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INFORMED CONSENT: NO LONGER JUST WHAT THE DOCTOR ORDERED?

THE “CONTRIBUTIONS” OF MEDICAL ASSOCIATIONS AND COURTS TO A MORE PATIENT FRIENDLY DOCTRINE

MARC D. GINSBERG^{*}

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I. INTRODUCTION

Unquestionably, the doctrine of informed consent is one of the hallmarks of the physician-patient relationship. At a time when the patient is in need of treatment, the patient is most reliant on the knowledge and skill of the

physician. The patient needs the physician's services and the physician knows it. The physician has all of the medical, scientific, and technical information about the necessary treatment or procedure and the patient knows it. There is no balance of power in this relationship. In fact, there is a characteristic "imbalance of power, owing to the vulnerability of illness and treatment and physicians' vastly superior knowledge and skills."¹

The doctrine of informed consent may, in a sense, act in an effort to level the uneven playing field. It is grounded in patient autonomy² and the notion that unconsented treatment constitutes an intentional tort or negligence.³ Judge Cardozo's pronouncement in *Schloendorff v. Society of New York Hospital*,⁴ that:

[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages,⁵ has occupied a sacred place in the law of informed consent.⁶ Interestingly, from a historical perspective, there is reliable evidence that medical informed consent dates back to ancient times.⁷

The doctrine of informed consent requires physicians to disclose to patients (without having been asked by the patient) the risks and benefits of, and

1. MARK A. HALL, MARY ANNE BOBINSKI & DAVID ORENTLICHER, MEDICAL LIABILITY AND TREATMENT RELATIONSHIPS 200 (Erwin Chemerinsky et al. eds., 2005).

2. BARRY R. FURROW ET AL., HEALTH LAW 310 (West Group, 2d ed. 2000).

3. *Id.* at 311-13.

4. *Schloendorff v. Society of New York Hosp.*, 105 N.E. 92 (N.Y. 1914), *abrogated by* *Bing v. Thunig*, 143 N.E.2d 3 (N.Y. 1957), *superseded by statute* N.Y. Public Health Law § 2805-d (2010), *as recognized in* *Staroztynyk v. Reich*, 871 A.2d 733, 741 (N.J. Super. Ct. App. Div. 2005) (*abrogated in Bing* on issue of charitable immunity).

5. *Schloendorff*, 105 N.E. at 93.

6. *See Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir. 1972) (citing *Schloendorff* and noting that "[t]rue consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each"); *Thor v. Superior Court*, 855 P.2d 375, 378 (Cal. 1993) (citing *Schloendorff* and noting that pronouncements such as the one made by Judge Cardozo "predate the recent rapid advancements in medical technology with their attendant ethical, moral, and social implications").

7. P. Dalla-Vorgio et al., *Is Consent in Medicine a concept only of Modern Times?*, 27 J. MED. ETHICS 59, 59-61 (2001); Constantinos Trompoukis & John Lascaratos, *Surgical Operations During The Ottoman Period: Informed Consent According to Documents of The Ottoman Archives of Crete*, 10 T. KLIN. J. MED. ETHICS, L. & HIST. 163, 163-67 (2002).

alternatives to, proposed treatment.⁸ The doctrine may be based in common law⁹ or in statute.¹⁰

There are various models of informed consent, which have been well described in the literature. Essentially, these are the physician-based and patient-based models.¹¹ Simplistically, the physician-based model requires disclosure of “risks, results or alternatives that a reasonable medical practitioner of the same school, in the same or similar circumstances, would have disclosed,”¹² while the patient-based model requires disclosure of information material to the patient’s treatment decision.¹³ There are also subcategories of these models that have been discussed.¹⁴

The doctrine of informed consent is, regrettably, more significant than it ought to be. At this point in time, the doctrine might assist the patient to access information which will remain unknown to all but knowledgeable, curious and inquisitive patients – information concerning the quality of the physician, physician performance, physician economic/research interests, physician illness and disability, operative logistics and operative devices. Yet this is only the case if the doctrine requires disclosure of this information.

II. CAN A PATIENT ACCESS MEANINGFUL INFORMATION ABOUT A PHYSICIAN?

Again, it is important to understand that the doctrine of informed consent requires a physician-to-patient disclosure even if the patient seeks no information from the physician,¹⁵ that is, asks no questions of the physician

8. *Canterbury*, 464 F.2d at 783. The classic informed consent case arises from the lack of physician voluntary disclosure. For a very recent decision concerning the physician’s duty to disclose physician-specific information following a patient inquiry, see *Willis v. Bender*, 596 F.3d 1244, 1254 (10th Cir. 2010) (applying Wyoming law).

9. See *Ficke v. Evangelical Health Systems*, 674 N.E.2d 888, 889 (Ill. App. Ct. 1996) (applying Illinois law and explaining that informed consent is a common law principle).

10. See *Blotner v. Doreika*, 678 S.E.2d 80, 81 (Ga. 2009) (noting that the state of Georgia does not recognize the common law doctrine of informed consent).

11. See Jaime Staples King & Benjamin Moulton, *Rethinking Informed Consent: The Case For Shared Medical Decision-Making*, 32 AM. J.L. & MED. 429, 480-83 (2006) (discussing both the physician based and patient based models). See also Julie M. Spanbauer, *Breast Implants as Beauty Ritual: Woman’s Sceptre and Prison*, 9 YALE J.L. & FEMINISM 157, 190 (1997) (mentioning both models as well).

12. *Guebard v. Jabaay*, 452 N.E.2d 751, 755 (Ill. App. Ct. 1983).

13. *Canterbury v. Spence*, 464 F.2d 772, 772 (D.C. Cir. 1972).

14. King & Moulton, *supra* note 11, at 480-83.

15. *Canterbury*, 464 F.2d at 783 (“We discard the thought that the patient should ask for information before the physician is required to disclose. Caveat emptor is not the norm for the consumer of medical services. Duty to disclose is more than a call to speak merely on the patient’s request, or merely to answer the patient’s questions; it is a duty to volunteer, if necessary, the information the patient needs for intelligent decision. The patient may be ignorant, confused, overawed by the physician or frightened by the hospital, or even ashamed to inquire. Perhaps relatively few patients could in any event identify the relevant questions in the absence

during a pre-treatment or pre-procedure conference with the physician. If the patient could rely on the physician to provide physician performance, quality, personal factor and other logistical information through the informed consent process, the patient would have access to significant information to allow for more reasoned treatment choices. Unfortunately, as this paper will reveal, this is, at best, a hit and miss proposition insofar as the informed consent process is largely shaped by courts. Exacerbating this problem is that this information is not otherwise routinely available to patients, and physician associations¹⁶ have not stressed to their members the need to use the informed consent process to disclose more than the classic “risks of the procedure, its necessity, and alternative procedures that might be preferable.”¹⁷

It is often considered, wished, hoped, urged or questioned that the modern patient is a healthcare consumer,¹⁸ although the characterization of the patient as consumer is not of totally recent vintage.¹⁹ Consumers of healthcare need and should have access to quality and performance informa-

of prior explanation by the physician. Physicians and hospitals have patients of widely divergent socio-economic backgrounds, and a rule which presumes a high degree of sophistication which many members of society lack is likely to breed gross inequities.”). See also *Sard v. Hardy*, 367 A.2d 525, 543 (Md. Ct. Spec. App. 1976) (Davidson, J., dissenting) (“It is also the fiducial quality of the relationship which relieves the patient from the obligation to inform himself.”), *rev'd*, 379 A.2d 1014 (Md. 1977).

16. This paper focuses primarily on the American Medical Association and the American College of Surgeons.

17. DAN B. DOBBS, *THE LAW OF TORTS* 653 (2000).

18. See AM. MED. ASS'N, *A GUIDE TO PATIENT SAFETY IN THE MEDICAL PRACTICE* 18 (2008) (noting that “[p]atients, as consumers, are becoming much better informed and more concerned about evidence-based medical care, health care, quality, and patient safety”) [hereinafter “AMA Guide”]; Robert A. Berenson & Christine K. Cassel, *Consumer-Driven Health Care May Not Be What Patients Need – Caveat Emptor*, 301 J. AM. MED. ASS'N. 321, 321-23 (2009) (discussing the modern patient consumer); Mark A. Hall & Carl E. Schneider, *Patients as Consumers: Courts, Contracts, and The New Medical Marketplace*, 106 MICH. L. REV. 643, 649-60 (2008) (mentioning the difficulties of the patient as a consumer). See generally Carl E. Schneider & Mark A. Hall, *The Patient Life: Can Consumers Direct Health Care?*, 35 AM. J.L. & MED. 7 (2009) (discussing the information available to patients as consumers, among many other issues relating to patients as consumers). See also Gunther Eysenbach & Alejandro R. Jadad, *Evidence-Based Patient Choice and Consumer Health Informatics in the Internet Age*, 3 J. MED. INTERNET RES. e19 (2001) (noting the difficulty of getting high-quality reliable information about providers); Orna Baron-Epel, Marina Dushenat, and Nurit Friedman, *Evaluation of the Consumer Model: Relationship Between Patients' Expectations, Perceptions and Satisfaction With Care*, 13 INT'L J. QUALITY HEALTH CARE 317, 317-23 (2001) (discussing the consumer model); Alastair V. Campbell, *The Patient as Consumer*, 40 BRIT. J. GEN. PRAC. 131, 131-32 (1990) (discussing generally the patient as a consumer); James C. Robinson, *Reinvention of Health Insurance in the Consumer Era*, 291 J. AM. MED. ASS'N. 1880, 1880-86 (2004) (discussing insurance in relation to the patient as a consumer); James C. Robinson, *Managed Consumerism in Health Care: A new vision for pursuing public ends through private means*, 24 HEALTH AFFAIRS 1478, 1478-89 (2005) (noting consumerism issues).

19. Leo G. Reeder, *The Patient-Client as a Consumer: Some Observations on the Changing Professional-Client Relationship*, 13 J. HEALTH & SOC. BEHAV. 406, 406-12 (1972).

tion about their physicians. Unfortunately, this information is typically unavailable. The Journal of the American Medical Association, in its Clinician's Corner, recently addressed the need of an executive looking for a new physician and health care system²⁰ and stated:

[u]nfortunately, Mr. A will find little evidence-based guidance to help him choose an individual physician. In general, currently available performance measures do not provide the kind of reliable comparisons among physicians that Mr. A might want. On the other hand, he can easily find out whether his physician is board certified from the American Board of Medical Specialists Although studies are heterogeneous, quality of care and patient outcomes are associated with physicians' board certification, licensing test results, and certification scores. Mr. A can also check his physicians' licensure status, public disciplinary history, and sometimes other factors by querying his state medical board²¹

There is good reason for the apologetic tone of this statement. There are, for example, more than 55,000 board certified general surgeons.²² The fact of board certification and presumed licensure simply will not provide patients with information personal to their physicians which could be important in physician choice and treatment decisions.

Perhaps physician groups – voluntary associations, such as the American Medical Association or American College of Surgeons – could provide quality and performance information to patients or, at least, assist their members in disclosing this information in order to provide real substance to the informed consent process. These associations have substantial memberships²³ and, therefore, should be positioned to influence large numbers of practicing physicians.

20. Michael D. Howell, *A 37-Year Old Man Trying to Choose a High-Quality Hospital: Review of Hospital Quality Indicators*, 302 J. AM. MED. ASS'N. 2353, 2353 (2009).

21. *Id.* at 2356. See also Hall & Schneider, *supra* note 18, at 19, 21.

22. The American Board of Surgery, *Diplomate and Examination Statistics – Summary* (2009), <http://home.absurgery.org/default.jsp?statsummary>.

23. The American Medical Association website does not contain membership statistics. AMA, <http://www.ama-assn.org/> (last visited Apr. 10, 2010). AMA membership has been estimated at 250,000 members. *American Medical Association*, ANSWERS.COM, <http://www.answers.com/topic/american-medical-association> (last visited Apr. 10, 2010). As of 2005, the estimate was approximately 244,000 members, including medical students. Peggy Peck, *AMA: Membership Bounces Back Slightly*, MEDPAGE TODAY (2006), <http://www.medpagetoday.com/MeetingCoverage/AMA/3516>. The American College of Surgeons has approximately 77,000 members. AMERICAN COLLEGE OF SURGEONS, <http://www.facs.org/> (last visited Nov. 9, 2009).

III. THE AMERICAN MEDICAL ASSOCIATION AND INFORMED CONSENT

The American Medical Association (AMA) website²⁴ contains references to and the text of patient-physician relationship topics and AMA opinions. Additionally, the AMA publishes a Code of Medical Ethics²⁵ and A Guide To Patient Safety in the Medical Practice.²⁶ These “resources” can be examined to determine if they provide assistance to patients or physicians on the disclosure of quality and performance information in the informed consent process.

The language of the AMA’s patient physician relationship topic, “Informed Consent,”²⁷ is clearly directed to the physician. In relevant part, it states:

[i]nformed consent is more than simply getting a patient to sign a written consent form. It is a process of communication between a patient and physician that results in the patient’s authorization or agreement to undergo a specific medical intervention.

In the communications process, you, as the physician providing or performing the treatment and/or procedure (not a delegated representative), should disclose and discuss with your patient:

- The patient’s diagnosis, if known;
- The nature and purpose of a proposed treatment or procedure;
- The risks and benefits of a proposed treatment or procedure;
- Alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance);
- The risks and benefits of the alternative treatment or procedure; and
- The risks and benefits of not receiving or undergoing a treatment or procedure.

In turn, your patient should have an opportunity to ask questions to elicit a better understanding of the treatment or procedure so that he or she can make an informed decision to proceed or to refuse a particular course of medical intervention.

This communications process, or a variation thereof, is both an ethical obligation and a legal requirement spelled out in statutes and case law in all 50 states. Providing the patient relevant information has

24. AMERICAN MEDICAL ASSOCIATION, <http://www.ama-assn.org/> (last visited Oct. 25, 2010).

25. *See generally* COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, AM. MED. ASS’N, CODE OF MEDICAL ETHICS OF THE AMERICAN MEDICAL ASSOCIATION: CURRENT OPINIONS WITH ANNOTATIONS (2008-09 ed.) (outlining the code of medical ethics).

26. AMA Guide, *supra* note 18.

27. *Informed Consent, Patient Physician Relationship*, AM. MED. ASS’N (2009), <http://www.ama-assn.org/ama/pub/physician-resources/legal-topics/patient-physician-relationship-topics/informed-consent.shtml> (last visited Oct. 25, 2010).

long been a physician's ethical obligation, but the legal concept of informed consent itself is recent.²⁸

This statement refers to informed consent in a general fashion. There is no suggestion that the physician reveal any information personal to the physician that might assist in a patient's treatment decision.

