayment to the extent of 5 extra payments.

Of course, we cannot determine which are the five extra cases. What can be done to avoid overcompensation? We would award damages to each patient who suffers an adverse outcome under these circumstances, but reduce the amount of the recovery to account for the proportion of "extra" cases in which the adverse outcome would have occurred if an alternate provider had performed the procedure. Thus, applying the proportional recovery rule to this example, the patient's recovery would be reduced by  $\frac{1}{3}$  to account for the 5 out of every 15 patients who would have suffered the adverse outcome if an alternate provider had performed the procedure. By giving each patient who

suffers an adverse outcome such a proportionate recovery, the aggregate compensation will be accurate. The disadvantage of this approach, of course, is that while aggregate compensation will always be accurate, individual compensation will never be accurate. Ten of the 15 patients will be undercompensated and 5 will be overcompensated.

One final question must be addressed. The preceding analysis has dealt with recovery for a negligent decision to perform a procedure. Is there any role for evidence as to whether the procedure in question was itself *performed* negligently in a lawsuit based on the negligent *decision* to perform the procedure?

In cases in which the decision to perform the procedure is negligent, evidence that the procedure was also performed negligently does not augment the case that the provider should be liable for her improper decision. The improper decision to perform the procedure is sufficient for liability to attach. However, evidence of negligent performance may provide the predicate for a classical malpractice action.<sup>39</sup>

What about evidence that the procedure was not performed negligently? Can the provider introduce this evidence in a case

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<sup>39</sup> It could be argued that the possible overlap of classical (negligent performance) malpractice and a cause of action for a negligent decision to perform a procedure could result in excess liability for providers. The theory would be that an important ingredient of a provider's high risk factor might be a frequency of cases in which the provider performs the procedure negligently. If, under traditional malpractice law, those who could prove that they were victims of the negligent performance recovered 100% of their harm, while, under the cause of action set forth in this article, those who had similar adverse outcomes, but could not prove negligent performance, got a proportionate recovery, the total of all recoveries would exceed the total harm. This excess liability problem is theoretically present. However, given the small percentage of malpractice victims who bring claims against their providers, is very unlikely to ever result in actual overpayment by defendants. See REPORT BY THE HARVARD MEDICAL PRACTICE STUDY TO THE STATE OF NEW YORK, PATIENTS, DOCTORS, AND LAWYERS, MEDICAL INJURY, MALPRACTICE LITIGATION, AND PATIENT COMPENSATION IN NEW YORK (1990).

It is interesting that this problem of overdeterrence is inescapable whenever the law permits recovery on a statistical basis, but also simultaneously permits traditional individual litigation. For example, most courts that allow market-share liability in products liability litigation, see *Sindell v. Abbott Laboratories*, 607 P.2d 924 (Cal. 1980), cert. denied, 449 U.S. 912 (1980), also permit an individual defendant to prove itself out of the case by establishing that its product was not the cause of the plaintiff's harm. A defendant who proves itself out of the case shifts its percentage of the harm to other defendants who are not able to prove that their products were not responsible for the harm. For a more extensive discussion of this phenomenon, see Aaron D. Twerski, *The Problem of Indeterminate Defendants: Market Share and Non-Market Share Liability—A Tale of Two Centuries*, 55 BROOK. L. REV. 869, 872-73 (1989).

based on the provider's negligent decision to perform the procedure? The answer here is quite subtle. The action against the provider for a negligent *decision* to perform does not depend on the performance itself being negligent—it was negligent to expose the patient to the higher risk associated with even competent performance of the procedure by this provider. However, if the provider can demonstrate that *this* patient would have suffered the adverse outcome even if an alternate provider had performed the procedure, the causal link between the negligent *decision* and the outcome is broken and the patient should not recover. In most circumstances, though, it is highly unlikely that the provider can make this showing.<sup>40</sup>

## 2. Informed Consent

We begin our analysis of the informed consent doctrine as it relates to provider-specific information by first outlining the traditional cause of action where the information concerns risks associated with the procedure. What must plaintiffs prove when they claim that a doctor failed to disclose the risk of, or the alternatives to, a recommended treatment? Courts universally agree that a doctor has a duty to inform a patient about material risks of a therapeutic intervention.<sup>41</sup> Considerable controversy exists as to how materiality is to be measured. In the early years of informed consent litigation, courts took the position that the standard for medical disclosure was that information which a "reasonable doctor" would provide under the circumstances.<sup>42</sup>

