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LIABILITY, REGULATION AND POLICY IN SURGICAL INNOVATION: THE CUTTING EDGE OF RESEARCH AND THERAPY

Anna C. Mastroianni[†]

*"There is a public interest in encouraging new and more widely available surgical technology and treatment providing that, in the sprint to the finishing tape, scientific methods are not abused, ethical principles are not trampled and the law is not trespassed."*¹

INTRODUCTION

Surgeons have been at the forefront of major progress in the treatment of diseases and other health conditions. These include advances in all specialty areas, including gastroenterology,² plastic and reconstructive surgery,³ transplantation,⁴ cardiology,⁵ infertility,⁶

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¹ C.M. Ward, *Surgical Research, Experimentation and Innovation*, 47 BRIT. J. PLASTIC SURGERY 90, 90 (1994).

² See Lawrence I. Bonchek, *Are Randomized Trials Appropriate For Evaluating New Operations?*, 301 NEW ENG. J. MED. 44, 45 (1979).

³ See Ward, *supra* note 1, at 90.

⁴ J.B. Dosssetor, *Innovative Treatment Versus Clinical Research: An Ethics Issue In Transplantation*, 22 TRANSPLANTATION PROC. 966, 966-67 (1990).

In the field of transplantation and its allied fields, examples of new endeavors which have been introduced as 'innovations,' without initially going through the rigorous peer review include: Kolff's early use of hemodialysis (14 of 15 patients dying during the first period of clinical trial); early allogenic renal transplants, prior to immunosuppression . . . in 1963 . . . ; development of surgery within the cavity of the heart by CW Lillehei including a period where adults provided cross-circulation to children with heart defects, prior to introduction of extracorporeal bubble oxygenation; clinical xenogeneic renal or cardiac allografts; the worldwide 'rash' of cardiac transplants from 1969 to 1971; early attempts in liver transplantation prior to cyclosporine; early attempts at allogenic bone marrow engraftment for marrow aplasia or malignancy; implantation of fertilized ova (IVF) as treatment for infertility; early effort to use an implanted artificial heart; human fetal neural implants into the substantia nigra for advanced Parkinson's

gynecology,⁷ and orthopedics,⁸ just to name a few. In addition, surgical procedures that in the past would have required large incisions have become less invasive through technological advancement in surgical tools, such as the laparoscope and arthroscope,⁹ reducing recovery times and in many cases enhancing health benefits to patients.¹⁰ At the same time, the surgical literature

disease; and . . . transplantation of multiple (4 or 5) abdominal viscera.
Id. (citations omitted).

⁵ See Bonchek, *supra* note 2. See also J.P. Bunker et al., *Surgical Innovation and Its Evaluation*, 200 Sci. 937, 938-39 (1978).

⁶ This includes the treatment of infertility by *in vitro* fertilization, the process of fertilizing human ova and implanting them in a woman's uterus. See Dossetor, *supra* note 4, at 967.

⁷ See David A. Grimes, *Technology Follies: The Uncritical Acceptance of Medical Innovation*, 269 JAMA 3030, 3030 (1993) (discussing laparoscopic tubal sterilization).

⁸ See John J. Callaghan et al., *Symposium: Introducing Technology Into Orthopaedic Practice. How Should It Be Done?*, 87 J. BONE & JOINT SURGERY 1146 (2005).

⁹ The laparoscope is an instrument through which structures within the abdomen and pelvis can be seen. A small surgical incision (cut) is made in the abdominal wall to permit the laparoscope to enter the abdomen or pelvis. A diversity of tubes can be pushed through the same incision or other small incisions permitting the introduction of probes and other instruments. In this way, a number of surgical procedures can be performed without the need for a large surgical incision.

MedicineNet.com, Definition of Laparoscope, <http://www.medterms.com/script/main/art.asp?articlekey=9931> (last visited Mar. 11, 2006). The arthroscope is a

thin flexible fiberoptic scope which is introduced into a joint space through a small incision in order to carry out diagnostic and treatment procedures within the joint. An arthroscope is about the diameter of a drinking straw. It is fitted with a miniature camera, a light source and precision tools at the end of flexible tubes. An arthroscope can be used not only for diagnostic procedures but a wide range of surgical repairs, such as debridement, or cleaning, of a joint to remove bits of torn cartilage, ligament reconstruction, and synovectomy (removal of the joint lining). All are done without a major, invasive operation, and, since arthroscopy requires only tiny incisions, many procedures can be done on an outpatient basis with local anesthetic.

MedicineNet.com, Definition of Arthroscope, <http://www.medterms.com/script/main/art.asp?articlekey=33986> (last visited Mar. 11, 2006).

¹⁰ "The risk of intraoperative and postoperative complications, the cost of treatment, and hospitalization time are generally less with laparoscopic surgery than with traditional open procedures." STEDMAN'S MEDICAL DICTIONARY 9666 (27th ed. 2000) (defining laparoscopy). The rapid adoption of laparoscopic procedures has been described as an epidemic of "laparoscopic fever." Ward, *supra* note 1, at n.20 (citing J.N. Baxter & P.J. O'Dwyer, *Laparoscopic or Minilaparotomy in Cholecystectomy*, 304 BRIT. MED. J. 559, 599 (1992). *But see* Steven M. Strasberg & Philip A. Ludbrook, *Who Oversees Innovative Practice? Is There a Structure That Meets the Monitoring Needs of New Techniques?*, 196 J. AM. C. SURGEONS 938 (2003) (discussing

also reveals innovations that caused harm to patients in their early development (e.g., the use of less invasive techniques for gall bladder removal)¹¹ and discredited surgical innovations (e.g., routine episiotomies,¹² certain fetal surgeries,¹³ certain approaches for treatment of peptic ulcers¹⁴ and correction of coronary artery blockage).¹⁵ Concern about harm or potential harm to patients continues into the present, including controversy over particular approaches to the treatment of liver tumors and liver transplantation.¹⁶

Most new surgical techniques have developed in the surgical suite or on simulators, while, for practical and other reasons, very few are subjected to the rigorous evaluation of safety and effectiveness applied to most new nonsurgical therapies.¹⁷ History has proven that perceptions of surgeons and patients of, for example, quicker recovery times and reduced pain, can spur rapid acceptance of a novel approach, and even prompt insurance reimbursement, while allowing little opportunity for rigorous comparisons to standard therapies or other outcome evaluations.¹⁸ A formal appraisal of the technique could have revealed its superiority or inferiority, potentially impacting the health outcomes of many patients.¹⁹

negative health outcomes that resulted during early adoption of laparoscopic adoption for gall bladder removal).