The AMA publishes "Opinions" which directly and indirectly relate to the informed consent process. Opinion 8.08-Informed Consent²⁹ provides:

[t]he patient's right of self-decision can be effectively exercised only if the patient possesses enough information to enable an informed choice. The patient should make his or her own determination about treatment. The physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice. Informed consent is a basic policy in both ethics and law that physicians must honor, unless the patient is unconscious or otherwise incapable of consenting and harm from failure to treat is imminent. In special circumstances, it may be appropriate to postpone disclosure of information, (see Opinion E-8.122, "Withholding Information from Patients"). Physicians should sensitively and respectfully disclose all relevant medical information to patients. The quantity and specificity of this information should be tailored to meet the preferences and needs of individual patients. Physicians need not communicate all information at one time, but should assess the amount of information that patients are capable of receiving at a given time and present the remainder when appropriate. (I, II, V, VIII).³⁰

It is clear that Opinion 8.08 does not identify the component of informed consent disclosures and, therefore, does not urge the physician to disclose personal factors which could be significant to the patient.

AMA Opinion 10.01 – Fundamental Elements of the Patient-Physician Relationship³¹ states:

[f]rom ancient times, physicians have recognized that the health and well-being of patients depends upon a collaborative effort between physician and patient. Patients share with physicians the responsibil-

28. *Id.*

29. *Code of Medical Ethics, Opinion 8.08 – Informed Consent*, AM. MED. ASS'N (2009), <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion808.shtml>.

30. *Id.*

31. *Code of Medical Ethics, Opinion 10.01 – Fundamental Elements of the Patient-Physician Relationship*, AM. MED. ASS'N (2009), <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion1001.shtml>.

ity for their own health care. The patient-physician relationship is of greatest benefit to patients when they bring medical problems to the attention of their physicians in a timely fashion, provide information about their medical condition to the best of their ability, and work with their physicians in a mutually respectful alliance. Physicians can best contribute to this alliance by serving as their patients' advocate and by fostering these rights:

- (1) The patient has the right to receive information from physicians and to discuss the benefits, risks, and costs of appropriate treatment alternatives. Patients should receive guidance from their physicians as to the optimal course of action. Patients are also entitled to obtain copies or summaries of their medical records, to have their questions answered, to be advised of potential conflicts of interest that their physicians might have, and to receive independent professional opinions.
- (2) The patient has the right to make decisions regarding the health care that is recommended by his or her physician. Accordingly, patients may accept or refuse any recommended medical treatment.
- (3) The patient has the right to courtesy, respect, dignity, responsiveness, and timely attention to his or her needs.
- (4) The patient has the right to confidentiality. The physician should not reveal confidential communications or information without the consent of the patient, unless provided for by law or by the need to protect the welfare of the individual or the public interest.
- (5) The patient has the right to continuity of health care. The physician has an obligation to cooperate in the coordination of medically indicated care with other health care providers treating the patient. The physician may not discontinue treatment of a patient as long as further treatment is medically indicated, without giving the patient reasonable assistance and sufficient opportunity to make alternative arrangements for care.
- (6) The patient has a basic right to have available adequate health care. Physicians, along with the rest of society, should continue to work toward this goal. Fulfillment of this right is dependent on society providing resources so that no patient is deprived of necessary care because of an inability to pay for the care. Physicians should continue their traditional assumption of a part of the responsibility for the medical care of those who cannot afford essential health care. Physicians should advocate for patients in dealing with third parties when appropriate. (I, IV, V, VIII, IX).³²

32. *Id.*

This Opinion refers to the informed consent disclosure components of risk, benefit and physician conflict of interest.³³ It does not, however, refer to an obligatory disclosure of physician performance and quality information.

AMA Opinion 10.015 – The Patient-Physician Relationship³⁴ provides:

[t]he practice of medicine, and its embodiment in the clinical encounter between a patient and a physician, is fundamentally a moral activity that arises from the imperative to care for patients and to alleviate suffering.

A patient-physician relationship exists when a physician serves a patient's medical needs, generally by mutual consent between physician and patient (or surrogate). In some instances the agreement is implied, such as in emergency care or when physicians provide services at the request of the treating physician. In rare instances, treatment without consent may be provided under court order (see Opinion 2.065, "Court-Initiated Medical Treatments in Criminal Cases"). Nevertheless, the physician's obligations to the patient remain intact.

The relationship between patient and physician is based on trust and gives rise to physicians' ethical obligations to place patients' welfare above their own self-interest and above obligations to other groups, and to advocate for their patients' welfare.

Within the patient-physician relationship, a physician is ethically required to use sound medical judgment, holding the best interests of the patient as paramount. (I, II, VI, VIII)³⁵

This Opinion refers to the sanctity of the physician-patient relationship. It does not pronounce a need for its member physicians to disclose performance and quality information as part of the informed consent process.

The AMA also publishes "A Guide to Patient Safety in the Medical Practice,"³⁶ which refers to "The Informed Patient"³⁷ and the "Patients' Bill of Rights."³⁸ These sections provide, in relevant part, as follows:

The Informed Patient

Patients, as consumers, are becoming much better informed and more concerned about evidence-based medical care, health care quality, and patient safety. More and more patients are well informed on the latest medical advances and treatment and are not afraid to ask informed questions and to challenge physicians as to the reasons for

33. To regard physician conflict of interest, see *Moore v. Regents of Univ. of California*, 793 P.2d 479 (Cal. 1990), which will be discussed later in this paper.

34. *Code of Medical Ethics, Opinion 10.015 – The Patient-Physician Relationship*, AM. MED. ASS'N (2009), <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion10015.shtml>.

35. *Id.*

36. See generally AMA Guide, *supra* note 18.

37. *Id.* at 18.

38. *Id.* at 18-19.

their treatment plan, choice of products and drugs, and the use of patient safety measures.

The American Medical Association . . . advocated successfully for passage of the comprehensive Patient's Bill of Rights Act by Congress in 1998. It . . . assures that doctors and patients can openly discuss treatment options . . .³⁹

Patients' Bill of Rights

....

IV. Participation in Treatment Decisions. You have the right to know all your treatment options and to participate in decisions about your care.⁴⁰

Again, these statements give lip service to the doctrine of informed consent. They do not encourage physicians to make specific quality or performance disclosures.

In 2000, the AMA published "Law for Physicians: An Overview of Medical Legal Issues."⁴¹ It contains a chapter on informed consent.⁴² In the section entitled "Criteria for Valid Consent"⁴³ the authors state:

[t]he law is now clear in almost every jurisdiction that a physician has the duty to disclose to the patient, before any treatment or procedure, sufficient information to enable the patient to make an informed decision.

....

The major issue is . . . what information the physician must provide to the patient. Courts have generally agreed that the patient must be advised of the nature and purpose of the treatment, the risks and consequences involved, and the alternative courses of treatment, including the consequences of no treatment. The physician must explain the steps that will be involved and the diagnostic or therapeutic results that are sought.⁴⁴

In the section entitled "The Amount of Disclosure Required"⁴⁵ the authors state:

First, the nature of the patient's condition and the proposed treatment must always be disclosed. The nature and probability of the material risks must also be described, along with information regarding the reasonably expected benefits to the patient If the procedure or treatment the physician is proposing is irreversible, the physi-

39. *Id.* at 18.

40. *Id.* at 18-19.

41. *See generally* CARL HORN III ET AL., LAW FOR PHYSICIANS: AN OVERVIEW OF MEDICAL LEGAL ISSUES (2000).

42. *Id.* at 93-106.

43. *Id.* at 94-96.

44. *Id.* at 95.

45. *Id.* at 96.

cian must so inform the patient. Finally, the physician must explain to the patient the expected results of no treatment and alternative treatments Courts generally agree that risks that are common knowledge and should already be known to the patient need not be disclosed.⁴⁶

This publication does not advise physicians to disclose personal risk factors, or performance and quality information during the informed consent process to assist the patient in making treatment choices. In fact, it characterizes informed consent as requiring a “dialogue between patient and physician in which both parties exchange information and questions culminating in the patient’s agreement to a specific medical or surgical intervention.”⁴⁷ It cannot be overemphasized that the informed consent process does not require a dialogue. The doctrine requires voluntary disclosure, not patient inquiry.⁴⁸

The AMA is in a position to influence the behavior of medical students and practicing physicians. However, AMA statements and publications do not suggest the disclosure of physician performance and quality information during the informed consent process. Although the AMA recognizes the significance of the informed patient and the physician’s obligation to disclose, the limited scope of AMA pronouncements do too little to advance the doctrine of informed consent in the direction of patient safety.

IV. THE AMERICAN COLLEGE OF SURGEONS AND INFORMED CONSENT

The American College of Surgeons (ACS) publishes “public information” entitled “Giving Your Informed Consent.”⁴⁹ This statement, in relevant part, provides:

[b]efore having your operation, you will be asked to indicate that you understand the nature of the surgical procedure to be performed and that you give your permission for the operation.

This may appear to be a formality, but, in fact, this process should be taken very seriously. Before your operation, frankly discuss with your surgeon any questions or concerns that you have. Of course, not everyone wants to know all the specific details of the surgical procedure itself, but *you should seek the answers to questions such as:*

- What are the indications that have led your doctor to the opinion that an operation is necessary?
- What, if any, alternative treatments are available for your condition?
- What will be the likely result if you don’t have the operation?

46. *Id.*

47. *Id.* at 93-94.

48. *Canterbury v. Spence*, 464 F.2d 772, 783 n. 36 (D.C. Cir. 1972).

49. *Giving Your Informed Consent, Public Information from the American College of Surgeons*, AM. COLL. OF SURGEONS (2010), http://www.facs.org/public_info/operation/consent.html.

- What are the basic procedures involved in the operation?
- What are the risks?
- How is the operation expected to improve your health or quality of life?
- Is hospitalization necessary and, if so, how long can you expect to be hospitalized?
- What can you expect during your recovery period?
- When can you expect to resume normal activities?
- Are there likely to be residual effects from the operation?

Of course, your surgeon may volunteer much of this information. However, if you still have questions, don't hesitate to ask. Remember, the operation is being performed on you, and you should seek any information that you need to improve your understanding. Your doctor should be willing to take whatever time is necessary to make sure that you are fully informed. No doctor can, or should, guarantee outcomes, because each operation is different, depending upon the individual condition and response of each patient. Nonetheless, your surgeon will be able to give you a good idea of what to expect.

The principle of informed consent is endorsed by the American College of Surgeons, the largest organization of surgeons in the world with more than 54,000 members. The *Statements on Principles* of the College says, in part, "Patients should understand the indications for the operation, the risk involved, and the result that it is hoped to attain."⁵⁰

The curious nature of this statement is how it appears to place a burden of inquiry on the patient to obtain knowledge. The statement indicates only that the physician "may" volunteer much of this information.⁵¹ Even so, the list of questions does not implicate physician performance and quality information.

Recently, the ACS published "*I Need an Operation ... Now What? A Patient's Guide to a Safe and Successful Outcome*."⁵² The section of the book purporting to explain informed consent unfortunately emphasizes written permission for the operation (consent form)⁵³ and a discussion with the surgeon regarding the patient's questions or concerns prior to signing the consent form.⁵⁴ At

50. *Id.* (emphasis added).

51. *Id.* Keep in mind that under the doctrine of informed consent, the obligation to disclose is the physician's. See *Canterbury*, 464 F.2d at 783 n.36 (indicating that the patient has no obligation to inquire).

52. THOMAS R. RUSSELL, AM. COLL. OF SURGEONS, *I NEED AN OPERATION . . . NOW WHAT? A PATIENT'S GUIDE TO A SAFE AND SUCCESSFUL OUTCOME* (2008).

53. For a sample informed consent document, which includes physician and hospital experience information, see Harlan M. Krumholz, *Informed Consent to Promote Patient-Centered Care*, 303 J. AM. MED. ASS'N. 1190, 1191 (2010).

54. RUSSELL, *supra* note 52, at 32.

the end of chapter entitled “What to Ask the Surgeon at the First Meeting”⁵⁵ there is a list of recommended questions *for the patient to ask the surgeon*, including:

- “Why do I need an operation?”⁵⁶
- “What are the treatment options?”⁵⁷
- “What are the risks and benefits?”⁵⁸
- “What result can I expect?”⁵⁹
- “Who else is on the surgical team?”⁶⁰

All of these questions, including the one regarding surgical team members (to be discussed later), relate to matters that should be voluntarily disclosed by the surgeon pursuant to the informed consent disclosure obligation. The patient does not have the burden to extract this information from the surgeon.

In the section of this ACS publication entitled “Choosing the Surgeon Who is Best For You”⁶¹ there is a listing of questions, which a patient is encouraged to ask the surgeon, including:

- “What kind of surgery were you trained to do?”⁶²
- “Do you have any health problems that would interfere with your ability to do this operation?”⁶³
- “What is your percentage success rate with this operation? Do you have your outcomes in writing?”⁶⁴
- “What is your safety record regarding complications?”⁶⁵

These questions implicate physicians’ personal factors such as performance, quality, and disability. Again, why should a patient be required to pry this information from the physician? A more patient-friendly informed consent process, sponsored by the ACS, would greatly advance the purpose of the informed consent doctrine by encouraging its membership to disclose more than simply the classic procedure related risks, benefits, and results.

55. *Id.* at 23-34.

56. *Id.* at 34.

57. *Id.*

58. *Id.*

59. *Id.*

60. *Id.*

61. *Id.* at 11-22.

62. *Id.* at 22.

63. *Id.*

64. *Id.*

65. *Id.*

V. THE COURTS, INFORMED CONSENT AND THE PHYSICIAN'S OBLIGATION
TO DISCLOSE PERSONAL FACTORS, QUALITY, AND PERFORMANCE
RELATED INFORMATION

Reliance on court opinions in an effort to investigate the breadth of the informed consent doctrine is not a particularly comforting exercise. A court will only address an issue facing it in a particular context, at a particular time. Most medical negligence litigation occurs at the state level. Therefore, there is a dimension of randomness to this exercise. Nevertheless, without the assistance of key medical associations in expanding informed consent to a more patient-friendly doctrine, it is necessary to examine court opinions to determine if the doctrine is expanding, even if only randomly to one which will obligate physicians to disclose more physician-related information to their patients.

A. Physician Experience

A required disclosure of physician experience potentially entails two components: (1) overall experience in, for example, performing a procedure (i.e., how often) and (2) specific cases or outcomes the physician has experienced, including unfortunate outcomes, which if known to the patient would influence the patient's decision making. Both components are considered in this paper.

Courts in at least ten states have issued published and unpublished opinions on the informed consent and physician experience issues.⁶⁶ These opinions will be reviewed on a state-by-state basis.