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<sup>40</sup> The analogy to *res ipsa loquitur* is quite compelling. Once a plaintiff has established a credible *res ipsa* case it is difficult for the defendant to rebut it by merely producing evidence of "reasonable conduct" on his part. As one commentator noted, it raises a gnawing question: if the defendant's conduct was so good, why did the injury occur? See Fleming James, Jr., *Proof of Breach in Negligence Cases (Including Res Ipsa Loquitur)*, 37 VA. L. REV. 179, 227 (1951); see also *Cox v. Northwest Airlines, Inc.*, 379 F.2d 893 (7th Cir. 1967), cert. denied, 389 U.S. 1044 (1968); *Goldstein v. Levy*, 132 N.Y.S. 373 (N.Y. App. Term. 1911). At most, such rebuttal evidence of non-negligence goes to the jury together with the *res ipsa* inference. Ultimately, the only effective way to rebut a *res ipsa* case is to point to an alternative cause that explains why the injury happened. A provider who is found to be negligent for having undertaken to perform a procedure will have difficulty defending his case unless he can establish another cause—other than his presumed negligence—that would have caused the injury even if the procedure were performed by an alternate provider.

<sup>41</sup> See PROSSER & KEETON, *supra* note 2, § 32 at 189-192; *FOWLER v. HARPER ET AL.*, THE LAW OF TORTS § 17.1 at 558-67 (2d ed. 1989).

<sup>42</sup> Beginning with *Natanson v. Kline*, 350 P.2d 1093 (Kan. 1960), courts articulated

This test was identical to the standard that governed negligent medical treatment. Expert medical testimony regarding what a prudent doctor would tell similarly situated patients was almost invariably required. Two decades ago several leading courts took issue with this medical standard, finding it an inadequate measure of the amount of information that a patient should be entitled to receive before choosing a therapeutic intervention.<sup>43</sup> To foster greater patient autonomy, these courts defined a risk as material if a reasonable person in the patient's position would wish to know of the risk or the therapeutic alternative prior to making a decision. Because the standard was no longer based on medical expertise, a plaintiff was not obliged to produce expert testimony to establish what information should have been transmitted. Juries were entitled to conclude from a description of the options whether a "reasonable person" would have desired the information in question.

If a patient successfully establishes breach of the duty to inform, yet another set of obstacles must be overcome. First, the plaintiff must establish that the medical procedure chosen by the physician was responsible for the plaintiff's injuries (injury causation).<sup>44</sup> For the most part this aspect of causation is rather easily established. Almost always the risk not warned against materialized. Had a different intervention or no intervention been chosen, that risk would not have resulted. Admittedly, problems arise because of the possibility (often the likelihood) that had another course of action been chosen other risks would have materialized in injury.<sup>45</sup> But the direct cause of the harm that the plaintiff actually did suffer is not often in question. The

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the standard for medical disclosure as that information which a reasonable medical doctor would provide under the circumstances. See, e.g., *Rush v. Miller*, 648 F.2d 1075, 1076 (6th Cir. 1981); *Shetter v. Rochelle*, 409 P.2d 74, 86 (Ariz. 1965), modified, 411 P.2d 45 (Ariz. 1966); *Fuller v. Starnes*, 597 S.W.2d 88, 89 (Ark. 1980); *Ditlow v. Kaplan*, 181 So.2d 226, 228 (Fla. 1965); see also, Annotation, *Modern Status of Views as to General Measure of Physician's Duty to Inform Patient of Risks of Proposed Treatment*, 83 A.L.R. 3d 1008 (1978).

<sup>43</sup> See, e.g., *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972); *Cobbs v. Grant*, 502 P.2d 1 (Cal. 1972); *Wilkinson v. Vesey*, 295 A.2d 676 (R.I. 1972); *Miller v. Kennedy*, 522 P.2d 852 (Wash. 1974), *aff'd per curiam*, 530 P.2d 334 (Wash. 1975).