¹¹ See Joel E. Frader & Donna A. Caniano, *Research and Innovation in Surgery*, in SURGICAL ETHICS 216, 220-21, (Laurence B. McCullough et al. eds., 1998).

¹² *Id.* See Grimes, *supra* note 7, at 3031.

¹³ See Angelique M. Reitsma & Jonathan D. Moreno, *Maternal-Fetal Research and Human Research Protections Policy*, 30 CLINICS PERINATOLOGY 141 (2003).

¹⁴ Frader & Caniano, *supra* note 11, at 220-21.

The history of medicine and surgery clearly demonstrates the harms done in the name of 'treatments' of unproven worth. Surgical examples include routine episiotomy; internal mammary artery ligation for angina; gastric freezing for peptic ulcer disease; initial attempts with implantable devices to provide artificial support of circulation; indiscriminate adoption of endoscopic, especially laparoscopic, surgery; and various operations for disparate forms of cancer.

Id.

¹⁵ See Strasberg & Ludbrook, *supra* note 10, at 938 ("[s]ome [surgical] innovations . . . have been associated with unexpected harm to patients").

¹⁶ See *id.*, at 939-41. See also David Cronin et al., *Transplantation of Liver Grafts from Living Donors into Adults—Too Much, Too Soon*, 344 NEW ENG. J. MED. 1633 (2001).

¹⁷ Russell L. Gruen et al., *Professionalism in Surgery*, 197 J. AM. C. SURGEONS 605, 607 (2003). See also Dossetor, *supra* note 4.

¹⁸ See Clyde F. Barker & Larry R. Kaiser, *Is Surgical Science Dead?*, 198 J. AM. C. SURGEONS 1 (2004). See also Grimes, *supra* note 7, at 3031-32 (discussing various hurdles to technology assessment).

¹⁹ See Strasberg & Ludbrook, *supra* note 10, at 938-41 (documenting harm

Current practices in surgical innovation raise concerns about the appropriate balancing of patient safety and medical progress. A review of the surgical and bioethics literature reveals disagreement about whether the practice of surgical innovation is in need of urgent attention, as well as varying opinions on the appropriate characterization of innovations.²⁰ Calls for change predominate and are primarily founded on claims of patient safety, i.e., that development of innovations on patients outside of the research context can harm present or future patients.²¹ Some commentators have suggested that the risk of patient harm and the corresponding need for increased accountability are significant enough that surgeons should subject their approaches to some form of independent prior review²² and ensure that patients are specifically informed of the innovation²³ during the informed consent process. Some proponents of this approach would suggest that certain innovations require treating the patient as a research subject, and submitting such innovations to the review, approval and implementation processes applicable to formal research protocols involving human subjects.²⁴ Other commentators are content with the *status quo*, contending that innovation is, and should be, treated as part of the routine, therapeutic practice of surgery.²⁵ They express concerns that a formal review process would be burdensome and slow progress in the surgical field, resulting in its own attendant risks to patient health.²⁶

and potential harm in surgical innovation in laparoscopic cholecystectomy, radiofrequency ablation of metastatic colorectal tumors in the liver, and live donor right hemiliver transplantation).

²⁰ See *infra* Part I.A. See, e.g., Bunker et al., *supra* note 5; David H. Spodick, *Numerators Without Denominators: There Is No FDA For the Surgeon*, 232 JAMA 35 (1975); Bonchek, *supra* note 2.

²¹ Resource allocation is another issue of concern. Grimes, *supra* note 7, at 3030 (describing “squandered resources, wasted effort, and in some cases, harm[ing] or kill[ing] . . . patients”).

²² Such a review might take the form of the federal regulatory review of research performed by local institutional review boards (IRBs) in the federal human subjects protection system, as under 45 C.F.R. § 46. See discussion *infra* note 284. See also Editorial, *Qualms About Innovative Surgery*, 1 LANCET 149 (1985) [hereinafter *Editorial*].

²³ See, e.g., Strasberg & Ludbrook, *supra* note 10, at 941-43.

²⁴ See, e.g., Reitsma & Moreno, *supra* note 13.

²⁵ George A. Gates, Letter to the Editor, *Surgical Innovation and Research*, 129 ARCHIVES OTOLARYNGOLOGY HEAD & NECK SURGERY 1352, 1353 (2003) (“The ad hoc process whereby technical innovations developed by one person are discussed with colleagues, presented at meetings, and published in the literature has served the profession well.”).

²⁶ *Id.*; Vicki Brower, *The Ethics of Innovation: Should Innovative Surgery Be Exempt from Clinical Trials and Regulations?*, 4 EMBO REP. 338, 339 (2003).

Still others have highlighted the uniqueness of surgery relative to other areas of medical intervention, and have suggested the need for a dedicated system of enhanced reporting and short-term and long-term outcome monitoring following innovative surgical procedures.²⁷ At issue, thus, is whether an innovative surgical technique should be treated as research, or as therapy, or as a distinct entity.