1. *Connecticut*

In *Duffy v. Flagg*,⁶⁷ the Supreme Court of Connecticut considered the plight of plaintiff, a pregnant woman expecting her second child.⁶⁸ Her first child was delivered by caesarian section. Plaintiff and Dr. Flagg discussed the possibility of a vaginal birth after C-section (VBAC).⁶⁹ They discussed a prior

66. Connecticut: *Duffy v. Flagg*, 905 A.2d 15 (Conn. 2006); *Degennaro v. Tandon*, 873 A.2d 191 (Conn. App. Ct. 2005); Delaware: *Barriocanal v. Gibbs*, 697 A.2d 1169 (Del. 1997); Maryland: *Goldberg v. Boone*, 912 A.2d 698 (Md. 2006); New Jersey: *Howard v. Univ. of Med. and Dentistry*, 800 A.2d 73 (N.J. 2002); North Carolina: *Foard v. Jarman*, 387 S.E.2d 162 (N.C. 1990); Pennsylvania: *Duttry v. Patterson*, 771 A.2d 1255 (Pa. 2001); Texas: *Avila v. Flangas*, No. 04-95-00106-CV, 1996 WL 63036 (Tex. App. Feb. 14, 1996); Virginia: *Tashman v. Gibbs*, 556 S.E.2d 772 (Va. 2002); Washington State: *Whiteside v. Lukson*, 947 P.2d 1263 (Wash. Ct. App. 1997); *Housel v. James*, 172 P.3d 712 (Wash. Ct. App. 2007); *Bush v. Stack*, No. 41817-3-I, 1999 WL 364120 (Wash. Ct. App. June 7, 1999); Wisconsin: *Johnson v. Kokemoor*, 545 N.W.2d 495 (Wis. 1996).

67. 905 A.2d at 15.

68. *Id.* at 15.

69. *Id.* at 16-17.

bad outcome of VBAC experienced by a former patient of Dr. Flagg's, although Dr. Flagg did not advise plaintiff that the bad outcome included the death of the baby following a uterine rupture.⁷⁰ Plaintiff opted for a VBAC.⁷¹

A VBAC was attempted but "after she displayed possible signs of a uterine rupture,"⁷² she delivered the baby by C-section. The baby died eight days after birth.⁷³

The Connecticut Supreme Court reasoned that plaintiff was not offering evidence to suggest that Dr. Flagg's "prior experience with [VBAC] increased the risks or hazards of that procedure for the plaintiff."⁷⁴ Dr. Flagg's prior experience was not relevant to the Connecticut formula for informed consent as an objective test.⁷⁵ It was not information "which a reasonable patient would find material."⁷⁶

The Appellate Court of Connecticut considered a dental informed consent claim in *Degennaro v. Tandom*.⁷⁷ Here, the defendant dentist did not inform the patient (1) that she had no experience in the use of particular equipment in her office⁷⁸ and (2) that she typically utilized an assistant when performing the procedure.⁷⁹ During the procedure, plaintiff suffered a tongue injury, causing "several permanent defects."⁸⁰

The Appellate Court framed the issue as follows, "[w]hether these provider specific facts [inexperience with equipment] can be considered by a jury for a lack of informed consent claim, where the patient did not request information regarding these facts, presents an issue of first impression in our state."⁸¹

The court held that provider specific information, such as inexperience, must be disclosed in order to obtain informed consent "where the facts and circumstances of the particular situation suggest that such information would be found material by a reasonable patient in making the decision to embark on a particular course of treatment, *regardless of whether the patient has sought to elicit the information from the provider*."⁸² Although the opinion does not cite to

70. *Id.* at 19.

71. *Id.* at 15.

72. Connecticut: Duffy v. Flagg, 905 A.2d 15, 17 (Conn. 2006).

73. *Id.* at 16-18.

74. *Id.* at 21.

75. *Id.* at 20 (noting that the objective formula for "informed consent involves four specific factors: (1) the nature of the procedure; (2) the risks and hazards of the procedure; (3) the alternatives to the procedure; and (4) the anticipated benefits of the procedure").

76. *Id.* at 21.

77. 873 A.2d 191, 191 (Conn. App. Ct. 2005).

78. *Id.* at 195.

79. *Id.*

80. *Id.* (noting a loss of sensation in the area of injury, loss of taste, lisp, loss of food control, drooling and a tongue scar).

81. *Id.* at 195-96.

82. *Id.* at 196 (emphasis added).

Canterbury v. Spence,⁸³ it makes the point that the process of informed consent does not entail a patient inquiry as a prerequisite to obtaining provider specific information.

It should be noted that *Degennaro*⁸⁴ earned comment from the Connecticut Supreme Court in *Duffy*.⁸⁵ The Supreme Court commented that the *Degennaro* opinion did not conflict with the court's opinion in *Duffy* insofar as the dentist's undisclosed inexperience with dental equipment was related to the patient's risks under the circumstances.⁸⁶

Therefore, case law in Connecticut supports the required disclosure of health provider "inexperience" to obtain informed consent when the inexperience would increase the risks attendant to the procedure.

2. Delaware

In *Barriocanal v. Gibbs*⁸⁷ the Supreme Court of Delaware considered a medical negligence/wrongful death action involving neurosurgery. Here, the defendant physician performed brain aneurysm surgery without disclosing "that he had not performed aneurysm surgery recently, that Christiana Hospital would be thinly staffed the day of surgery since it was Easter Sunday, and that there were other hospitals in nearby cities that specialized in this type of surgery."⁸⁸

The trial court excluded testimony from plaintiff's expert that the defendant should have disclosed this information in the informed consent process.⁸⁹ The Supreme Court noted that the Delaware law of informed consent is statutory.⁹⁰ The statute defines informed consent as:

the consent of a patient to the performance of health care services by a health care provider given after the health care provider has informed the patient, to an extent reasonably comprehensible to general lay understanding, of the nature of the proposal procedure or treatment and of the risks and alternatives to treatment or diagnosis which a reasonable patient would consider material to the decision whether or not to undergo the treatment or diagnosis.⁹¹

The Supreme Court noted that since plaintiff's physician-expert witness identified defendant's non-disclosures as a standard of care violation, the exclusion of this evidence was reversible error.⁹²

83. *Canterbury v. Spence*, 464 F.2d 772, 772 (D.C. Cir. 1972).

84. *Degennaro v. Tandon*, 873 A.2d 191, 191 (Conn. App. Ct. 2005).

85. *Duffy v. Flagg*, 905 A.2d 15, 22 (Conn. 2006).

86. *Id.*

87. 697 A.2d 1169, 1169 (Del. 1997).

88. *Id.* at 1170.

89. *Id.*

90. *Id.*

91. *Id.* at 1172 (citing DEL. CODE ANN. tit.18, § 6801 (2008)).

92. *Id.* at 1174.

The opinion is, thus, significant in that it interprets the Delaware informed consent statute to potentially encompass the disclosure of provider specific information. The key here was that plaintiff could introduce evidence, which linked the non-disclosure to the standard of care.

3. Maryland

In *Goldberg v. Boone*,⁹³ the Court of Appeals of Maryland considered a medical negligence claim against defendants as a result of a revisionary surgical procedure. Here, the informed consent issue pertained to whether “a surgeon with little experience in a complex procedure performed close to the brain had no duty to inform his patient of the abundance of more experienced specialists available?”⁹⁴ Specifically, the defendant physician had performed one such procedure in the three years prior to the patient’s surgery.⁹⁵

At trial, plaintiff introduced expert medical testimony to substantiate the prudence of such disclosure of inexperience.⁹⁶ The trial court submitted an informed consent instruction to the jury.⁹⁷ Judgment was entered for the plaintiff following the jury trial.⁹⁸ The Court of Special Appeals “held that a surgeon does not have a duty to advise a patient that there are more experienced physicians in the locality to perform an operation, and therefore the trial judge erred in submitted the informed consent question to the jury.”⁹⁹ That court also held that this constituted non-prejudicial error insofar as the jury found the defendant had negligently performed surgery and that “there was sufficient evidence presented regarding Dr. Goldberg’s relative lack of experience . . . to warrant that finding”¹⁰⁰

The Court of Appeals of Maryland utilized a reasonable patient test to determine that the breadth of the disclosure by a physician may include “other considerations,”¹⁰¹ to be “determined by what information would be material to a reasonable person in the position of the patient having to decide whether to submit to the medical treatment [at] issue.”¹⁰² The court concluded that due to plaintiff’s condition and the inexperience of the defendant physician (having performed 1 such procedure in the prior 3 years), the defendant phy-

93. 912 A.2d 698, 698 (Md. 2006). As to evidentiary issues arising in the case concerning cross-examination, see Brigham J. Lundberg, *Goldberg v. Boone: Getting Away With “Murder” – An Attempt To Exploit The Arbitrary Limits On Cross-Examination Questioning*, 67 MD. L. REV. 780 (2008) (analyzing *Goldberg*, and discussing the facts and the court’s reasoning).

94. *Goldberg*, 912 A.2d at 701.

95. *Id.* at 717.

96. *Id.* at 703.

97. *Id.* at 701.

98. *Id.* at 701.

99. *Goldberg v. Boone*, 912 A.2d 698, 707 (Md. 2006).

100. *Id.*

101. *Id.* at 716 (citing *Dingle v. Belin*, 749 A.2d 157, 165 (Md. 2000)).

102. *Id.*

sician had the duty to inform the patient of his relative inexperience. The jury would then determine if a reasonable person, in plaintiff's position, "would have deemed this information material to the decision whether to risk having the [surgery] undertaken by Dr. Goldberg."¹⁰³

There is quite a difference between the disclosure of experience and inexperience. When is a surgeon experienced? After more than one procedure? After three or more? The problem is obvious. There are very likely always physicians "somewhere else" with more experience. How does a physician become experienced without performing procedures as an inexperienced physician? Will patients always refuse the inexperienced physician such that this physician cannot gain experience? These issues are worth pondering along with the discussion of mandatory disclosure.

4. New Jersey

In the context of the physician-patient relationship, the tort of misrepresentation¹⁰⁴ is not analogous to the physician's failure to obtain informed consent. The Supreme Court examined the distinction in *Howard v. Univ. of Med. and Dentistry of New Jersey*.¹⁰⁵ It was during a discussion with a patient and in response to a question that a neurosurgeon allegedly advised the patient that he was board certified when he was not.¹⁰⁶ The neurosurgeon also denied that he claimed to have performed a substantial number of specific surgical procedures during his career as a neurosurgeon.¹⁰⁷

Insofar as informed consent was concerned, the court noted that New Jersey case law "never has held that a doctor has a duty to detail his background and experience as part of the required informed consent disclosure"¹⁰⁸ and further stated that "[c]ourts generally have held that claims of lack of informed consent based on a failure to disclose professional-background information are without merit."¹⁰⁹ The court did express the view, however, that physician misrepresentations could "affect the validity of the consent obtained."¹¹⁰

103. *Id.* at 717.

104. DOBBS, *supra* note 17, at 1343-84.

105. 800 A.2d 73, 73 (N.J. 2002).

106. *Id.* at 76.

107. *Id.*

108. *Id.* at 82. See *In re Conroy*, 486 A.2d 1209 (N.J. 1985).

109. *Id.* at 83 (citing *Ditto v. McCurdy*, 947 P.2d 952, 958 (Haw. 1997); *Foard v. Jarman*, 387 S.E.2d 162, 167 (N.C. 1990)).

110. *Howard*, 800 A.2d at 83.

5. North Carolina

The North Carolina law of informed consent is based in statute.¹¹¹ The statute provides the standard of care and prohibits recovery for lack of informed consent where:

(2) A reasonable person, from the information provided by the health care provider under the circumstances, would have a general understanding of the procedures or treatments and of the usual and most frequent risks and hazards inherent in the proposed procedures or treatments which are recognized and followed by other health care providers engaged in the same field of practice in the same or similar communities.¹¹²

In *Foard v. Jarman*,¹¹³ the Supreme Court of North Carolina commented that “[t]he statute imposes no affirmative duty on the health care provider to discuss his or her experience”¹¹⁴

6. Pennsylvania

In *Duttry v. Patterson*,¹¹⁵ the Supreme Court of Pennsylvania considered an informed consent claim against a surgeon based upon his less than disclosed surgical experience. *Duttry* is another example of a case in which the patient claimed that the physician was questioned about his experience and misled the patient with his response.

The court addressed the informed consent issue and simply held “that evidence of a physician’s personal characteristics and experience is irrelevant to an informed consent claim.”¹¹⁶ The court recognized the expansion of the doctrine in other states in other contexts,¹¹⁷ but refused to join.

7. Texas

In *Avila v. Flangas*,¹¹⁸ an unpublished opinion of the Court of Appeals of Texas, the court considered a medical negligence case concerning a referral to a surgeon for the potential treatment of a seizure disorder. Surgery was recommended and a surgical team was assembled.¹¹⁹ During the procedure the

111. N.C. GEN. STAT. § 90-21.13 (West 1985).

112. *Id.*

113. 387 S.E.2d at 162.

114. *Id.* at 167.

115. 771 A.2d 1255, 1255 (Pa. 2001).

116. *Id.* at 1259.

117. *Moore v. Regents of Univ. of California*, 793 P.2d 479, 479 (Cal. 1990); *Johnson v. Kokemoor*, 545 N.W.2d 495, 495 (Wis. 1996).

118. No. 04-95-00106-CV, 1996 WL 63036, at *1 (Tex. App. Feb. 14, 1996).

119. *Id.* at *1-2.

patient “suffered seizure activity and decreased responsiveness,”¹²⁰ as well as bleeding. Ultimately, the patient became hemiplegic.¹²¹

The patient alleged that she did not provide informed consent due to, among other things, the non-disclosure of “the surgical team’s inexperience.”¹²² The court found that physician experience was not a risk “inherent to the procedure”¹²³ and “cannot form the basis for an informed consent claim.”¹²⁴

8. Virginia

In *Tashman v. Gibbs*,¹²⁵ the Supreme Court of Virginia recognized the potential for an informed consent claim based upon a physician’s failure to disclose his experience. In this case, the defendant performed a gynecological procedure without disclosing his limited experience.¹²⁶ The plaintiff did not “establish by expert testimony that the appropriate standard of care in 1996 for an obstetrician and gynecologist in Virginia required [defendant] to disclose . . . the extent of his experience in performing sacrospinous procedures.”¹²⁷ The court did not engage in a policy analysis of informed consent. The discussion was focused on evidence of the standard of care. Consequently, Virginia law would embrace an informed consent claim based on non-disclosure of experience if the plaintiff introduces evidence that the standard of care required the disclosure.

9. Washington State

The Court of Appeals of Washington has had multiple opportunities to consider the non-disclosure of physician experience and the doctrine of informed consent.¹²⁸

In *Whiteside v. Lukson*,¹²⁹ the court considered this informed consent issue in a gallbladder removal case. At the time the defendant physician obtained plaintiff’s consent for surgery, he had never performed a human laparoscopic cholecystectomy and never so advised his patient.¹³⁰ Surgery was delayed, by

120. *Id.* at *1.

121. *Id.* at *1.

122. *Id.* at *2.

123. *Id.*

124. *Avila v. Flangas*, No. 04-95-00106-CV, 1996 WL 63036, at *2 (Tex. App. Feb. 14, 1996).

125. 556 S.E.2d 772, 772 (Va. 2002).

126. *Id.* at 775-77.

127. *Id.* at 778.

128. See, e.g., *Housel v. James*, 172 P.3d 712, 712 (Wash. Ct. App. 2007); *Bush v. Stack*, No. 41817-3-I, 1999 WL 364120 (Wash. Ct. App. June 7, 1999); *Whiteside v. Lukson*, 947 P.2d 1263, 1263 (Wash. Ct. App. 1997).

129. 947 P.2d at 1263.