<sup>44</sup> See Alan Meisel & Lisa D. Kabnick, *Informed Consent to Medical Treatment: An Analysis of Recent Legislation*, 41 U. PITT. L. REV. 407, 438-39 (1980).

<sup>45</sup> See Epstein, *supra* note 17, at 121-25; Schultz, *supra* note 2, at 283-91.



procedure chosen by the physician to treat the patient will almost always be responsible for the adverse result.

A second obstacle to recovery involves the requirement that a patient must convince the court that, had the information withheld been given, the patient would have chosen a different course of action—one that would have avoided the injury (decision-causation). Once again courts differ in how properly to articulate the test for determining this aspect of causation. Most ask whether a reasonable person would have decided to forgo the injury-causing therapy had the information been given.<sup>46</sup> A few courts focus directly on the particular plaintiff—would *this* patient have decided otherwise.<sup>47</sup> Under either test the plaintiff's burden is significant.

In an informed consent case the contention is not that the doctor's medical advice in recommending a given procedure was deficient, but rather that the patient's consent would have been withheld if more information had been provided. As noted earlier, it is often difficult to convince a jury that a patient would have rejected sound medical advice to cure or alleviate an immediate problem had he known the risk, or that a patient would have chosen another therapeutic procedure against the advice of his treating physician who believed that the recommended therapy was best for the patient.<sup>48</sup>

While the fundamental structure of the traditional informed consent case and a case based on the failure to inform patients of the special risks that arise due to the identity of the provider remain the same, provider-specific informed consent raises a host of issues that have never been addressed.

First and foremost, does a provider have a duty to disclose information that identifies the provider as an independent risk factor? The answer, we believe, is yes. This information relates

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<sup>46</sup> *Canterbury*, 464 F.2d at 790-91; *Cobbs*, 502 P.2d at 11-12; *Reikes v. Martin*, 471 So.2d 385, 392-93 (Miss. 1985). A large majority of courts that adopted the *Canterbury* test, which judges materiality by a lay rather than a medical standard, follow this view on causation. See 3 MAKING HEALTH CARE DECISIONS, *supra* note 2, App. L., at 193, 206-45.

<sup>47</sup> Following *Canterbury*, only a small minority of jurisdictions test causation by a subjective standard (i.e., what would this particular patient have decided if provided with the requisite information?). *Scott v. Bradford*, 606 P.2d 554, 557-58 (Okla. 1979); *Arina v. Gingrich*, 733 P.2d 75, 79 (Or. 1987); *Wilkinson v. Vesey*, 295 A.2d 676, 689 (R.I. 1972).

<sup>48</sup> See *supra* note 15.

directly to the results likely to flow from a decision to have this provider perform this procedure. It is not difficult to conclude that a reasonable doctor should provide this potentially outcome determinative information to the patient and that a reasonable patient would want this information as part of the decision-making process.

This type of potentially outcome determinative information can be distinguished from other provider-specific information. One of the authors regularly asked his class over the years whether an obstetrician is required to tell her patients that she received a grade of C- on her examination in obstetrics. What if she took examinations for board certification and failed them the first two times and barely passed the last time? Might not a "reasonable patient" want to know that information before placing herself in the hands of the surgeon? That a patient might wish to have this information does not resolve the duty question. A patient might wish to know many things about the background of a surgeon before going under the knife. Did the surgeon sleep poorly the night before surgery due to a domestic dispute with a spouse? Before coming to surgery, did the provider's stockbroker call, insisting that a margin call be met?

Ultimately the decision of what information is material for the purpose of informed consent is a question of law for the courts. Courts will likely conclude that this sort of general background information and much idiosyncratic data about a physician need not be revealed because as a matter of public policy it is not sufficiently focused, relating only tangentially to physician performance. Any link to likely results in a particular case is highly speculative. Moreover, if this genre of information were introduced at trial, there would be legitimate concern that the prejudicial impact would outweigh its probative value.<sup>49</sup>

There is no litmus test to help discern which items need be revealed and which may be concealed. However, provider-specific data geared to a clearly delineated surgical procedure will pass a threshold duty test. If information is available that identifies a particular provider as an independent risk factor, courts will treat this information just as they treat other risk information that must be passed on to patients for their consideration.