This article examines the implications of the foregoing competing claims from a U.S. legal perspective, focusing particularly on how the legal system addresses patient safety concerns and autonomous decision-making of surgeons in the context of surgical innovation. The lack of oversight and the risks borne by patients during surgeons' development and subsequent refinement of a novel procedure must be balanced with the need to encourage medical progress through the development of improved techniques designed to benefit the health of current and future patients. This article argues that current reliance on the medical malpractice system and the federal regulatory system of oversight of human subjects research is inadequate in appropriately balancing patient safety and medical progress. The deficiencies in relying on the current approaches are further highlighted in a legal review and case study analysis of one surgical innovation that stimulated a wave of legal claims in the 1990s. A comprehensive legal analysis ultimately leads to a critique of current policy approaches and the recommendation of a three-pronged policy approach distinctly tailored to surgical innovation, which includes monitoring, local institutional oversight, and educational initiatives. As will be observed, complicating this examination is the cultural context in which surgical innovation takes place, lack of consensus about the appropriate treatment of surgical innovation, and the wide variation in procedures that could conceivably fall within a definition of surgical innovation.

Part I of this article briefly examines the practice and culture of surgical innovation, describing the high value placed on innovation and professional autonomy and the definitional challenge in characterizing innovative surgery. Part II introduces the two currently available alternate legal pathways relevant to concerns for patient safety—the

[B]ioethicist George Agich . . . disagrees with the call for more control over surgical innovation by IRBs, or others. He maintains that surgery is different from medicine and should be treated as such, and we should not require it to 'live' with the same safeguards that apply to drug and device development.

Id. See also Strasberg & Ludbrook, *supra* note 10, at 943 (while advocating change in the oversight of surgical innovation, the authors recognize that concerns about "stifling innovation" must be balanced with the protection of patients).

²⁷ See Strasberg & Ludbrook, *supra* note 10, at 945-46.

medical practice pathway and the human subjects research pathway—and describes the surgeon's critical role in determining the pathway. Part III discusses the medical practice pathway and the conclusions that can be drawn from the law on point, particularly in the areas of negligence and informed consent, and analyzes their implications for the treatment of innovative surgery. Part IV describes the human subjects research pathway in detail. It begins with a discussion of the federal system of regulatory oversight and protection, its history and potential application to innovative surgery. It continues by examining the potential cause of action for research negligence, followed by conclusions and implications for the treatment of innovative surgery. Part V analyzes and extracts lessons from one example of surgical innovation, its legal pathways and malpractice history. Lastly, this article concludes by examining some of the legal implications of current policy approaches and ultimately recommends a distinct approach designed to balance medical progress with greater accountability and opportunities for improved patient safety.

For purposes of this article, "surgical innovation" will mean "a novel procedure, a significant modification of a standard technique, a new application of or new indication for an established technique, or an alternative combination of an established technique with another therapeutic modality that was developed and tested for the first time."²⁸ It may also include the novel application of a previously existing surgical tool or technology, such as the arthroscope or laparoscope. It excludes the novel or off-label use of drugs or medical devices in surgery²⁹ and excludes surgical research involving placebo control groups, commonly referred to as research involving "sham" surgery or placebo surgery-controlled research.³⁰

²⁸ Angelique M. Reitsma & Jonathan D. Moreno, *Ethical Regulations for Innovative Surgery: The Last Frontier?*, 194 J. AM. C. SURGEONS 792, 793 (2002).

²⁹ Off-label use of drugs and medical devices by physicians may raise similar concerns about the lack of evaluation of safety and efficacy. Indeed some commentators advocate that patients should be specifically informed of off-label prescription and that a physician's intention to use a drug or medical device in many patients should prompt research review by an institutional review board. John D. Casler, *Clinical Use of New Technologies Without Scientific Studies*, 129 ARCHIVES OTOLARYNGOLOGY HEAD & NECK SURGERY 674, 675 (2003).

³⁰ In research involving a sham or placebo surgery control group, the decision has already been made that the innovation should be characterized as research rather than medical therapy. Research involving sham surgery requires a formal research protocol and may be subject to federal regulatory provisions concerning research with human subjects (including regulatory provisions for independent review and enhanced disclosure in informed consent, among other requirements). See, e.g., Robert M. Zwolak, *Research Involving Sham Surgery*, in INSTITUTIONAL REVIEW BOARD: MANAGEMENT AND FUNCTION 458 (Robert J. Amdur & Elizabeth A. Bankert

I. UNDERSTANDING SURGICAL INNOVATION

There is considerable disagreement reflected in the surgical and ethics literature about whether and when to characterize a surgical innovation as: (1) research, (2) therapy, or (3) some other distinct entity.³¹ As will be discussed throughout this article, each of these possible characterizations has potential implications for informed consent, oversight, and review (including regulatory review),³² with potential effects on patient safety as well as insurance reimbursement decisions and overall resource allocation.³³ They also may involve different understandings about the intended beneficiary of the innovation—the present patient (therapeutic intervention), future patients (research), or both. Further, the culture of surgery influences the context from which such a characterization emerges. All of these factors create challenges in evaluating and developing policy in this area.

A. The “Gray Zone” of Surgical Innovation

The ambiguity surrounding innovation’s place on a continuum from research to therapeutic practice is not unique to surgery.³⁴ There are vast areas in medicine where nearly all authorities can agree that certain treatments are well established, with proven efficacy and known risks, and constitute the standard approaches to a medical condition.³⁵ Indeed, there is little disagreement that such areas are clearly

eds., Jones and Bartlett Publishers 2002); Franklin G. Miller, *Sham Surgery: An Ethical Analysis*, AM. J. BIOETHICS, Fall 2003, at 41.

³¹ Angelique M. Reitsma & Jonathan D. Moreno, *Ethics of Innovative Surgery: US Surgeons’ Definitions, Knowledge and Attitudes*, 200 J. AM. C. SURGEONS 103, 103-04 (2005).

³² *Id.*

³³ Mark Bernstein & Joseph Bampoe, *Surgical Innovation or Surgical Evolution: An Ethical and Practical Guide to Handling Novel Neurosurgical Procedures*, 100 J. NEUROSURGERY 2, 3 (2004).