130. *Id.* at 1264.

which time the surgeon had performed two such procedures.¹³¹ During surgery for the plaintiff, the surgeon misidentified a bile duct and damaged it.¹³²

The case was tried to a jury, which found the surgeon not negligent. The jury did find that his non-disclosure of inexperience resulted in a failure to obtain informed consent.¹³³ The trial court granted a judgment notwithstanding the verdict ("JNOV") for the surgeon on the basis that "a health care provider's experience is not a material fact of which the patient must be informed."¹³⁴ Washington has a statutory scheme pertaining to informed consent claims.¹³⁵ It uses the "reasonable patient standard: the physician must disclose those facts a reasonable person would consider in deciding whether to consent to the proposed treatment."¹³⁶

After referring to case law in other states which have recognized the expansion of the informed consent doctrine to include provider specific disclosures,¹³⁷ the court of appeals explained that "Washington courts have not yet adopted the more expansive construction of the physician's duty to disclose."¹³⁸ The Court concluded that "a surgeon's lack of experience in performing a particular surgical procedure is not a material fact for purposes of finding liability predicated on failure to secure an informed consent."¹³⁹

Not long after *Whiteside*, in an unpublished opinion, *Bush v. Stack*,¹⁴⁰ the court of appeals followed *Whiteside* in disposing of an informed consent physician non-disclosure of experience claim. Since the extent of physician's experience is not a material fact under the Washington informed consent statute, evidence of the physician's experience was inadmissible due to its irrelevance.¹⁴¹

More recently, in *Housel v. James*,¹⁴² the court of appeals considered an informed consent claim against a general surgeon who had performed one type

131. *Id.* at 1264.

132. *Id.* at 1264. Bile duct injuries are well-reported complications of laparoscopic cholecystectomy. See, e.g., Charles E. Ray, John F. Hibbeln & Andrew C. Wilbur, *Complications After Laparoscopic Cholecystectomy: Imaging Findings*, 160 AJR 1029, 1029-32 (1993) (discussing the various complications that may arise and providing a number of images of them); S. Lalwani et al., *Common Bile Duct Injury In Laparoscopic Cholecystectomy: Inherent Risk of Procedure or Medical Negligence – A Case Report*, 1 WORLD J. OF LAPAROSCOPIC SURGERY 28, 28-30 (2008) (indicating the risks of the surgery).

133. *Id.*

134. *Whiteside v. Lukson*, 947 P.2d 1263, 1263, 1264 (Wash. Ct. App. 1997).

135. WASH. REV. CODE § 7.70.030 (West 2009); WASH. REV. CODE § 7.70.050 (West 2009).

136. *Whiteside*, 947 P.2d at 1264.

137. See, e.g., *Moore v. Regents of Univ. of California*, 793 P.2d 479, 479 (Cal. 1990); *Hidding v. Williams*, 578 So. 2d 1192 (La. Ct. App. 1991); *Faya v. Almaraz*, 620 A.2d 327 (Md. 1993); *Wisconsin: Johnson v. Kokemoor*, 545 N.W.2d 495, 495 (Wis. 1996).

138. *Whiteside*, 947 P.2d at 1264.

139. *Id.* at 1265.

140. *Bush v. Stack*, No. 41817-3-I, 1999 WL 364120, at *3 (Wash. Ct. App. June 7, 1999).

141. *Id.*

142. *Housel v. James*, 172 P.3d 712, 712 (Wash. Ct. App. 2007).

of hernia repair procedure prior to operating on the plaintiff. The surgeon did not disclose his operative "inexperience." Plaintiff alleged that the defendant surgeon "should have informed her of his inexperience because it increased the risk of surgical complication and led to premature surgery."¹⁴³

Interestingly, the court commented that plaintiff "failed to make an adequate showing that Dr. James's alleged inexperience was a material treatment-related fact,"¹⁴⁴ but then stated:

we are not categorically holding that a physician's inexperience is never material to an informed consent claim. There may well be situations where evidence of a physician's experience would be a significant factor in a patient's decision to undertake a particular cause of treatment. But such a situation is not present here.¹⁴⁵

When is physician "inexperience" immaterial to a patient's decision to undergo a surgical procedure? In order to answer this question, the patient would need to be aware of the surgeon's experience. That will occur if the physician is required to disclose "experience" in the informed consent process. Otherwise, the patient would be obligated to inquire, which is not contemplated by the informed consent process¹⁴⁶ or the physician would, fortuitously, have to volunteer the information.

10. Wisconsin

In 1996, the Supreme Court of Wisconsin decided *Johnson v. Kokemoor*,¹⁴⁷ an opinion that revealed the Court's willingness to apply the informed consent doctrine to physician-specific factors.¹⁴⁸ *Kokemoor* concerned a claim against a non-board certified neurosurgeon who successfully clipped plaintiff's brain aneurysm.¹⁴⁹ Pre-operatively, the plaintiff had no neurological deficits other than headaches.¹⁵⁰ Post-operatively, she was "an incomplete quadriplegic,"¹⁵¹ ¹⁵² "unable to walk or control her bowel and bladder movements . . . her vision, speech and upper body coordination are partially impaired."¹⁵³

143. *Id.* at 715.

144. *Id.* at 716.

145. *Id.*

146. *Canterbury v. Spence*, 464 F.2d 772, 783 n. 36 (D.C. Cir. 1972).

147. 545 N.W.2d 495, 495 (Wis. 1996).

148. As will be discussed later in this paper, the *Johnson* opinion comments on the disclosure of physician risk statistics and the availability of other centers and physicians better able to perform surgery, as well as physician experience.

149. *Kokemoor*, 545 N.W.2d at 498, n. 11.

150. *Id.* at 498 n. 9.

151. *Id.* at 499.

152. See Lisa K. Sharp, Philip G. Bashook, Martin S. Lipsky, Sheldon D. Horowitz & Stephen H. Miller, *Specialty Board Certification and Clinical Outcomes: The Missing Link*, 77 J. ASS'N AM. MED. C. 534, 534-42 (2002) (indicating a study regarding the association between board certification status and clinical outcomes).

153. *Johnson v. Kokemoor*, 545 N.W.2d 495, 499 (Wis. 1996).

Although the defendant neurosurgeon had experience with aneurysm surgery, he “had never operated on a large basilar bifurcation aneurysm such as the plaintiff’s aneurysm.”¹⁵⁴ He did not disclose this fact to plaintiff. Plaintiff did question the defendant about his experience but his response was “that he had operated on aneurysms comparable to her aneurysm ‘dozens’ of times.”¹⁵⁵ The trial court admitted into evidence the fact of defendant’s inexperience. The Supreme Court approved, stating that “[a] reasonable person in the plaintiff’s position would have considered such information material in making an intelligent and informed decision about the surgery.”¹⁵⁶

Kokemoor portrays a practical problem for physicians with respect to required disclosure of “inexperience.” Here, the neurosurgeon had operative experience but had not performed the specific procedure plaintiff required. Presumably, he had hospital staff privileges¹⁵⁷ to perform the procedure. Whether the grant of privileges to perform procedures is indicative of competency could be disputed, particularly in view of this neurosurgeon’s experience or lack thereof.

B. Physician Disability & Health (Non-HIV)

Physicians as patients or former patients have a realistic expectation of confidentiality with respect to their current or former conditions.¹⁵⁸ Should this remain true if the health of the physician may increase a risk of harm to the patient? Should the physician disclose his or her health issues in order to obtain informed consent?

1. Georgia

In *Albany Urology Clinic v. Cleveland*,¹⁵⁹ the Supreme Court of Georgia considered the interesting case of a urologist with a history of drug use outside of work and while not on call.¹⁶⁰ Here, the patient consulted with the urologist for a condition of penile cancer.¹⁶¹ The urologist performed surgery and the patient suffered unfortunate complications and sued the urologist, claiming that he “negligently performed unnecessary surgery for non-existent penile

154. *Id.*

155. *Id.* at 505.

156. *Id.* Wisconsin has codified its common law approach to the reasonable or prudent patient standard for informed consent claims. WIS. STAT. § 448.30 (West 2009); *Scaria v. St. Paul Fire & Marine*, 227 N.W.2d 647 (Wis. 1975).

157. *FURROW*, *supra* note 2, at 97-98.

158. *Id.* at 143-71 (discussing medical information and confidentiality).

159. 528 S.E.2d 777 (Ga. 2000).

160. The “on call” status arises as a condition of the physician’s hospital privileges. When the physician is “on call” he or she is required to consult with physicians who may seek advice. *See Mead v. Legacy Health System*, 220 P.3d 118, 120 (Ore. Ct. App. 2009) (considering if a physician-patient relationship is established with an “on-call” physician after a consult).

161. *Albany*, 528 S.E.2d at 778.

cancer.”¹⁶² It was later alleged that the urologist “had fraudulently concealed or misrepresented his ‘illegal use and abuse of cocaine, substance abuse problem, and impairment.’”¹⁶³

Plaintiff won a verdict on his claim for fraudulent concealment or misrepresentation of his cocaine use at the time of surgery. However, the trial court entered JNOV for the defendant, holding he had no duty to disclose his substance abuse.¹⁶⁴ The Court of Appeals reversed and the Supreme Court of Georgia “granted certiorari to determine: (1) [w]hether there exists a duty arising from all professional relationships to disclose any factor or factors of the professional’s life which might adversely affect the professional’s performance; (2) [w]hether the failure to disclose such factors supports an action for fraud and battery.”¹⁶⁵

The Supreme Court commented upon the Georgia history of the law of informed consent. The common law did not recognize the claim such that if a patient did not inquire of potential surgical risks, the physician had no duty to volunteer.¹⁶⁶ The common law rule was changed in 1988 by statute¹⁶⁷ but the “statutory list of mandatory disclosures does not include a requirement that physicians disclose to their patients any aspect of their personal lives which might adversely affect their professional performance.”¹⁶⁸

In concluding that the court of appeals erroneously held that the defendant had the duty under Georgia common law or statute “to disclose his drug use to his patients prior to rendering services,”¹⁶⁹ the Supreme Court acknowledged that the Georgia informed consent statute “is in derogation of the common law rule against requiring physicians to disclose medical risks to their patients,”¹⁷⁰ requires strict construction “and cannot be extended beyond its plain and explicit terms.”¹⁷¹ The Supreme Court did not discount the evidence of illicit drug use as relevant to a medical negligence claim but it would not support an independent cause of action.¹⁷²

2. Louisiana

In *Hidding v. Williams*,¹⁷³ the Court of Appeals of Louisiana was receptive to an informed consent claim based on a physician’s non-disclosure of his

162. *Id.*

163. *Id.*

164. *Id.* at 779.

165. *Albany Urology Clinic v. Cleveland*, 528 S.E.2d 777, 779 (Ga. 2000).

166. *Id.*

167. GA. CODE ANN. § 31-9-6.1 (West 2009).

168. *Albany*, 528 S.E.2d at 780.

169. *Id.*

170. *Id.*

171. *Albany Urology Clinic v. Cleveland*, 528 S.E.2d 777, 780 (Ga. 2000).

172. *Id.* at 781.

173. 578 So. 2d 1192, 1192 (La. Ct. App. 1991).

chronic alcohol abuse. *Hidding* involved an orthopedic surgical procedure with attendant, severe neurological consequences.¹⁷⁴ The defendant surgeon had not disclosed to plaintiff that he “was suffering from alcohol abuse at the time of the surgery.”¹⁷⁵

At trial, there was substantial testimony and other evidence as to the surgeon’s prior medical license suspension,¹⁷⁶ the impact of chronic alcoholism,¹⁷⁷ history of alcoholism,¹⁷⁸ how alcoholism impacted his home and family life¹⁷⁹ and his divorce.¹⁸⁰ The defendant testified at trial that “he is not dependent on alcohol and has never been an alcohol abuser,”¹⁸¹ and “contended that the license suspension was based on unsubstantiated hearsay.”¹⁸²

The court agreed with the trial judge’s finding that the surgeon’s “failure to disclose his chronic alcohol abuse to [the patient and his wife] vitiated their consent to surgery.”¹⁸³ The defendant’s chronic alcohol abuse created “a material risk associated with the surgeon’s ability to perform, which if disclosed would have obliged the patient to have elected another course of treatment.”¹⁸⁴

A relatively recent study addresses alcohol use by physicians while on duty.¹⁸⁵ The study refers to a difference of opinion among physicians as to the obligation to “tell a patient if they have taken alcohol before treating them.”¹⁸⁶ The study refers to the doctrine of informed consent and notes “that most patients want to know”¹⁸⁷ about physician alcohol use while on duty.

3. Tennessee

In *Hawk v. Chattanooga Orthopedic Group*,¹⁸⁸ the informed consent issue concerned an orthopedic surgeon’s failure to disclose his affliction with Ray-

174. *Id.*

175. *Id.* at 1194.

176. *Id.* at 1196-97.

177. *Id.*

178. *Id.*

179. *Hidding v. Williams*, 578 So. 2d 1192, 1197 (La. Ct. App. 1991).

180. *Id.*

181. *Id.*

182. *Id.*

183. *Id.* at 1196.

184. *Id.*

185. *See generally* Norman A. Desbiens, Mukta Panda, Neema Doshi & James Peterman, *Public Perceptions of Alcohol Use by Physicians*, 98 S. MED. J. 5 (2005) (assessing public perceptions of alcohol use by physicians on duty using a random telephone survey of 408 adults in one Tennessee county).

186. *Id.* at 7.

187. *Id.* at 8.

188. 45 S.W.3d 24 (Tenn. Ct. App. 2001).

naud's Syndrome,¹⁸⁹ affecting his hand. The surgeon had performed a right total hip replacement for plaintiff, who was unsatisfied with the results and filed suit.¹⁹⁰ Apparently, the surgeon's health condition was learned through the discovery process.¹⁹¹

The Court of Appeals referred to plaintiff's allegations that "a surgeon, suffers from a hand condition that affects the use of those hands"¹⁹² and that this information should have been disclosed under the Tennessee Medical Malpractice Act.¹⁹³ The court of appeals held that "an informed consent malpractice action" was alleged.¹⁹⁴

4. Wisconsin

The Wisconsin Court of Appeals has taken the position that a physician's prior health history or prior drug and alcohol abuse are not subject to disclosure insofar as there is no current increased risk to the patient.¹⁹⁵ In *May v. Cusick*,¹⁹⁶ the patient sued a surgeon and claimed that pursuant to the Wisconsin informed consent statute¹⁹⁷ the surgeon's failure to disclose his history of strokes resulted in a lack of informed consent. The two strokes were "slight,"¹⁹⁸ and occurred some years prior to plaintiff's operation.¹⁹⁹ The court of appeals reasoned that the surgeon "had made a complete recovery from his earlier strokes and had suffered no residual effects. Thus, the doctor's health history was not material because a reasonable person would not have attached any significance to it."²⁰⁰

Similarly, in *Mau v. Wisconsin Patients Compensation Fund*,²⁰¹ the same court held that a surgeon was not obligated to disclose to the patient his history of drug and alcohol problems, since this information "has no relevance to a particular course of treatment."²⁰² There was evidence showing that the surgeon "had not been using drugs in the months before, during and after [the pa-

189. See Gregory J. Landry et al., *Long-term Outcome of Raynaud's Syndrome in a Prospectively Analyzed Patient Cohort*, 23 J. VASCULAR SURGERY 76 (1996) (discussing the potential progression of the disease process which may include serious hand conditions).