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<sup>49</sup> JOHN W. STRONG, *MCCORMICK ON EVIDENCE* § 185 (4th ed. 1992).

Having decided that provider-specific risk information is subject to the same disclosure principles as other risk information, the next issue to determine is under what circumstances such information must be disclosed. To establish a claim, a patient must prove that a medical provider failed to inform him of material risks. In this context, as was the case with the provider's negligent decision to perform the procedure, materiality encompasses two separate considerations. First, a determination must be made that a difference exists between the performance of one provider and another.<sup>50</sup> Second, the magnitude of the difference must be such that disclosure is warranted.<sup>51</sup>

These two factors—the significance of the difference in relative risks between the provider in question and an alternate provider, and the magnitude of that difference—are the same factors identified in the discussion concerning a provider's negligent decision to perform a procedure.<sup>52</sup> However, the factors would be applied somewhat differently here. First, we would not require as large a difference in risks in the duty to disclose context as in the negligent decision to perform context. Imagine a provider whose performance of a particular procedure is riskier than the performance of a typical provider, but not so much so that it is negligent for the provider to perform the procedure at all. The increased level of risk may be substantial enough, nonetheless, that a reasonable doctor would disclose it to her patient and a reasonable patient would want to know about it in making his decision.

Second, a less stringent significance test would be employed to determine whether the difference in risk factors between the provider in question and the alternate provider is significant—such as whether the difference in risk factors reflects a true difference in likely outcomes or is merely an illusion resulting from random factors in the data. Similarly, in determining whether the magnitude of the difference between the provider's risk factor and that of the alternate provider exceeds the threshold described in the previous paragraph, a less stringent significance test would also be used. The less stringent the test, the easier it will be for the patient to demonstrate significance. In

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<sup>50</sup> See *supra* note 25.

<sup>51</sup> See *supra* text accompanying note 26.

<sup>52</sup> See *supra* notes 25-26 and accompanying text.

choosing a less stringent significance test in the informed choice context, the authors are guided by the observation that relative costs of erroneous determinations in the informed choice context are different than in the negligence context. The cost to the provider of an incorrect determination that she should disclose relative risk information about a procedure is much less than the cost to a provider of an incorrect determination that she should refrain from performing the procedure at all.<sup>53</sup>

Assuming that a patient can establish that the provider should have disclosed the provider-specific information, he must still successfully establish a causal relationship between the failed communication and the injury suffered. Strangely enough, the causation issue will remain a formidable obstacle for plaintiff recovery, albeit for reasons that are very much different than are present in a traditional informed consent case. Earlier it was noted that two causation questions must be addressed—*injury-causation* and *decision-causation*. In the run-of-the-mill informed consent case, *decision-causation* is quite difficult to demonstrate while *injury-causation* is relatively simple to prove. With regard to provider-specific informed consent, the reverse is likely to be true.

Establishing the *decision-causation* linkage that is so problematic in the traditional informed consent case is much more plausible in provider-specific cases. In the traditional informed consent case it is often difficult to convince a jury that a patient faced with a serious illness and having received a proposed treatment plan would have rejected treatment had the doctor informed the patient of risks attendant to the procedure, or the possibility of undergoing an alternative procedure with its own set of risks. Since, by hypothesis in an informed consent case, the doctor's advice is non-negligent, a jury is likely to conclude that a patient's *ex post* remonstrations would never have been

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<sup>53</sup> Significance tests—whether they require significance at the 0.01 level (99% confidence level), 0.05 level (95% confidence level) or 0.10 level (90% confidence level)—reflect a choice about how to balance the cost of errors resulting from incorrect determinations as to whether the truth of an hypothesis has been demonstrated. See Cohen, *supra* note 26. By choosing a less stringent test in the informed choice context than in the negligence context, we reflect our belief that the ratio between the cost of incorrectly determining that there is a substantial difference in risk between the provider in question and an alternate provider, and incorrectly determining that there is no substantial difference, is higher in the negligence context than in the informed choice context. *Id.*

made *ex ante* even had the information been made available.<sup>54</sup> With regard to provider-specific information, however, it is very likely that a jury will find a patient's statement credible that, had he known that a physician with a better success rate was available, the patient would not have agreed to undergo surgery at the hands of a less skilled surgeon. This assertion has a common sense ring of truth.