³⁴ Jeffrey Lyon retells a real life story from Jay Katz, the preeminent Yale professor of law and psychiatry and renowned authority on human subjects research. A physician presents a paper at a conference that describes his use of chemotherapy in young children suffering from leukemia. The doctor assessed the chemotherapy’s effectiveness with six bone marrow biopsies in a short period following chemotherapy. Professor Katz asked the physician how such a protocol could be approved by an IRB in light of the significant discomfort experienced by the children during the bone marrow biopsies. The physician’s response was that he did not subject the protocol to review because he characterized the procedures as therapeutic interventions, designed to aid in the clinical management of their disease. Jeffrey Lyon, *Experimenting with Humans. Part 2: Innovation or Exploitation?*, 8 SECOND OPINION 10, 14 (1988).

³⁵ David Sabiston, *The Boundaries Between Biomedical Research Involving Human Subjects and the Accepted or Routine Practice of Medicine, with Particular Emphasis on Innovation in the Practice of Surgery*, in NAT’L COMM’N FOR THE

characterized as medical practice for the benefit of the individual patient.³⁶ They constitute the majority of medical approaches that are in use on a daily basis, including surgical approaches.³⁷ Similarly there are also areas in medicine that are unmistakably characterized as research, i.e., areas where there is no intention that the patient will receive any direct medical benefit from the procedure.³⁸ Between these extremes, there is a large “gray zone”³⁹ where it becomes challenging⁴⁰ to define an intervention as either medical practice or research—innovations may become assimilated into standard practice after limited formal evaluation, informal evaluation, or even no evaluation of safety and efficacy.⁴¹ This “gray zone” of surgical innovation is the

PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH, APPENDIX II, 17-1 (1979).

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.*

³⁹ Reitsma & Moreno, *supra* note 28, at 796. From their recent survey of surgeons, the authors conclude that

a large ‘gray zone’ exists between sound research and incrementally introduced novelties, although both ultimately produce innovations. Apparently, distinguishing between gradual implementation of minor surgical modifications and more permanent or extensive alterations of a technique is a challenge. This is especially true when modifications are made on an as-needed basis for the benefit of the individual patient. Such distinctive modifications have been and will always be necessary for the best possible patient outcomes, and surgeons know best when to make them. But a surgeon may begin to change his standard operating room technique more permanently based on experiences with individual cases. If he then decides to publish results of the new technique, the line is clearly crossed and even originally spontaneous, and patient-centered modifications become research in retrospect, justifying [prospective] review and sometimes informed consent of the patients, who have now become research subjects.

Id.

⁴⁰ Although surgeons and policymakers may experience these definitional challenges, empirical research indicates that even patients have difficulty appreciating the distinction between research and therapy. *See, e.g.*, ADVISORY COMM. ON HUMAN RADIATIONS EXPERIMENTS, FINAL REPORT 459-81 (Oxford Univ. Press 1996) (describing the results of the Subject Interview Study) [hereinafter ACHRE]; Nancy E. Kass et al., *Trust: The Fragile Foundation of Contemporary Biomedical Research*, 26 HASTINGS CENTER REP., Sept.-Oct. 1996, at 25, 27.

⁴¹ Strasberg and Ludbrook, both physicians, describe this as a “spectrum of innovation” in the clinical practice of surgery. At the extremes are “minor changes that are inherent and appropriate in individual practice” and “innovations that are allowed into general use only after their safety and efficacy have been proven in extensive trials using human subjects. Between these extremes are innovations, which are permitted entry into ordinary use after much more limited evaluation, or even after no evaluation at all.” Strasberg & Ludbrook, *supra* note 10, at 938.

particular focus of this article. Unlike standard practice, the novelty of the procedure means that the benefits and risks are inherently uncertain.⁴² “Unlike research, innovation always involves sick patients.”⁴³

A recent survey indicates discrepancies and a lack of clarity among U.S. surgeons about the circumstances under which a surgical innovation should be characterized as research.⁴⁴ A large number of surveyed surgeons indicated that use of a formal protocol or asking a patient for specific permission to perform the innovation was a sign of research.⁴⁵ Other qualities that many surgeons found to be relevant in distinguishing medical practice (surveyed as “routine variation in surgical technique”) from research concerned the degree of variation from standard care, the degree of risk, and whether the innovation was premeditated or spontaneous: a “great” degree of variation from standard care, a “great” degree of risk, and premeditation were identified by many as hallmarks of research.⁴⁶ Otherwise, the survey revealed a vast range of opinions about exactly what constitutes research versus practice and a deficit of knowledge about the regulatory requirements of research.⁴⁷ As one distinguished surgeon and his colleagues have stated elsewhere, “Every surgeon has a clear idea of personal boundaries, but it is safe to say that the limits of acceptable innovation are neither widely accepted nor closely observed by the profession at large.”⁴⁸

⁴² See Nancy M.P. King, *The Line Between Clinical Innovation and Human Experimentation*, 32 SETON HALL L. REV. 573, 574-75 (2002).

⁴³ *Id.* at 574. Further, “[b]y virtue of its individualized focus, [surgical innovation] lacks the theoretical and empirical preclinical groundwork that characterizes the search for knowledge generalizable beyond an individual patient.” *Id.* Bioethicist Robert Levine characterizes innovation as “nonvalidated” practices: either novel practices (i.e., those that have not been tested enough to permit predictions of efficacy and safety), or practices that during the course of use raise questions about safety and efficacy. ROBERT J. LEVINE, *ETHICS AND REGULATION OF CLINICAL RESEARCH* 4 (2d ed. 1986).

⁴⁴ Reitsma & Moreno, *supra* note 31.

⁴⁵ *Id.* at 108.

⁴⁶ *Id.* at 107, tbl.3.

⁴⁷ *Id.* See also Randi L. Rutan et al., *Academic Surgeons' Knowledge of Food and Drug Administration Regulations for Clinical Trials*, 132 ARCHIVES SURGERY 94 (1997).