190. *Hawk*, 45 S.W.3d at 24.

191. *Id.*

192. *Id.* at 33.

193. TENN. CODE ANN. § 29-26-115 *et seq.* (West 1980).

194. *Hawk v. Chattanooga Orthopaedic Grp.*, 45 S.W.3d 24, 33 (Tenn. Ct. App. 2001).

195. *May v. Cusick*, No. 99-2520, 2001 WL 436286 (Wis. Ct. App. May 1, 2001) (discussing the history of stroke); *Mau v. Wisconsin Patients Compensation Fund*, No. 02-0244, 2003 WL 21706407 (Wis.App. July 24, 2003) (noting the history of drug and alcohol abuse).

196. 2001 WL 43686, at *1

197. WIS. STAT. § 448.30 (West 2005).

198. *May*, 2001 WL 43686, at *5.

199. *Id.*

200. *Id.*

201. No. 02-0244, 2003 WL 21706407 (Wis. Ct. App. July 24, 2003).

202. *Id.* at *2.

tient's] surgery, a fact substantiated by random drug testing."²⁰³ Therefore, the surgeon was not obligated to disclose "his history of drug and alcohol abuse under the informed consent law because [he] was not using those substances during the period in which he operated on [plaintiff]."²⁰⁴

5. *Pennsylvania*

Kaskie v. Wright,²⁰⁵ concerned a medical negligence action against a surgeon who did not disclose his alcoholism to the patient. The Supreme Court identified its inquiry as "whether the patient was made aware of all material risks which are collateral to a given procedure, including, at least 'the nature of the operation to be performed, the seriousness of it, the organs of the body involved, the disease or incapacity sought to be cured, and the possible results.'"²⁰⁶ Referring to the physician's alleged alcoholism as "some alleged characteristics of the person performing [the procedure],"²⁰⁷ the court simply refused to expand the doctrine of informed consent to "matters not specifically germane to surgical or operative treatment."²⁰⁸ The court asked the central question as follows: "[a]re patients to be informed of every fact which might conceivably affect performance in the surgical suite?"²⁰⁹ It answered the question by stating,

[m]atters such as personal weakness and professional credentials of those who provide healthcare are the responsibility of the hospital employing them, the professional corporations who offer their services, or the associations which are charged with oversight. Their failure to fulfill their obligations in this regard becomes a matter of negligence, and it is from them that recovery must be sought.²¹⁰

This commentary suggests that the court minimizes the direct disclosure of information that would likely be of interest to a patient. That disclosure is not the obligation of the physician seems to enforce physician paternalism, a target of the "patient as consumer" concept.

6. *Alberta, Canada*

The Alberta Court of Appeal has weighed in on the obligation of a surgeon to disclose a personal health history of epilepsy in order to obtain in-

203. *Id.*

204. *Id.*

205. 589 A.2d 213 (Pa. 1991).

206. *Id.* at 216 (quoting *Gray v. Grunnagle*, 223 A.2d 663, 674 (Pa. 1996)).

207. *Kaskie*, 589 A.2d at 216.

208. *Id.* at 217.

209. *Id.*

210. *Id.*

formed consent. In *Halkyard v. Mathew*,²¹¹ the defendant Ob-Gyn performed a total hysterectomy for the patient. After post-operative complications and subsequent surgery, the patient died.²¹² The Ob-Gyn had epilepsy but suffered neither an epileptic seizure nor complication of his epilepsy medication. The physician's epilepsy did not contribute to his patient's death.²¹³

The court undertook a rather curious analysis when compared with the law of informed consent more typical in the states. Plaintiff urged the court to look to the physician's non-disclosure of his epilepsy as sufficient to vitiate consent.²¹⁴ Had the patient been advised of the epileptic condition, consent would not have been given.²¹⁵ The court also noted that the patient, a nurse, with the knowledge of her physician's condition, would have consulted another surgeon.²¹⁶ The court doubted that the evidence proved that the patient would have refused her consent if she knew of her physician's health.²¹⁷

The court then focused on causation and stated that,

"we do not accept that the law in Canada imposes any liability in negligence on a doctor who fails to disclose his personal medical problems in a case where those medical problems cause no harm to the patient. When harm is caused by the lack of disclosure, liability in negligence may arise."²¹⁸

Of course, if the law requires a nexus between the undisclosed condition and the patient injury, the law would trivialize the non-disclosure. If, as the court suggests, battery claims are limited "to cases where surgery or treatment has been performed or given to which there has been no consent at all or where . . . surgery or treatment has been performed or given beyond that to which there was consent,"²¹⁹ that the patient would not have consented to treatment with knowledge of the physician's health would not support a battery claim. Apparently, only the use of fraud or misrepresentation to secure the patient's consent would support a battery claim.²²⁰

The *Halkyard*²²¹ opinion essentially constitutes a "hindsight" approach to the physician's disclosure of a personal health condition. If the duty to disclose is premised upon a causal relationship between the physician's health and injury suffered by the patient, the informed consent process is undermined. The patient is not required to be injured by the health risk; rather, the injury is that the patient was not given information which might lead to the patient's refusal to have the procedure or to the patient's choice of another

211. [2001] 91 Alta. L.R.3d 201 (Can.).

212. *Id.* at para. 2.

213. *Id.* at para. 4.

214. *Id.* at para. 5.

215. *Id.* at para. 5, 10.

216. *Id.* at para. 10.

217. *Halkyard v. Mathew*, [2001] 91 Alta. L.R.3d 201, para. 10 (Can.).

218. *Id.* at para. 11.

219. *Id.* at para. 7. (citing *Reibl v. Hughes*, [1980] 2 S.C.R. 880, 890-92 (Can.)).

220. *Halkyard*, 91 Alta L.R.3d at para. 12.

221. *Id.*

physician. *Halkeyard*²²² has been the subject of comment,²²³ some of which questions the limit of the informed consent doctrine if provider-specific health must be disclosed.

C. HIV

The intersection of the HIV+ physician and the doctrine of informed consent has formed the basis for passionate debate. If HIV+ physicians have a duty to disclose this status to patients in order to obtain informed consent,²²⁴ it is only a short step to requiring physicians who engage in invasive procedures to submit to mandatory HIV testing. This position has been advocated.²²⁵

Before examining case law, it is important to examine opinions and recommendations of influential medical organizations to determine if they are advocating the disclosure of physician HIV positivity in the informed consent process. The positions of the American Medical Association, the American College of Surgeons, the American College of Obstetricians and Gynecologists and the Centers for Disease Control will be explored.

The AMA published an Opinion concerning, in part, HIV infected physicians.²²⁶ This Opinion, in relevant part, provides:

[a] physician who knows that he or she is seropositive should not engage in any activity that creates a significant risk of transmission of the disease to others. A physician who has HIV disease or who is seropositive should consult a colleagues as to which activities the physician can pursue without creating a risk to patients.²²⁷

222. *Id.*

223. See generally Brenda J. Johnson, *Recent Decisions: Must Doctors Disclose Their Own Personal Risk Factors?* *Halkeyard v. Mathew*, 10 HEALTH L. REV. 18 (2001) (discussing the *Halkeyard* decision and imposing requirements on doctors to disclose information to patients about themselves); Cynthia Heinz, *How Much Is Enough? Patients' Right-To-Know Versus Privacy Rights Of Healthcare Providers*, 7 LEGAL FOCUS ON RISK & INS. STRATEGIES 81 (2007) (noting basic negligence principles).

224. See Theodore R. LeBlang, *Obligations of HIV-Infected Health Professionals to Inform Patients of Their Serological Status: Evolving Theories of Liability*, 27 J. MARSHALL L. REV. 317, 326 (1994) (recognizing "an obligation for physicians to respond truthfully to specific inquiries from patients regarding their HIV status"). See generally Michael L. Closen, *HIV-AIDS, Infected Surgeons and Dentists, and the Medical Profession's Betrayal of its Responsibility to Patients*, 41 N.Y.L. SCH. L. REV. 57 (1996) (arguing for mandatory disclosure and discussing the cases where courts have considered the issue).

225. See generally Michael L. Closen, *A Call for Mandatory HIV Testing and Restriction of Certain Health Care Professionals*, 9 ST. LOUIS U. PUB. L. REV. 421 (1990).

226. *Code of Medical Ethics, Opinion 9.13 – HIV-Infected Patients and Physicians*, AM. MED. ASS'N (1998), <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion913.shtml>.

227. *Id.*

Clearly, this opinion neither mandates nor recommends that an HIV+ physician disclose this status to a patient in order to obtain informed consent.

The American College of Surgeons has published a lengthy "*Statement on the Surgeon and HIV Infection*."²²⁸ It provides, in relevant part:

[b]ecause the disease is blood-borne and transmissible, and due to the nature of surgical work, a concerned surgical community has become involved and has offered leadership in developing enhanced sterile surgical barriers, and improved surgical techniques and procedures. Surgeons are at-risk for exposure to HIV and are concerned about this risk. Patients have been concerned about their potential risk of exposure to HIV infection from blood transfusions, other patients, health care workers, and surgeons.

....

There has been no documented transmission of HIV infection in the performance of surgical treatment from a surgeon to a patient to this date.

....

Guidelines published in July 1991 by the Centers for Disease Control and Prevention (CDC) have been widely distributed and have not been amended or changed since that time. The College has expressed concern that these actions were not based upon direct scientific data, were not cost-effective, and were intrusive to the extreme. We continue to feel that the recommendations of defining "risk-prone procedures," as was recommended by the CDC, cannot be determined in a scientific or rational way. We have felt, and continue to feel, that these recommendations were irrelevant and counterproductive. In formulating these guidelines, the CDC ignored the overwhelming testimony of the scientific community, and the fact that all currently available data indicate that transmission from surgeon to patient in a hospital setting continues to be a hypothetical event.

While basic, clinical, and epidemiological research continues, a number of issues remain unresolved. The surgical community emphasizes that available scientific data indicate that transmission of HIV infection from physician, surgeon, or nurse to patient is extremely rare. The overall risk of transmission of HIV from infected surgeons to patients appears to be so low that costly measures, such as testing and limiting of work, are not justified. This is especially true now that antiretroviral therapy has advanced to a level to make many infected individuals virtually free of virus in their blood.

We continue to believe in operating room behavior that will minimize the risk of transmission of HIV or any other blood-borne or environmentally transmissible pathogen. We believe in enforcing a high standard of infection control and universal precautions, which remain

228. *Statement on the Surgeon and HIV Infection, ST-13*, AMERICAN COLLEGE OF SURGEONS (2010), http://www.facs.org/fellows_info/statements/st-13.html.

the best strategy for protecting patients and surgeons from accidental exposure. We should continue to emphasize the absence of scientific data about any transmissions in the operating room environment, so that a healthy atmosphere can be maintained in the minds of patients and the public regarding the problem of HIV transmission. Any regulatory efforts should be based solely on documented scientific data and not on unfounded hysteria.

....

While therapy for HIV infection has not resulted in eradication of the disease, effective combination antiretroviral therapy is available that reduces antigenemia from the infection, improves quality of life, and appears to significantly improve life expectancy. Surgeons should know their HIV serologic status in the same way that they would want to have knowledge of any other disease about which they may have personal concerns. This personal and confidential information about HIV infection would allow the surgeon to obtain important treatment and counseling for his or her own personal health, and should not be used for any determinations of credentialing or privileging for surgical practice.

Based on data that are currently available, we make the following recommendations:

1. Surgeons have the same ethical obligations to render care to HIV-infected patients as they have to care for other patients.
2. Surgeons should utilize the highest standards of infection control, involving the most effective known sterile barriers, universal precautions, and scientifically accepted infection control practices. This practice should extend to all sites where surgical care is rendered and to all patients who receive surgical care.
3. Based on data in the current literature, HIV-infected surgeons may continue to practice and perform invasive procedures and surgical operations unless there is clear evidence that a significant risk of transmission of infection exists through an inability to meet basic infection control procedures, or the surgeon is functionally unable to care for patients. These determinations are to be made by the surgeon's personal physician and/or an institutional panel so designated for confidential counseling. Such a panel should be composed of infectious disease specialists, surgeons, and other health care professionals who are knowledgeable about blood-borne infections.
4. Postexposure prophylaxis with antiretroviral chemotherapy is recommended. Counseling and recommendations for surgeons are available through the National Clinicians' Postexposure Hotline at 1888- 448-4911, or at <http://www.ucsf.edu/hivcntr>.
5. Surgeons should know their own status for HIV infection, as they would be knowledgeable about any other disease or illness that is of concern to them personally. Treatment of HIV infection, while not curative, has been effective and is recommended. Knowledge of the HIV infection status of the individual is not to be used in the deter-

mination of suitability of the surgeon for surgical practice. The HIV status of a surgeon is personal health information and does not need to be disclosed to anyone.

6. Various College committees should continue to consider the concerns and problems of HIV- infected surgeons and their families in their deliberations. The College committees will continue to monitor new developments in HIV infection and its treatment to optimize patient safety and safety in surgical practice.²²⁹

This ACS statement neither discourages HIV+ surgeons from performing invasive procedures nor requires that they disclose their HIV status to patients as a component of the informed consent process. The ACS statement essentially dismisses the CDC's July 1991 recommendations,²³⁰ including that which states:

HCWs [Health Care Workers] who are infected with HIV . . . should not perform exposure-prone procedures unless they have sought counsel from an expert review panel and been advised under what circumstances, if any, they may continue to perform these procedures. *Such circumstances would include notifying prospective patients of the HCW's seropositivity before they undergo exposure-prone invasive procedures.*²³¹

Therefore, the CDC recommends physician disclosure of seropositivity to patients, and the ACS does not.

The American College of Obstetricians and Gynecologists (ACOG), an organization of more than 51,000 members,²³² has spoken on the topic of the HIV+ Ob-Gyn. The ACOG Code of Professional Ethics advises that:

5. The obstetrician-gynecologist who has reason to believe that he or she is infected with the human immunodeficiency virus (HIV) . . . should voluntarily be treated for the protection of his or her patients. In making decisions about patient care activities, a physician infected with such an agent should adhere to the fundamental professional obligation to avoid harm to patients.²³³

Although this ethical obligation does not refer to informed consent, ACOG's Committee Opinion on the Human Immunodeficiency Virus does contain the following: "[i]f physicians avoid procedures that place patients at risk of harm, they have no obligation to inform the patient of their positive

229. *Id.* (emphasis added).

230. Centers for Disease Control & Prevention, *Recommendation for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures*, 40 MORBIDITY & MORTALITY WEEKLY REPORT 1, 1-9 (1991).

231. *Id.* at 5. (emphasis added).

232. *ACOG Fact Sheet*, AM. COLL. OF OBSTETRICIANS AND GYNECOLOGISTS (2010) http://www.acog.org/from_home/ACOGFactSheet.pdf.