In traditional informed consent cases, a patient rarely has difficulty in establishing that the injury was caused as a result of the physician's unauthorized medical intervention. The patient almost always predicates the case on the doctor's failure to inform him of a specific risk or an alternative treatment that would have avoided the risk that eventuated. Thus the answer to the "but-for" question—had the doctor properly informed the patient and had the patient chosen against the therapeutic intervention would the injury have been avoided—is almost certainly affirmative.

In provider-specific informed choice claims, on the other hand, the injury causation question will be far more troublesome. Had the patient chosen a different physician, or a different hospital, to perform the surgery, it is still possible that the same injury would have resulted. Even an alternate provider would have some adverse outcomes. If a court is required to resolve this question using traditional causation norms, injury-causation will be difficult to establish and the same type of over and under compensation problem discussed earlier will surface.<sup>55</sup> Accordingly, courts should draw on proportional causation principles to resolve the causation dilemma.<sup>56</sup> However, unlike cases involving the negligent decision to perform the medical procedure, the differential between one provider and an alternate (once this type of negligence is removed from the picture) is not likely to result in a significant proportional recovery.

At this point, the question of whether in a world of perfect information all patients would have access to the very best surgeons is put aside. The authors suspect that ranking is likely to lead to a very significant rush to the top of the list, thus relegating many patients to other than the "super stars." This would,

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<sup>54</sup> See *supra* notes 25-26.

<sup>55</sup> See *supra* discussion in text accompanying notes 32-39.

<sup>56</sup> *Id.*

of course, complicate the materiality and injury-causation questions even further. If most patients would have no access to other than second-tier surgeons, for example, the skill differential between the surgeon actually chosen and the available surgeon may turn out to be either statistically insignificant, or so small that injury causation cannot be established in any credible way.

### 3. The Real World: Where Negligence and Informed Consent Meet

The foregoing discussion posited a world where negligent performance of a procedure and informed consent are very separate and easily distinguishable causes of action. In the real world of litigation, lawyers know that not to be true. Plaintiffs consider them as complementary causes of action with each strengthening the other. Thus, whether the informed choice case is strong enough to stand alone is often of little relevance. If a patient can portray the physician as less than forthright or downright unknowledgeable about the treatment alternatives, it helps bolster the claim that the medical intervention actually chosen was not the proper one for this particular patient. As long as the patient has presented a plausible case on informed consent or negligent decision to perform a procedure, whether the patient wins or loses on informed consent alone may make little difference. Even if the plaintiff should lose the informed consent claim, the jury will have been privy to the evidence. The value of limiting instructions in wiping away the impressions left by the damaging testimony is questionable.

In this context, litigation involving provider-specific risk information may have major significance. Of course, this raises a question of whether courts should refuse to try provider-specific informed choice or negligent decision to perform a procedure cases in conjunction with the traditional malpractice claims because one will so heavily prejudice the other. Although the spillover effect is present today when both informed consent and medical malpractice are tried together, the taint would probably become more serious when a physician charged with malpractice was portrayed as one whose relative risk factor places her below the average.

## CONCLUSION

This Note has attempted to provide a sneak preview of the fascinating issues that will surface when litigators attempt to use provider-specific statistics in the context of tort litigation against hospitals and doctors. Many may argue that the pervasive use of such statistical data in the legal arena is against public policy, contending that: many physicians will refuse to take on high-risk patients for fear that their statistics will be negatively effected; intern and resident programs will be hampered by statistics which show that beginners do not perform as well as seasoned veterans; medical consumers are incapable of understanding the fine points of statistical significance and will misunderstand and thus misuse the information that is revealed to them; and an already overburdened court system cannot handle such difficult statistical problems and integrate them into highly individualistic malpractice litigation. While these arguments have merit, they will ultimately fail. As the quantity and quality of provider-specific statistics increase, the pressure for the legal system to integrate them into litigation will become inexorable. Provider specific statistics will likely be used for peer review, insurance rate-setting and physician selection by patients. It is unlikely that these statistics will be excluded from the tort litigation system.