⁴⁸ James W. Jones et al., *Ethics of Surgical Innovation to Treat Rare Diseases*, 39 J. VASCULAR SURGERY 918, 918 (2004) (referencing the study discussed in Reitsma & Moreno, *supra* note 28). See also Angelique M. Reitsma & Jonathan D. Moreno, *Surgical Research, an Elusive Entity*, AM. J. BIOETHICS, Nov. 2003, at 49, 49 (2003) (“There appears to be a tradition in surgery that significant changes in technique are regarded as mere modifications and not as research.”).

The boundaries of research and practice were explored in the 1970s by a congressionally appointed ethics commission.⁴⁹ The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission) was created by the National Research Act of 1974⁵⁰ and was composed of experts in medicine, science, law, ethics, and religion.⁵¹ One of the tasks assigned to the commission was to “identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles.”⁵² The charge to the National Commission specifically requested consideration of, *inter alia*, “the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine”⁵³ This examination was considered critical in determining which types of activities would be subject to the ethical principles developed by the National Commission.⁵⁴ Responding to its charge, the National Commission requested scholarly analyses on the innovation-therapy distinction⁵⁵ and ultimately issued a 1979 report which has become recognized as the seminal document in research ethics, *The Belmont Report: Ethical Principles and Guide-*

⁴⁹ NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979) [hereinafter *The Belmont Report*].

⁵⁰ National Research Act, Pub. L. No. 93-348, 88 Stat. 342 (1974).

⁵¹ *The Belmont Report*, *supra* note 49.

⁵² *Id.* The National Commission had a significant impact on the development of research policy in the United States. During its four year tenure (1975-1979), it issued ten reports on bioethics, research ethics, and policy, including, *inter alia*, reports on research involving vulnerable populations (the fetus, prisoners, children, the mentally infirm, and psychosurgery research) and the oversight of research. For a list of National Commission reports, see The President's Council on Bioethics, Former Bioethics Commissions, http://www.bioethics.gov/reports/past_commissions/ (last visited Mar. 9, 2006).

⁵³ *The Belmont Report*, *supra* note 49.

⁵⁴ *Id.*

⁵⁵ The commissioned papers on this topic include a paper by a physician who explicitly addressed innovative surgery, and a law professor who explored the legal implications of the research-practice distinction. See Sabiston, *supra* note 35; John Robertson, *Legal Implications of the Boundaries Between Biomedical Research Involving Human Subjects and the Accepted or Routine Practice of Medicine*, in NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH, APPENDIX II, 16-1 (1979).

lines for the Protection of Human Subjects of Research (*The Belmont Report*).⁵⁶

The Belmont Report succinctly explains that the critical distinction between research and therapeutic practice rests on identification of the intended beneficiary of the procedure. *The Belmont Report* defined "practice" as "interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose . . . is to provide diagnosis, preventive treatment or therapy to particular individuals."⁵⁷ "Research" on the other hand, "designates an activity designed to test an [sic] hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge . . ." and is "usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective."⁵⁸ *The Belmont Report* does acknowledge that innovative practices have attributes of both practice and research. It provides some direction on the characterization of innovation as research or practice: "When a clinician departs *in a significant way* from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is . . . new, untested or different, does not automatically place it in the category of research . . ."⁵⁹ At the same time, the National Commission made clear that any evaluation of the efficacy and safety of a therapeutic intervention generally falls within the realm of research and should prompt human subjects protection review.⁶⁰

Thus, from a bioethics perspective,⁶¹ the fact that a surgical intervention is innovative does not immediately require its classification as research; in such a case the intended benefit from the intervention will accrue to the individual patient, but there exists the potential for benefit to future patients based on an accumulation of generalizable knowledge.⁶² For example, a surgeon's decision to perform a novel

⁵⁶ The Belmont Report, *supra* note 49.

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.* at Part A (emphasis added).

⁶⁰ *Id.*

Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy. This need not cause any confusion regarding whether or not the activity requires review; the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects.

Id.

⁶¹ For a detailed examination of ethical issues in surgical innovation, see generally Frader & Caniano, *supra* note 11.

⁶² See Strasberg & Ludbrook, *supra* note 10, at 942.

combination of a less-invasive surgical procedure (e.g., laparoscopy) for removal or repair of an organ (e.g., colon, gall bladder) may be intended to benefit the individual patient undergoing the procedure, but repeated uses of the procedure may also result in knowledge that can be generalized to future patients (e.g., numerous performances of the innovation revealing risks and benefits of the surgical approach, such as injuries to surrounding tissue or organs or quicker recovery rates).⁶³ In the area of innovation, as indicated above, a “significant departure” from standard practice does not automatically trigger research requirements. Indeed, *The Belmont Report* ultimately recommends that only “radically new procedures” should prompt formal evaluations of safety and efficacy as early as possible: once such a procedure is incorporated into a formal research protocol, it is classified as research and subject to all of its attendant human subjects protections.⁶⁴ The report suggests that medical practice committees be responsible for triggering such a research review requirement.⁶⁵ Unlike many of the other influential recommendations of the National Commission related to research that were incorporated into federal regulations, this explicit classification and limited recommendation related to the ethical treatment of innovative practices was never promulgated as federal policy.⁶⁶

Ultimately, in the absence of explicit guidance that would aid in deciding whether an innovation is research or practice, decision-making responsibility falls to the individual surgeon.⁶⁷ That decision may be influenced by departmental or peer practices, but it is also set within a culture of deference to surgeon decision-making and a culture that highly values those who innovate.

⁶³ *See id.*

⁶⁴ The Belmont Report, *supra* note 49, at Part A.

⁶⁵ *Id.*

⁶⁶ Strasberg and Ludbrook suggest three criteria for identifying “significant innovation” which would trigger “a patient protection process” for that procedure: (1) “the need for retraining and recertification [sic] of physicians in order to be allowed to perform a new procedure”; (2) “[the innovation] provides diagnosis or treatment for a condition for which none previously existed”; and (3) “the innovation, though directed toward improving the health of a sick individual, would also place at risk a healthy individual who receives no direct [physical health] benefit.” Strasberg & Ludbrook, *supra* note 10, at 943-44.