233. *Code of Professional Ethics of the American College of Obstetricians and Gynecologists*, AM. COLL. OF OBSTETRICIANS AND GYNECOLOGISTS (2008), http://www.acog.org/from_home/acogcode.pdf.

HIV serostatus.”²³⁴ This statement recognizes the need for disclosure by the Ob-Gyn to the patient if a risk of transmission to the patient is inherent in the procedure.

With the varying positions of influential medical organizations as a background, judicial opinions will be explored.

1. Maryland

*Faya v. Almaraz*²³⁵ concerned an HIV+ oncological surgeon who performed breast surgery without disclosing his HIV status to patients. The surgeon subsequently died of AIDS and, thereafter, his patients learned of the circumstances of his death from a newspaper account.²³⁶

Complaints for medical negligence were filed against the surgeon, including informed consent claims. The Court of Appeals of Maryland found that the surgeon “was negligent in failing to disclose his HIV-positive status before operating on Faya and Rossi.”²³⁷ The foreseeability of transmission despite its low risk was central to the decision.²³⁸

2. Minnesota

In *K.A.C. v. Benson*,²³⁹ the Supreme Court of Minnesota had the opportunity to resolve the HIV+ physician disclosure issue but chose not to do so. Here, the defendant was a family practice physician who performed gynecological procedures while HIV+.²⁴⁰ His dermatologist reported his HIV status to the state medical board, which “advised [him] to wear two pairs of gloves when caring for patients and to refrain from performing surgery,”²⁴¹ which he did. Later, the board restricted the defendant “from delivering babies, from performing surgery, or performing invasive procedures using a sharp instrument in a patient’s body cavity.”²⁴² Thereafter, the board contacted patients of the defendant by letter, signed by the defendant to alert them of the defendant’s diagnosis.²⁴³

The claims considered by the Supreme Court were battery and negligent nondisclosure, premised upon the defendant’s nondisclosure of his HIV

234. Am. Coll. of Obstetricians and Gynecologists, Committee of Ethics, *ACOG Committee Opinion No. 389: Human Immunodeficiency Virus*, 110 OBSTETRICS & GYNECOLOGY 1473, 1477 (2007).

235. 620 A.2d 327, 327 (Md. 1993).

236. *Id.* at 329.

237. *Id.* at 333.

238. *Id.*

239. 527 N.W.2d 553 (Minn. 1995).

240. *Id.* at 553.

241. *Id.* at 556.

242. *Id.*

243. *Id.* at 556-57.

status. Apparently, one plaintiff inquired of defendant's weight loss and skin condition.²⁴⁴ Defendant's explanation did not include his HIV+ status.²⁴⁵

As to the battery claim, the court noted that the defendant neither "performed a different procedure from that to which [plaintiff] consented"²⁴⁶ nor "significantly increase[d] the risk that T.M.W. would contract HIV."²⁴⁷ As such, he did not fail "to disclose a material aspect of the nature and character of the procedure performed."²⁴⁸ The battery claim failed.²⁴⁹

With respect to the negligent nondisclosure claim, the court was not anxious to reach the issue of whether a physician is obligated to disclose his HIV status to his patient. The court stated:

[w]hether or not Dr. Benson had a legal duty to disclose his HIV status to his patients, the breach of a legal duty without compensable damages recognized by law is not actionable. Here, the undisclosed, miniscule 'risk' of HIV exposure did not materialize in harm to plaintiff because T.M.W. tested negative for the HIV antibody. Therefore, T.M.W.'s claim for negligent nondisclosure fails.²⁵⁰

The court used a "hindsight approach" to avoid addressing the informed consent issue. If an informed consent based claim is viable only upon the materialization of the undisclosed risk (transmission of HIV), the gist of the claim that, with knowledge of the risk, the patient would have opted for a different physician, is marginalized.

3. New Jersey

In *Estate of Bebringer v. Medical Center at Princeton*,²⁵¹ the court considered claims brought on behalf of an HIV+ otolaryngologist (ENT) against the medical center where he had staff privileges for breach of its duty to keep his medical condition confidential and for discrimination. The opinion details the physician's illness and the response and actions taken by the medical center, including requiring the physician to disclose his HIV status to surgical patients in order to obtain informed consent.²⁵²

The court referred to the "reasonable patient" standard in defining informed consent. "The physician's duty is to explain, in words the patient can understand, that medical information and those risks which are material. Medical information or a risk of a medical procedure is material when a reasonable patient would be likely to attach significance to it in deciding whether

244. *Id.* at 561.

245. *K.A.C. v. Benson*, 527 N.W.2d 553, 561 (Minn. 1995).

246. *Id.* at 561.

247. *Id.*

248. *Id.*

249. *Id.* at 553.

250. *Id.* (citations omitted).

251. 592 A.2d 1251 (N.J. Super. Ct. Law Div. 1991).

252. *See generally id.*

or not to submit to the treatment.”²⁵³ The court dismissed the physician’s arguments regarding the remoteness of risk and scope of the informed consent doctrine.²⁵⁴ The court, applying informed consent law, concluded:

that the risk of accident and implications thereof would be a legitimate concern to the surgical patient, warranting disclosure of this risk in the informed-consent setting. It is inconsistent with the underlying policy considerations expressed in *Largey*²⁵⁵ to suggest that the patient should be informed *after* the fact of the need for HIV testing and surveillance.²⁵⁶

The court rejected plaintiff’s position, with its lack of concern for patient risk, as “anachronistic paternalism.”²⁵⁷

4. *Pennsylvania*

*In re Application of Milton S. Hershey Medical Center*²⁵⁸ considered the propriety of a court order authorizing hospitals to disclose the name and medical information of an HIV+ Ob-Gyn resident to certain patients and medical staff members. Although the court was not required to resolve an informed consent dispute, the Court framed the issue as follows:

[s]hould a patient be told of his/her physician’s health status before consenting to medical care by that professional? In order to make an informed choice, should not the patient have before him/her all of the pertinent available information regarding the doctor’s qualifications, including the fact that s/he might be carrying a transmittable, deadly virus?²⁵⁹

The court did not accept the invitation to answer the question, urging that “these issues were raised by the non-moving party and their resolution is not pertinent to the disposition of this appeal.”²⁶⁰ Of interest is that the court referred to the patient’s access to “the doctor’s qualifications,”²⁶¹ certainly a broad “patient as consumer” approach to informed consent.

In *Scoles v. Mercy Health Corp.*,²⁶² the court considered claims of an HIV+ orthopedic surgeon against health care institutions under the Rehabilitation Act²⁶³ and the Americans With Disabilities Act²⁶⁴ after he was prohibited from

253. *Id.* at 1278.

254. *Id.* at 1264-65.

255. *See generally* *Largey v. Rothman*, 540 A.2d 504 (N.J. Super. Ct. Law Div. 1988).

256. *Estate of William Behringer*, 592 A.2d at 1280.

257. *Id.* at 1282.

258. 595 A.2d 1290 (Pa. Super. Ct. 1991).

259. *Id.* at 1299 (citations omitted).

260. *Id.* at 1300.

261. *Id.* at 1299.

262. *Scoles v. Mercy Health Corp. of Southeastern Pa.*, 887 F. Supp. 765 (E.D. Pa. 1994).

263. The Rehabilitation Act, 29 U.S.C. § 794 (West 1973).

264. American Disabilities Act, 42 U.S.C. § 12113(a)-(b) (West 1990).

performing surgery without patients' informed consent regarding his HIV status. This was not a medical negligence claim, and therefore, informed consent was not discussed in that context. The court did note, however, that "[d]efendants reasonably decided that Dr. Scoles's patients should not undergo an invasive procedure without knowledge of his HIV status."²⁶⁵

D. Physician Qualifications and Training

Patients assume that their physicians are qualified to render care – a reasonable assumption. But some physicians are undoubtedly more qualified than others. Many physicians are "board certified," typically indicating that they have completed residency and/or fellowship training and have passed rigorous examinations. Some "boards" are approved by the American Board of Medical Specialties (ABMS)²⁶⁶ and others are not. If membership in an ABMS recognized board carries greater dignity and weight, is the patient entitled to know that a physician is a member of an "independent board?" Is the patient entitled to know that "turf battles" exist between plastic and cosmetic surgery or orthopedic surgery and neurosurgery? Is the surgeon obligated to advise the patient of the qualifications of the operating room personnel in order to obtain informed consent?

1. *Hawaii*

In *Ditto v. McCurdy*,²⁶⁷ the Supreme Court of Hawaii considered a medical negligence action against a surgeon in connection with breast augmentation surgery for the plaintiff, who suffered severe complications. The defendant surgeon was a board certified ENT who also held board certification from the American Board of Cosmetic Surgery, a board not recognized by the ASMS.²⁶⁸ The defendant did not disclose those qualifications to the plaintiff in the informed consent process.²⁶⁹

The Supreme Court noted that Hawaii's informed consent statute²⁷⁰ requiring its board of medical examiners to establish informed consent criteria.²⁷¹ Recognizing this informed consent issue as one of the first impression in the state,²⁷² the court held that the surgeon had no duty to disclose his qualifications. For the criteria to change, the matter would have to be addressed by the Hawaii legislature and board of medical examiners.

265. *Scoles*, 887 F. Supp. at 772.

266. There are twenty-four member boards of the Am. Board of Med. Specialties.

267. 947 P.2d 952, 952 (Haw. 1997).

268. *Id.* at 955.

269. *Id.* at 955.

270. HAW. REV. STAT. § 671-3 (West 2008).

271. *Ditto*, 947 P.2d at 958.

272. *Id.*

2. New York

The New York Supreme Court, Appellate Division has addressed the mandatory disclosure of qualifications on multiple occasions. In *Zimmerman v. New York City Health and Hospital Corp.*,²⁷³ the court held that the doctrine of informed consent, under the circumstances of the case, did not include the disclosure of “details as to the surgeon’s training.”²⁷⁴ The surgeon was a chief resident. In *Abram v. Children’s Hospital*,²⁷⁵ the court referred to the informed consent statute²⁷⁶ and held that “it cannot reasonably be read to require disclosure of qualifications of personnel providing that treatment.”²⁷⁷ Here, the issue was whether the patient was entitled to a disclosure “that a nurse anesthetist and/or a student physician and/or a resident in obstetrics and gynecology were to participate vitally in the administration of anesthetic during her surgery.”²⁷⁸ In *Johnson v. Jacobowitz*,²⁷⁹ the court approved the trial court’s order in limine precluding “plaintiff from introducing evidence that [the physicians] did not have the proper credentials to perform the heartport procedure during the surgery.”²⁸⁰ The doctrine of informed consent did not require the disclosure of physician qualifications.

3. Washington State

In *Thomas v. Wilfac*,²⁸¹ the state court of appeals considered claims against a physician who rendered care to the plaintiff in a “walk-in emergency treatment facility.”²⁸² The physician, “a resident in radiology with experience in emergency room medicine”²⁸³ did not advise the plaintiff that he was not a specialist in emergency medicine. In referring to the informed consent statute,²⁸⁴ the court noted that it did not require the “disclosure of a physician’s qualifications.”²⁸⁵

273. 458 N.Y.S.2d 552 (N.Y. App. Div. 1983).

274. *Id.* at 554.

275. 542 N.Y.S.2d 418 (N.Y. App. Div. 1989).

276. N.Y. PUB. HEALTH LAW § 2805(d).

277. *Abram*, 542 N.Y.S.2d at 419.

278. *Id.* at 418.

279. 884 N.Y.S.2d 158 (N.Y. App. Div. 2009).

280. *Id.* at 161.

281. 828 P.2d 597 (Wash. Ct. App. 1992).

282. *Id.* at 599.

283. *Id.*

284. WASH. REV. CODE § 7.70.050(1) (West 1975).

285. *Thomas*, 828 P.2d at 601.

E. Participation of Resident Physicians, Physicians Assistants

Physicians in training (residents²⁸⁶), physician assistants²⁸⁷ and surgeons' assistants²⁸⁸ may participate in surgery. The latter two categories of healthcare practitioners are not licensed physicians. Is the patient entitled to a disclosure of the participation of these individuals in the informed consent process?

1. Maryland

In *Dingle v. Belin*,²⁸⁹ the Court of Appeals of Maryland considered an informed consent claim based upon the failure to disclose a resident's participation in gallbladder removal surgery. The patient claimed that had she been aware of the resident's role, she would not have given consent.²⁹⁰ The defendant surgeon argued that "[c]reating a duty to disclose a resident's precise role . . . would permit patients to choreograph how an operation is to be performed negating all possibility of informed medical judgment occurring during the operation."²⁹¹ The court recognized only if a physician:

agrees to a specific allocation of responsibility or a specific limitation on his or her discretion in order to obtain the consent of the patient to the procedure and then, absent some emergency or other good cause, proceeds in contravention of that allocation or limitation has not obtained the informed consent of the patient.²⁹²

Of course, this holding presupposes a discussion with the patient and, likely, a patient inquiry. It does not obligate the physician to disclose the resident's role to obtain the classic informed consent.

2. New York

In *Henry v. Bronx Lebanon Med. Center*,²⁹³ the court considered an informed consent claim involving the delivery of a child by a second year resident. There were post-delivery complications.²⁹⁴ At trial, the jury found that the "failure to get Ms. Henry's consent to have Dr. Umali deliver her baby

286. A resident has been defined as "a physician in an accredited graduate medical education specialty program." *Glossary*, ACCREDITATION COUNCIL FOR GRADUATE MEDICAL EDUCATION (2010), http://www.acgme.org/acwebsite/about/ab_acgmeglossary.pdf.

287. *About Physician Assistants*, AMERICAN ACADEMY OF PHYSICIAN ASSISTANTS (2010), <http://www.aapa.org/about-pas>.

288. See *Official Position on Non-Physician Surgical Assistants*, AM. MED. ASS'N (2010) <http://www.ilsaa.net/aboutus/qualifications.php> (discussing the qualifications and duties of surgeons assistants).

289. 749 A.2d 157 (Md. 2000).

290. *Id.* at 160.

291. *Id.* at 163 (internal quotations omitted).

292. *Id.* at 166.

293. 385 N.Y.S.2d 772 (N.Y. App. Ct. 1976).

294. *Id.* at 774.

under the supervision of Dr. Weinstein”²⁹⁵ was a proximate cause of the child’s injuries. Here, the court noted that the custom at the hospital was for residents in training to perform “complicated deliveries.”²⁹⁶ Since the patient went to that hospital, she “consented to the customs and practices of that hospital.”²⁹⁷

3. Wisconsin

In *Prissel v. Physicians Ins. Co.*,²⁹⁸ the Court of Appeals of Wisconsin considered an informed consent claim pertaining to the performance of coronary bypass surgery. There was “no dispute that [defendant surgeon] was an experienced cardiovascular surgeon.”²⁹⁹ The issue here was that a physician’s assistant assisted the cardiovascular surgeon. Post-operative complications ensued, perhaps due to pre-existing risk factors and post-operative care. The Court referred to the Wisconsin informed consent statute³⁰⁰ and the *Kokemoor*³⁰¹ decision and concluded that the disclosure of the participation of a physician’s assistant at surgery was not required. Essentially, the use of the physician’s assistant did not increase the risk to the patient.