⁶⁷ Curtis E. Margo, *When Is Surgery Research? Towards an Operational Definition of Human Research*, 27 J. MED. ETHICS 40, 41 (2001) (“[T]he responsibility for judging when a new or novel clinical practice becomes research rests solely with the individual surgeon.”).

B. Surgical Culture and Context

Surgeons, as well as patients, place a high value on innovation and creativity.⁶⁸ Standardization is viewed as a negative quality, one that limits innovation and the surgeon's ability to meet the needs of the patient.⁶⁹ History has treated risk-taking in surgery favorably, e.g., the highly esteemed surgeon Francis Moore's decisions to test his hypotheses, even if "dangerous or unproved,"⁷⁰ on patients who were dying from standard treatments have been credited with advancing surgery in numerous specialty areas and saving "tens of thousands of lives a year."⁷¹ Patients, some of whom are desperate because of their illness or condition,⁷² seek out surgeons who are on the "cutting edge" of knowledge⁷³ and skill within their specialty area and the "latest and

⁶⁸ See, e.g., Ward, *supra* note 1, at 92.

[P]lastic surgeons are not renowned for dedication to meticulously planned and monitored research whether it be based on animal work or the more sophisticated style of human research in the form of RCTs. Research is more likely to be a chore undertaken to add a glitter to curricula vitae and to applications to higher posts. . . . There are, of course, notable exceptions in plastic surgery who have not only made major contributions to the specialty in the course of their training but continue to lead the way in research. The rest of us, having achieved our goal, now settle down to earn a living and indulge in what we all wanted to do in the first place—innovate.

Id. See also PETER D. JACOBSON, MEDICAL LIABILITY AND THE CULTURE OF TECHNOLOGY 2 (2004), http://www.pewtrusts.com/pdf/med_mal_092204.pdf ("American medicine thrives on the inexhaustible demand for high-technology medical interventions: a 'culture of technology.' Americans prize continued advances in technology and widespread availability of those innovations.").

⁶⁹ Yusuf N. Silk et al., *A New Technique for Decompression of the Biliary Tract*, 169 SURGERY GYNECOLOGY OBSTETRICS 547, 548 (1989) ("By avoiding the trap of standard procedures and retaining the ability to innovate, a good surgeon will be able to work out a satisfactory solution for a difficult problem for the ultimate betterment of the patient and self."); Gates, *supra* note 25, at 1353.

⁷⁰ Atul Gawande, *Desperate Measures*, NEW YORKER, May 5, 2003, at 70, 78.

⁷¹ *Id.* at 73. For a discussion of what scholars Fox and Swazey have termed "the courage to fail ethos" in the evolution of organ transplantation, see RENÉE C. FOX & JUDITH P. SWAZEY, THE COURAGE TO FAIL: A SOCIAL VIEW OF ORGAN TRANSPLANTS AND DIALYSIS 87-107 (2d ed. 1978).

⁷² Reitsma & Moreno, *supra* note 48, at 49; Nancy M. P. King & Gail Henderson, *Treatments of Last Resort: Informed Consent and the Diffusion of New Technology*, 42 MERCER L. REV. 1007, 1007 (1991); Brower, *supra* note 26, at 340 ("Surgeons in the USA are still often characterized, not entirely negatively, as 'cowboys'—individuals who function autonomously, with a good deal of power, and who are subject to few controls.").

⁷³ Gates, *supra* note 25, at 1353. See also JACOBSON, *supra* note 68 (discussing the culture of technology in the United States).

greatest” surgical innovations for their conditions.⁷⁴ Patient demand “puts pressure on [surgeons] to adopt the latest technology,”⁷⁵ and the news media play a role in stimulating consumer demand in high profile coverage of innovation.⁷⁶ Professional organizations reward innovation: journals dedicate sections to reports on new techniques, annual meetings highlight innovations, and innovators receive awards.⁷⁷ Medical students choosing surgery are told that innovation and creativity are sought-after qualities.⁷⁸ Marketing materials from surgical institutions and clinics routinely reference “innovation.”⁷⁹ Physicians and surgeons are keen to adopt the latest innovations. Factors that influence such adoption include reimbursement, quality of care, patient preferences, and professional competition.⁸⁰ Whether an innovative surgical procedure should be treated as research or standard medical practice is further complicated by traditional notions of professional autonomy and the fact that “[s]urgeons tend to view themselves as artists rather than scientists, custom-tailoring a treatment for a patient’s ailment.”⁸¹ All of the characteristics described shape the

⁷⁴ Gates, *supra* note 25, at 1353 (“Patients really want the ‘latest and greatest,’ i.e., the incremental improvements that result from intuitive innovation. . . .”); JACOBSON, *supra* note 68, at 58, 61 (“Americans expect, indeed demand . . . continued innovation. . . . Patients often want . . . the most cutting-edge surgical procedure when they fall ill. . . .”). See also RICHARD A. DEYO & DONALD L. PATRICK, *HOPE OR HYPE: THE OBSESSION WITH MEDICAL ADVANCES AND THE HIGH COST OF FALSE PROMISES* (2005).

⁷⁵ JACOBSON, *supra* note 68, at 61.

⁷⁶ King, *supra* note 42, at 575.

⁷⁷ See generally Am. Coll. of Surgeons, <http://www.facs.org/> (last visited Apr. 17, 2006).

⁷⁸ Am. Coll. of Surgeons, So You Want to Be a Surgeon: Surgical Traits, <http://www.facs.org/residencysearch/traits/traits.html> (last visited Apr. 10, 2006).

The surgical culture is one of continuous improvement. . . . As surgeons, we are able to test our hypotheses and see rapid, graphic results from our work. . . . The field of surgery needs a rich variety of motivated medical students to enter surgical training to continue this good work, as well as innovate and explore new directions.

Id.

⁷⁹ See, e.g., Univ. of Cincinnati, Center for Surgical Innovation, <http://surgery.uc.edu/csi/index.html> (last visited Apr. 17, 2006); Stanford Univ., Surgical Innovation Program, <http://surgery.stanford.edu/innovation/> (last visited Apr. 17, 2006); Univ. of Rochester Med. Ctr., Urology - Research and Innovation, <http://www.stronghealth.com/services/urology/research/index.cfm> (Apr. 17, 2006).

⁸⁰ JACOBSON, *supra* note 68, at 62 (“Even when the overall clinical benefits are marginal and the incremental cost substantial, physicians will opt for new technology if there is a perceived advantage in patient comfort or safety.”) (citation omitted).

⁸¹ BARRY R. FURROW ET AL., *HEALTH LAW* 291 (2d ed. 2000).

debate about the adequacy of the current policy stance towards surgical innovation.

A potentially significant financial influence on judgments about the appropriate characterization of innovation is the availability of insurance reimbursement. Insurers assess reimbursement requests according to the patient's benefits contract, basing their final decisions on determinations of medical necessity in light of the individual patient's medical needs and treatment alternatives.⁸² Insurers and others view reimbursement decisions as "validat[ion] that a technology is standard treatment and efficacious."⁸³ Experimental or investigational therapies are typically excluded from coverage as their clinical effectiveness is unknown.⁸⁴

An insurer would not undertake a scientific review and evaluation for a surgical procedure that is well established with known risks and benefits.⁸⁵ If the insurer considered the basic objective of a procedure to remain the same, it is unlikely that a variation in surgical technique would prompt a scientific evaluation for clinical efficacy.⁸⁶ For example, one major insurer reported that it did not conduct a formal evaluation of laparoscopic cholecystectomy (gall bladder removal) or hysterectomy (removal of the uterus) because, while the surgical approach was novel (using the laparoscope for organ removal), the procedures themselves (organ removal) had known risks and

⁸² Susan Gleeson, *Paying for Innovations in Surgery*, BULL. AM. C. SURGEONS, Apr. 1996, at 10, 11. Even before medical necessity determinations are made in a particular case, innovations involving new technology have likely undergone a scientific review and evaluation process for clinical efficacy, i.e., whether the new technology improves net health outcomes. Blue Cross and Blue Shield plans, for example, are reported to rely on the findings of a scientific review process, which include the assessment of the clinical efficacy of the technology according to five scientific criteria designed to elicit:

[W]hether the technology in question improves net health outcomes. . . : 1. The technology must have final approval from the appropriate government regulatory bodies. Although surgical procedures are not subject to FDA review, devices or pharmaceutical agents that are employed in surgical procedures would require final FDA approval. 2. The scientific evidence must permit conclusion concerning the effect of the technology on health outcomes. 3. The technology must improve the net health outcome. 4. The technology must be as beneficial as any established alternatives. 5. The improvement must be attainable outside the investigational settings. . . .

Id. at 11. The plan may also consider the cost-effectiveness of a procedure in their final decision.

⁸³ *Id.* at 12.

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ *Id.*

benefits.⁸⁷ However, a new surgical procedure or technique presenting substantially new or different benefits and risks would undergo such a review, e.g., transplants of certain organs.⁸⁸ The financial incentives to characterize innovation as practice rather than research are strong. If the surgeon explicitly characterizes an innovation as experimental, insurers are in good standing to deny coverage, with financial ramifications for the institution, surgeon, and the patient.

C. Development and Diffusion of Surgical Innovations

Debates surround claims about the distinctive characteristics of surgery and surgical innovation, in particular, during the process of development and diffusion into standard surgical practice. The process of development and introduction of new surgical techniques varies; there appear to be no standard pathways to introduce a surgical innovation into practice. The formal, systematic, highly regulated environment surrounding the testing of new drugs for safety and efficacy before they are ever prescribed to patients stands in stark contrast to the highly unregulated environment and variable approaches to establishing safety and efficacy in surgical innovation.⁸⁹ Drugs and medical devices must go through an intensely scrutinized federal regulatory process that requires testing for safety and efficacy in animals and humans before pharmaceutical and device manufacturers can receive federal approval to market their products for use in patients.⁹⁰

⁸⁷ *Id.* (discussing Blue Cross/Blue Shield's approach to coverage decisions related to innovative surgery).

⁸⁸ "For example, [the Blue Cross/Blue Shield scientific review and evaluation process] has assessed major organ transplants and continues to reassess those that have not met the [scientific] criteria, including small bowel transplants and pancreas-only transplants." *Id.* at 12. See also Patricia C. Kuszler, *Financing Clinical Research and Experimental Therapies: Payment Due, but from Whom?*, 3 DEPAUL J. HEALTH CARE L. 441 (2000) (discussing the challenges and the publicity related to reimbursement of the clinical efficacy of high dose chemotherapy with bone marrow transplant (known as HDC/ABMT) for the treatment of breast cancer); Gleeson, *supra* note 82, at 13.

⁸⁹ Commentators frequently begin their critique or defense of the current treatment of surgical innovation by contrasting it with the highly regulated area of medical drugs and devices. See, e.g., Reitsma & Moreno, *supra* note 28; Casler, *supra* note 29, at 675; Spodick, *supra* note 20, at 36; Jack W. Love, *Drugs and Operations: Some Important Differences*, 232 JAMA 37, 37 (1975). For a more detailed examination of the Food and Drug Administration review and approval process see Ctr. for Drug Evaluation & Research, Food & Drug Admin., *From Test Tube to Patient: Improving Health through Human Drugs* (1999), <http://www.fda.gov/cder/about/whatwedo/testtube-full.pdf>.