F. Disciplinary History

1. Nebraska

The Supreme Court of Nebraska in *Curran v. Buser*³⁰² addressed the issue of informed consent and the disclosure of a physician’s disciplinary history. The court referred to the Nebraska informed consent statute³⁰³ as encompassing the physician-friendly, professional theory of the doctrine. Physician related disclosures are required “only when mandated by the standard of care.”³⁰⁴ Since there was a lack of proof that the standard of care required such a disclosure, evidence pertaining to the physician’s disciplinary history was not relevant to the claim and was inadmissible.

295. *Id.* at 774.

296. *Id.* at 775.

297. *Id.*

298. No. 02-1729, 2003 WL 22998133 (Wis. Ct. App. Dec. 23, 2003).

299. *Id.* at *1.

300. WIS. STAT. § 448.30 (West 1982).

301. *See generally*, Johnson v. Kokemoor, 545 N.W.2d 495 (1996).

302. 711 N.W.2d 562 (2006).

303. NEB. REV. STAT. §§ 44-2816 (West 2004).

304. *Curran*, 711 N.W.2d at 572.

2. Alabama (Dental)

The Supreme Court of Alabama in *Ex parte Mendel*³⁰⁵ considered a discovery dispute arising from a dental negligence action (among other claims) brought pursuant to the Alabama Medical Liability Act.³⁰⁶ Plaintiff alleged that the defendant dentist failed to obtain the patient's informed consent to dental implant surgery by failing to disclose a history of license suspensions and revocations.³⁰⁷ The plaintiff issued a subpoena to the Alabama Dental Board requesting materials, including complaints, pertaining to defendant's practice of dentistry.³⁰⁸ The defendant and Dental Board sought to quash the subpoena.³⁰⁹ The defendants also moved for summary judgment, urging "that because a dentist has no common-law or statutory duty to disclose professional reprimands or licensure suspensions or revocations to his patients, [plaintiff's] 'licensure claims' did not represent cognizable causes of action."³¹⁰

Plaintiff also noticed defendant's deposition and the notice requested that he produce materials pertinent to his dental license suspensions and revocations. This strategy was met by a defense motion to quash or for a protective order. The trial court ultimately ordered the production by the Dental Board and the defendant dentist. The Alabama Supreme Court's review followed defendant's petition for a writ of mandamus.

The Alabama Supreme Court held that the requested discovery of licensure suspension and revocation materials was appropriate under the state Medical Liability Act³¹¹ and rules of civil procedure.³¹² Insofar as the Court reviewed this matter in a discovery dispute posture, it further commented that "we will assume, but need not decide, that Dr. Mendel owed [plaintiff] a duty to disclose 'multiple' suspensions or revocations; reprimands by 'numerous' dental review boards; or suspensions or revocations in 'numerous' states."³¹³ The court noted as well that the discovery is permissible only if "the revocations or suspensions relate to negligence or professional incompetence in the practice of dentistry."³¹⁴

Physician misconduct that leads to disciplinary action can be severe or relatively insubstantial. Inadequate record keeping may occupy one end of the spectrum and criminal conduct the other.³¹⁵ Licensing board decisions may

305. 942 So. 2d 829 (Ala. 2006).

306. ALA. CODE § 6-5-480 *et seq.* (West 1975); ALA. CODE § 6-5-540 *et seq.* (West 1975).

307. *Mendel*, 942 So. 2d at 832-33.

308. *Id.*

309. *Id.* at 832-34.

310. *Id.* at 833.

311. ALA. CODE. § 6-5-551 (West 1975).

312. ALA. R. CIV. P. 26(b)(1).

313. *Ex parte Mendel*, 942 So. 2d 829, 838 (Ala. 2006).

314. *Id.* at 837.

315. See generally James Morrison & Peter Wickersham, *Physicians Disciplined by a State Medical Board*, 279 J. AM. MED. ASS'N. 1889, 1889-93 (1998) (mentioning the various disciplinary actions taken).

be available to the public.³¹⁶ Of course, public information is not a substitute for disclosure required by the doctrine of informed consent. Patients may not be aware of publically available information and may not be able to access it. If a physician's disciplinary history relates to professional competence and patient safety, mandatory disclosure in the informed consent process is arguable. Hopefully, a physician with this history will simply have his or her practice privileges curtailed.³¹⁷

G. FDA Status of Medical Device

If a patient's surgical procedure utilizes the implantation of a device, perhaps hardware, which is not FDA approved, which is FDA approved for other purposes³¹⁸ or is experimental, must the patient be so advised by the surgeon in order to provide informed consent?³¹⁹ Is this a technical aspect of surgery beyond a patient's comprehension? Does the doctrine of informed consent "require that a surgeon inform a patient about, or obtain the patient's consent to, the details or mechanical means of performing an operation?"³²⁰ Courts in a number of states have wrestled with this issue. It should be noted that a patient enrolled in an experimental study in connection with a device not yet approved for use by the FDA is entitled to disclosure of the experimental nature of the study.³²¹

1. Florida

In *Alvarez v. Smith*,³²² the District Court of Appeal considered a claim involving the implantation of surgical screws in the patient's spine. The surgical screws were not FDA approved for use in the procedure.³²³ The court

316. See Frances H. Miller, *Illuminating Patient Choice-Releasing Physician-Specific Data to the Public*, 8 LOY. CONSUMER L. REV. 125, 131 (1995-96).

317. For a case concerning actions by a hospital review board to terminate a physician's privileges and deny an application for reappointment to the hospital's medical staff due to a seriously troubled past, see *Gabaldoni v. Washington County Hosp.*, 250 F.3d 255 (4th Cir. 2001).

318. See William H. Maisel, *Medical Device Regulation: An Introduction For The Practicing Physician*, 140 ANNALS INTERNAL MED. 296, 299-300 (2004) (noting unapproved uses of medical devices).

319. See James M. Beck & Elizabeth D. Azari, *FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions*, 53 FOOD & DRUG L. J. 71, 72 (1998) (arguing that FDA regulatory status should not be discussed with patients as the disclosure would expand the informed consent doctrine beyond medical matters).

320. See *Wachter v. United States*, 689 F. Supp. 1420, 1424 (D. Md. 1988) (noting that Maryland law does not name this disclosure), *aff'd* 877 F.2d 257 (4th Cir. 1989).

321. See *Fritter v. Iolab Corp.*, 607 A.2d 1111 (1992).

322. 714 So. 2d 652 (Fla. Dist. Ct. App. 1998).

323. *Id.* at 653.

framed the issue as “whether there was a duty to inform Appellants of the FDA status of the pedicle screws,”³²⁴ and answered in the negative.

The court favorably cited the opinion in *In re Orthopedic Bone Screw Products Liability Litigation*³²⁵ for the proposition that disclosure was not required as FDA “status is not a medical risk of surgery.”³²⁶ The court in that case specifically held that “the law of informed consent obligates a physician to advise a patient of the medical risks, benefits and alternatives directly related to the patient’s operative procedure. The terms ‘Class III,’ ‘investigational,’ and ‘significant risk’ device are terms adopted by the FDA for administrative or regulatory purposes and cannot be said to be risks of a specific surgical procedure.”³²⁷ The defense verdict was affirmed.

2. New Jersey

In *Blazoski v. Cook*,³²⁸ the court considered a medical negligence action involving the failure of implanted pedicle screws. The screws utilized were not FDA approved for the procedure.³²⁹ The Court held that the doctrine of informed consent did not require disclosure of the FDA status to the patient.³³⁰

3. Ohio

In *Klein v. Biscup*,³³¹ the court considered the informed consent doctrine and the off-label use of bone plates and bone screws. The court found that the off-label use of these devices “is not a material risk inherently involved in a proposed therapy which a physician should disclose to a patient prior to the therapy.”³³² Summary judgment was affirmed.³³³

4. Pennsylvania

In *Corrigan v. Methodist Hospital*,³³⁴ the federal trial court considered a claim arising from a lumbar spine surgery, which utilized a plate and pedicle screw system. Plaintiff claimed that her informed consent was not obtained insofar as she was not advised of the use of the system, the risk of failure, the

324. *Id.* at 653.

325. *In re Orthopedic Bone Screw Products Liab. Litig.*, No. 1014, 9408-0002, 1996 WL 107556 (E.D. Pa. Mar. 8, 1996).

326. *Alvarez*, 714 So. 2d at 653.

327. *Orthopedic Bone*, 1996 WL 107556 at *5.

328. 787 A.2d 910 (N.J. 2002).

329. *Id.* at 911.

330. *Id.*

331. 673 N.E.2d 225 (Ohio Ct. App. 1996).

332. *Id.* at 231.

333. *Blazoski*, 787 A.2d at 910.

334. 869 F. Supp. 1202 (E.D. Pa. 1994).

investigational status of the system and the physicians' financial interest in the manufacturer of the system.³³⁵ Plaintiff claimed that the surgical procedure was unnecessary and that the physicians failed to correctly diagnose a spinal tumor.³³⁶

Insofar as the informed consent claim was concerned, the court referred to Pennsylvania's "prudent patient standard"³³⁷ and the obligation of the jury to determine the materiality of the undisclosed information. The defendant physician contended that he was not obligated "to disclose the FDA status of the VSP Screws."³³⁸

Referring to expert opinions in the case, the court found that it created "an issue of fact as to whether the undisclosed risk of the investigational status of the VSP bone screws and the undisclosed possibility of additional and alternate tests would have encouraged [plaintiff] to opt for a different treatment, and therefore, not suffer her injuries."³³⁹ The court denied the physician's motion for partial summary judgment.

Not long after *Corrigan*, the federal trial court (in the same district), in *In re Orthopedic Bone Screw Products Liability Litigation*³⁴⁰ considered another motion for partial summary judgment in an informed consent claim relating to FDA regulatory status. Again, this case concerned pedicle screws used in spinal surgery.

In disagreeing with *Corrigan*, the court found that FDA regulatory status is not a risk of a procedure³⁴¹ and that "the FDA does not regulate the practice of medicine."³⁴² It distinguished the off-label use of the device in question from the participation of the patient in a clinical investigation. The latter requires disclosure of the investigational status of a product pursuant to FDA regulation, not state informed consent law.³⁴³

More recently, the Supreme Court of Pennsylvania followed suit in *Southard v. Temple University Hospital*.³⁴⁴ This case concerned the non-disclosure of the FDA regulatory status of bone screws and rods.

The court looked favorably upon the decision in *Orthopedic Bone*³⁴⁵ and commented that "[t]he category into which the FDA places the device for marketing and labeling purposes simply does not enlighten the patient as to the nature or seriousness of the proposed operation, the organs of the body

335. *Id.* at 1210.

336. *Id.*

337. *Id.* at 1206.

338. *Id.*

339. *Id.* at 1207.

340. *In re Orthopedic Bone Screw Products Liab. Litig.*, No. 1014, 9408-0002, 1996 WL 107556, at *1 (E.D. Pa. Mar. 8, 1996).

341. *Id.* at *1.

342. *Id.* at *3.

343. *Id.* at *3-4.

344. *Southard v. Temple Univ. Hosp.*, 781 A.2d 101 (Pa. 2001).

345. *Orthopedic Bone*, 1996 WL 107556 at *1.

involved, the disease sought to be cured, or the possible results.”³⁴⁶ Therefore, FDA regulatory status is not a topic for mandatory disclosure under the doctrine of informed consent.

5. South Dakota

In *DeNeui v. Wellman*,³⁴⁷ the federal trial court considered defendant’s motion to exclude expert medical testimony implicating a defendant surgeon’s failure to inform the patient of the FDA status of a product he utilized at surgery to enhance bone growth. The expert further opined that the patient’s post-operation problems resulted from the surgical use of the product.³⁴⁸ Without referring to case law concerned with the nature of the FDA status of products used in surgery, the court essentially relied on the Federal Rules of Evidence³⁴⁹ to deny the defendant’s motion to exclude the opinion regarding failure to disclose and informed consent.³⁵⁰

6. Tennessee

In *Shadrick v. Centennial Medical Center*,³⁵¹ the court of appeals, in a pedicle screw, informed consent claim, held that “there is a disputed issue of material fact as to whether the standard of care in Nashville, Tennessee in 1990 required a disclosure of the lack of FDA approval and the experimental nature of the use of pedicle screws.”³⁵² The court did not discuss the purpose of FDA regulatory status. The Supreme Court of Tennessee affirmed *Shadrick*.³⁵³ There was, likewise, no discussion of FDA status of medical devices.

There have been claims against hospitals for their failure to advise patients of the FDA status of surgical screws.³⁵⁴ As hospitals do not typically share the duty of disclosure with physicians, these cases are not discussed here.

346. *Southard*, 781 A.2d at 107.

347. No. 07-4172, 2009 WL 3188414, at *1 (D. S.D. Aug. 11, 2009).

348. *Id.* at *2.

349. FED. R. EVID. 702.

350. *DeNeui*, 2009 WL 3188414, at *1.

351. No. 01A01-9604-CV-00145, 1996 WL 591179, at *1 (Tenn. Ct. App. Oct. 11, 1996).

352. *Id.* at *7.

353. *Shadrick v. Coker*, 963 S.W.2d 726 (Tenn. 1998).

354. See generally *Staudt v. Froedtert Mem’l Lutheran Hosp.*, 580 N.W.2d 361 (Wis. Ct. App. 1998) (patients sued hospital for injuries resulting from use of screws to remedy back problems); *Reetz v. Jackson*, 176 F.R.D. 412 (D.D.C. 1997) (patient sued doctor and hospital for failure to inform of risks associated with pedicle screws); *Wyttenhove v. Fairview Hosp. & Healthcare Services*, No. C3-97-51, 1997 WL 585813, at *1 (Minn. Ct. App. Nov. 18, 1997) (FDA was aware of permitted off-label use of screw device, which did not violate FDCA).

H. Risk of Negligence

Although it stretches legal imagination, courts have considered whether the doctrine of informed consent requires physicians to disclose the risk that an appropriate procedure may be negligently performed. In theory, if this is a required disclosure, the disclosure would occur prior to *every* procedure performed by every physician. Therefore, this topic does not merit close attention.

1. Colorado

The Colorado Supreme Court and the Colorado Court of Appeals have had no problem disposing of this “issue.” In *Mallett v. Pirkey*³⁵⁵ and, very recently in *Hall v. Frankel*,³⁵⁶ these courts respectively have held that a physician has no duty to disclose the risk of negligence in the performance of a medical procedure.

2. Georgia

The aforementioned Colorado Supreme Court case³⁵⁷ refers to *Mull v. Emory University, Inc.*³⁵⁸ Here, the Court of Appeals of Georgia, in questioning whether the doctrine of informed consent was applicable in Georgia, stated that it “has no relation to the failure to inform of the hazards of an improper procedure.”³⁵⁹ Therefore, *Mull* does not truly support the Colorado Supreme Court’s position.

I. Statistics

Physicians are often well versed in the statistics pertaining to operative success and mortality associated with disease. Is this information subject to the disclosure requirement of informed consent?

1. California

In *Arato v. Avedon*,³⁶⁰ the Supreme Court of California considered an informed consent claim based upon the defendant’s alleged failure to disclose life expectancy rates for pancreatic cancer patients. Here, a pancreatic tumor was incidentally diagnosed during kidney removal surgery.³⁶¹ The patient was

355. 466 P.2d 466 (Colo. 1970).

356. *Hall v. Frankel*, 190 P.3d 852 (Colo. App. 2008).

357. *Mallett*, 466 P.2d at 466.

358. 150 S.E.2d 276 (Ga. Ct. App. 1966).

359. *Id.* at 292.

360. 858 P.2d 598 (Cal. 1993).

361. *Id.* at 600.

referred to an oncology practice for treatment.³⁶² Prior to the commencement of therapy, none of the physicians “specifically disclosed to the patient or his wife the high statistical mortality rate associated with pancreatic cancer.”³⁶³

The California Supreme Court “declin[ed] to endorse the mandatory disclosure of life expectancy probabilities.”³⁶⁴ The court considered these statistics impersonal and unreliable, stating, “statistical morbidity values derived from the experience of population groups are inherently unreliable and offer little assurance regarding the fate of the individual patient; indeed, to assume that such data are conclusive in themselves smacks of a refusal to explore treatment alternatives and the medical abdication of the patient’s well-being.”³⁶⁵

2. Michigan

In *Wlosinski v. Cohn*,³⁶⁶ the Court of Appeals of Michigan considered an informed consent claim in the context of a kidney transplant. The patient had post-operative complications and kidney failure.³⁶⁷ The transplanted kidney was removed and dialysis was commenced.³⁶⁸ The patient ceased dialysis and died.³⁶⁹

The defendant physician had not disclosed his kidney transplant success rate to the patient. The court found that the defendant’s “success rate was not a risk related to the medical procedure”³⁷⁰ and “that a physician’s raw success rates do not constitute risk information reasonably related to a patient’s medical procedure.”³⁷¹ The court held that the defendant “did not have a duty to disclose [his] statistical history of transplant failures to obtain the decedent’s informed consent.”³⁷²

The *Wlosinski* opinion represents good policy. Success rates do not speak to a particular patient’s outcome. Physicians do not desire to discourage patients from seeking treatment, which may be helpful, despite modest results reported over a large population of patients.

362. *Id.*

363. *Id.* at 598.

364. *Id.*

365. *Id.*

366. 713 N.W.2d 16 (Mich. Ct. App. 2006).

367. *Id.* at 18.

368. *Id.*

369. *Id.*

370. *Id.* at 20.

371. *Id.*

372. *Wlosinski v. Cohn*, 713 N.W.2d 16, 21 (Mich. Ct. App. 2006).

3. *Wisconsin*

In *Kokemoor*,³⁷³ the Supreme Court of Wisconsin considered an informed consent claim in connection with a surgery to repair a brain aneurysm. The patient suffered post-operative neurological complications.³⁷⁴ This case has been previously discussed in the context of physician disclosure of “experience.”

A related issue was whether the inexperienced physician was obligated to disclose surgical morbidity and mortality rates in order to obtain informed consent. Of significance, based on expert testimony, was that the “morbidity and mortality rate expected when a surgeon with the defendant’s experience performed the surgery would be significantly higher than the rate expected when a more experienced physician performed the same surgery.”³⁷⁵

The court discussed the risks attendant to the specific surgical procedure involved – a risky procedure in the most experienced hands. If the patient was aware that the procedure performed by the inexperienced surgeon carried a significantly higher risk than that “faced in the hands of another surgeon performing the same operation, that person might well have elected to forego surgery with the defendant.”³⁷⁶ The court also alluded to the risk of surgery in the hands of defendant as greater than a risk attendant to foregoing the surgery.³⁷⁷ Although the court did not wish to adopt a mandatory informed consent comparative risk statistics disclosure rule, it held that under the facts of the case, “when different physicians have substantially different success rates with the same procedure and a reasonable person in the patient’s position would consider such information material, the circuit court may admit this statistical evidence”³⁷⁸ for the informed consent analysis.

J. Research, Financial Interests

Physicians may have research interests in their patients. When physicians need patients for research purposes, there is a possibility that treatment recommendations may be based upon the requirements of the study, not upon patient needs. Patients may be given unnecessary treatment in order to fit within the parameters of the study. Physician conflicts of interest may arise and the issue is whether the patient is entitled to know of the conflict prior to treatment or enrolling in such a study.

373. *Johnson v. Kokemoor*, 545 N.W.2d 495, 495 (Wis. 1996).

374. *Id.*

375. *Id.* at 506.

376. *Id.* at 506-07.

377. *Id.* at 507.

378. *Id.*

1. California

The classic case on informed consent and the disclosure of the physician's research and economic interest is *Moore v. Regents of the University of California*.³⁷⁹ In *Moore*, the plaintiff underwent treatment for leukemia at UCLA Medical Center.³⁸⁰ For diagnostic purposes, plaintiff gave blood, tissue and other samples and these materials were known by the defendants to be valuable for research purposes.³⁸¹ Plaintiff's spleen was removed and portions were utilized for research.³⁸² Plaintiff was not informed and his permission was not sought for this usage.³⁸³

The defendants continued their research with plaintiff's cells and a defendant applied for a patent on a cell line established from plaintiff's blood products. The patent issued and two of the defendants were named as inventors. "With the [university's] assistance, [a defendant] negotiated agreements for commercial development of the cell line and products to be derived from it."³⁸⁴

Plaintiff's informed consent claim was characterized by the Supreme Court of California as follows: "that [the defendant] failed to disclose the extent of his research and economic interests in [plaintiff's] cells before obtaining consent to the medical procedures by which the cells were extracted."³⁸⁵ "This cause of action can properly be characterized either as the breach of a fiduciary duty to disclose facts material to the patient's consent or, alternatively, as the performance of medical procedure without first having obtained the patient's informed consent."³⁸⁶

The court had no trouble expanding the doctrine of informed consent to include the disclosure of "personal interests unrelated to the patient's health, whether research or economic, that may affect the physician's professional judgment."³⁸⁷ The reasonable patient would desire this information prior to giving consent to treatment.³⁸⁸

2. Florida

In *Greenberg v. Miami Children's Hospital Research Institute*,³⁸⁹ the federal court considered informed consent and other claims brought by parents of ill

379. 793 P.2d 479, 479 (Cal. 1990).

380. *Id.* at 480.

381. *Id.* at 500.

382. *Id.* at 481.

383. *Id.*

384. *Id.* at 482.

385. *Moore v. Regents of Univ. of California*, 793 P.2d 479, 483 (Cal. 1990).

386. *Id.*

387. *Id.*

388. *Id.*

389. 264 F. Supp. 2d 1064 (S.D. Fla. 2003).

children and “non-profit organizations that provided funding and information to Defendants to research and discover the Canavan disease gene.”³⁹⁰ Through blood and tissue donation, defendants were able to isolate the offending gene and, without advising plaintiffs, submitted a patent application which identified one of the defendants as inventor.³⁹¹ The patent was issued.³⁹² The court distinguished *Moore*, insofar as it concerned a non-disclosure within the physician-patient relationship.³⁹³ Here, the potential disclosure recipients were non-patient providers of information.³⁹⁴ They were not “objects of human experimentation.”³⁹⁵ “[T]he voluntary nature of their submissions warrants different treatment.”³⁹⁶ The doctrine of informed consent did not apply.

3. Illinois

In *Neade v. Portes*,³⁹⁷ the Supreme Court of Illinois refused to recognize a breach of fiduciary duty claim against a physician for failure to disclose his financial incentive derived from the patient’s HMO.³⁹⁸ The court simply believed that the fiduciary claim was repetitive of the medical negligence claim. The court also noted that the Illinois Managed Care Act³⁹⁹ “requires that managed care organizations disclose physician incentive plans to patients.”⁴⁰⁰ Of course, this disclosure requirement does not pertain to the physician.

4. Minnesota

In *D.A.B. v. Brown*,⁴⁰¹ the Court of Appeals of Minnesota considered an appeal from the dismissal of a class action complaint alleging, among other

390. *Id.* at 1066.

391. *Id.* at 1064.

392. *Id.* at 1070-73.

393. *Id.* at 1066.

394. *Id.* at 1064.

395. *Greenberg v. Miami Children’s Hosp. Research Inst.*, 264 F. Supp. 2d 1064, 1071 (S.D. Fla. 2003).

396. *Id.*

397. 739 N.E.2d 496 (Ill. 2000).

398. See Thomas L. Greaney, *Managed Competition, Integrated Delivery Systems and Antitrust*, 79 CORNELL L. REV. 1507, 1520 (1993-94) (noting that “physicians are employees or are paid through capitated payments and other financial arrangements that serve to align their incentives with those of the HMO”). For a recent decision in which the Appellate Court of Illinois approved the introduction into evidence of financial motive insofar as it addressed compliance with the standard of care, see *Martinez v. Elias*, 922 N.E.2d 457, 466 (Ill. App. Ct. 2010) (concluding that “the trial court did not abuse its discretion in permitting the evidence of financial motive to be introduced in a limited and specific manner to address the issue of the defendants’ compliance with the standard of care”).

399. 215 ILL. COMP. STAT. ANN. 134/15(b) (West 1999).

400. *Neade*, 739 N.E.2d at 504.

401. *D.A.B. v. Brown*, 570 N.W.2d 168 (Minn. Ct. App. 1997).

claims, a failure to disclose a Medicaid/Medicare kickback scheme against a physician and others. The court characterized “[t]he doctor’s duty to disclose the kickback scheme [as presenting] a classic informed consent issue.”⁴⁰² The claim was insufficient for other reasons.

VI. AFTERTHOUGHTS: ADDITIONAL REASONS WHY THE LAW OF INFORMED CONSENT SHOULD ASSIST THE PATIENT IN BECOMING A CONSUMER

Even filing and prosecuting a medical negligence lawsuit against a physician may not improve a patient’s chances of obtaining performance and quality information regarding a defendant physician. State and federal statutory schemes may operate as impediments to the discovery of information patients may desire to examine.

A. State Peer Review Statutes

The Illinois Medical Studies Act⁴⁰³ essentially protects from discovery and the admission into evidence, among other things, peer review information and information regarding morbidity and mortality, and quality assurance.

The purpose of the Act is to ‘encourage candid and voluntary studies and programs used to improve hospital conditions and patient care or to reduce the rates of death and disease’ . . . [t]he Act is premised on the belief that, absent the privilege, physicians might be reluctant to sit on peer-review committees and engage in frank evaluations of their colleagues.⁴⁰⁴

The Medical Studies Act does not, however, “protect against the discovery of information generated before the peer-review process begins or information generated after the peer-review process ends.”⁴⁰⁵ Other examples of similar statutes are those in Iowa,⁴⁰⁶ Massachusetts,⁴⁰⁷ Minnesota,⁴⁰⁸ Pennsylvania⁴⁰⁹ and Tennessee.⁴¹⁰ These statutes provide a valuable protection to the physician peer review process and foster the hospital self-policing process. Of course, it is precisely the type of information protected by these statutes that patients would like to know.

402. *Id.* at 171.

403. 735 ILL. COMP. STAT. ANN. 5/8-2101 (West 2004); 735 ILL. COMP. STAT. ANN. 5/8-2102 (West 2004).

404. *Anderson v. Rush-Copley Med. Ctr., Inc.*, 894 N.E.2d 827, 834 (Ill. App. Ct. 2008).

405. *Frigo v. Silver Cross Hosp. & Med. Ctr.*, 876 N.E.2d 697, 718 (Ill. App. Ct. 2007).

406. IOWA CODE ANN. § 147.135 (West 1975).

407. MASS. GEN. LAWS ANN. ch. 111, § 204 (West 2007).

408. MINN. STAT. ANN. § 145.64 (West 2003).

409. 63 PA. CONS. STAT. ANN. § 425.4 (West 1974).

410. TENN. CODE ANN. § 63-6-219 (West 1967).

B. The National Practitioner Data Bank (NPDB)

The NPDB is a statutory and regulatory creature⁴¹¹ through which “medical malpractice payers”⁴¹² “[m]ust report payments made for the benefit of physicians . . . in settlement of or in satisfaction in whole or in part of a claim or judgment against such practitioner.”⁴¹³ The public has no access to this information as the “routine uses of NPDB information, which are consistent with the law and the regulations under which it operates, do not include disclosure to the general public.”⁴¹⁴ The NPDB is utilized by healthcare institutions in the credentialing process.⁴¹⁵

VII. CONCLUSION

If patients are to be consumers of health care, they need access to quality, performance and other information personal to their physicians. Influential, voluntary medical associations have not been as patient-friendly as they could be regarding physician disclosures and informed consent. If the historic pronouncement of *Canterbury v. Spence*⁴¹⁶ is to have meaning, patients will likely need more than sporadic judicial opinions to shape the doctrine of informed consent. Informed consent statutes encompassing the disclosure of provider-specific information would assist in allowing patients to receive significant information at a time when they most need it.

There are, of course, problems with expansion of the doctrine of informed consent. One is “information overload.” How much information can a patient process? Another is “time.” How much time should a physician spend in obtaining informed consent? Another concern is patient status. Is the patient medicated? Is the patient in pain? Is the informed consent process occurring on the precipice of a procedure? These issues relate to the patient’s ability to absorb information disclosed by physicians. Yet another concern is an attempt to cover physician-specific information in an informed consent document.⁴¹⁷ Can a patient effectively read and understand such a document? This problem implicates the issue of “health literacy.”⁴¹⁸

411. See DIV. OF QUALITY ASSURANCE, U.S. DEP’T OF HEALTH & HUMAN SERVICES, NATIONAL PRACTITIONER DATA BANK GUIDEBOOK app. B-1, (2001), http://www.npdb-hipdb.hrsa.gov/pubs/gb/NPDB_Guidebook.pdf (listing seven links to various laws and regulations).

412. *Id.* at app. A-3.

413. *Id.* at C-2.

414. *Id.* at A-6.

415. Laura-Mae Baldwin et al., *Hospital Peer Review and the National Practitioner Data Bank: Clinical Privileges Action Reports*, 281 J. AM. MED. ASS’N. 349, 354 (1999).

416. 464 F.2d 772, 776 n. 36 (D.C. Cir. 1972).

417. Krumholz, *supra* note 53, at 1191.

418. Richard S. Safeer & Jann Keenan, *Health Literacy: The Gap Between Physicians & Patients*, 72 AM. FAM. PHYSICIAN 463 (2005); Mark V. Williams et al., *The Role of Health Literacy in Patient-Physician Communication*, 34 FAM. MED. 383 (2002).

It is easy to conclude that patients simply lack the wherewithal to process more information and that physicians should spend their time providing treatment. This approach is unsatisfactory. Patients should have access to information about their physicians, which, at least, approaches information available about consumer products. If modern informed consent focuses on “patient centered care,”⁴¹⁹ more information should be disclosed. In order for patients to choose good physicians, they need information indicating which physicians are good.

419. Krumholz, *supra* note 53, at 1191.