⁹⁰ See, e.g., Food & Drug Admin., *The New Drug Development Process: Steps from Test Tube to New Drug Application Review*, <http://www.fda.gov/cder/>

The evaluation of drug efficacy typically includes, *inter alia*, a randomized controlled trial (RCT) in order to minimize the potential for investigator bias, evaluate results based on statistical significance, and avoid inaccurate retrospective assessment of results.⁹¹ This process involves the comparison of outcomes resulting from the random allocation of the new treatment and the standard treatment among human subjects.⁹² The regulatory process includes oversight and implementation of human subjects protections, including prior review by an institutional review board and specific informed consent.⁹³

The process of introduction, development, refinement, and diffusion of surgical innovations can be more “haphazard.”⁹⁴ It may or may not have included prior animal testing, formal protocols reflecting experimental design, prior independent or peer review, or systematic collection and evaluation of follow-up data.⁹⁵ Indeed, the surgical literature reflects questions and debate over the benefits to the patient and future patients of RCTs, approaches that are considered to be the gold standard methodology in other areas of medicine for establishing clinical safety and efficacy.⁹⁶ In practice, a surgeon may even try out or modify a surgical technique based on anecdotal case reports discussed in meetings or in professional journals, and may do so without institutional or peer oversight or consultation.⁹⁷ In addition, profes-

handbook/develop.htm (last visited Feb. 26, 2006).

⁹¹ For a detailed discussion of the randomized controlled trial, see LEVINE, *supra* note 43, at 185-212.

⁹² *Id.* at 185-89. Where there is no standard treatment available, the comparison group receives no treatment. *Id.* at 185-90.

⁹³ FDA Protection of Human Subjects, 21 C.F.R. §§ 50, 56 (2005).

⁹⁴ Editorial, *supra* note 22 (citing E.A. Shinebourne, *Ethics of Innovative Cardiac Surgery*, 52 BRIT. HEART J. 597 (1984)).

⁹⁵ See Bunker et al., *supra* note 5. See also Dossetor, *supra* note 4, at 966 (from a transplant surgeon’s perspective, opining that there are “at least six routes of endeavour by which new modes of therapy become part of the body of established medical treatments”: (1) quackery, (2) innovative treatment, (3) inadequate uncontrolled clinical trials, (4) break-throughs, (5) the obvious, now become feasible, and (6) controlled (randomized) clinical trials.); Ward, *supra* note 1, at 91 (describing three phases of clinical research in surgery: (1) “anecdotal case report, providing little more than serendipitous clinical impressions . . . [with] little place in the context of proper evaluation”; (2) “case and case series without controls, prone to selection bias and suspect and false conclusions which can be as high as 50 [percent];” (3) “prospective randomized control trial (RCT)”).

⁹⁶ See, e.g., G. Gillett, *Ethics of Surgical Innovation*, 88 BRIT. J. SURGERY 897, 897 (2001); King & Henderson, *supra* note 72, at 1015-19; Spodick, *supra* note 20, at 36.

⁹⁷ See Ward, *supra* note 1, at 92.

sional journals report cases and case series without controls, whose results are open to claims of experimental biases.⁹⁸

The difference in regulatory treatment can be attributed in part to history. Stringent food and drug laws were shaped by congressional reactions to scandals and negligence that emerged from the 1900s on.⁹⁹ Surgery, on the other hand, was often viewed as a last-resort measure and experienced no equivalent public scandals.¹⁰⁰ Other attempts to distinguish rigorous assessments of drugs and medical devices from surgical innovation highlight claims about the distinctive characteristics of surgery that may independently affect patient outcomes regardless of a patient's presentation of a disease or condition. Skill can vary among surgeons; two surgeons performing the same procedure under the same conditions on similarly situated patients can have different outcomes.¹⁰¹ Also, the success rates and morbidity and mortality rates of an individual surgeon are expected to improve over time with increased experience with the procedure.¹⁰² This so-called "learning curve" applies to well-established and proven procedures, as well as innovative procedures.¹⁰³ The skill of a surgical

⁹⁸ See *id.*; Reitsma & Moreno, *supra* note 48, at 49 ("The majority of surgical publications involve interventional case reports that consist of a series of patients; outcome measures are usually clinical parameters that are obtained during routine clinical follow-up, without any type of formal written protocol.").

⁹⁹ King & Henderson, *supra* note 72, at 1015 (describing the harms prompting Congressional legislation in the 1930s from the drug elixir sulfanilamide that killed 107 people and in the 1960s from birth defects arising from the use of the drug thalidomide in pregnant women).

¹⁰⁰ *Id.* at 1019. Fox and Swazey describe efforts at professional monitoring through voluntary suspension of an experimental technique, using the example of heart transplants:

A clinical moratorium is the suspension of the use of a still experimental procedure on patients, which may last for weeks, months, or years. Moratoriums have occurred repeatedly in the history of therapeutic innovations. Typically, a moratorium takes place when the uncertainties and risk of a new treatment become starkly apparent and the patient mortality rate seems unbearable or unjustifiable. Pressure for a moratorium can come from physician-investigators' own reactions to the situation, from their colleagues, from the institution in which they work, or from patients and their families.

FOX & SWAZEY, *supra* note 71, at 108.

¹⁰¹ See, e.g., *Editorial, supra* note 22 ("What is established and successful in a specialist unit may be hazardous and experimental when introduced elsewhere by the well-meaning but inexperienced."); Love, *supra* note 89, at 37 ("Poor results with a new surgical procedure may indicate that the procedure is a bad one, or it may indicate that it was not well performed").

¹⁰² "In general, a competent surgeon will do a better job the 100th time than the first time he performs a given operation." Love, *supra* note 89, at 37.

¹⁰³ *Id.* at 38. See also ATUL GAWANDE, *COMPLICATIONS: A SURGEON'S NOTES ON AN IMPERFECT SCIENCE* 25-31 (2002).

team (e.g., the surgeon(s), nurses, anesthesiologists, and others) and their experience working together may also influence outcomes from a particular procedure.¹⁰⁴

Comparatively, it is claimed that drugs may be prescribed by physicians or developed in controlled clinical trials without reference to variable physician skill.¹⁰⁵ Also, it is claimed that surgical techniques undergo rapid evolution and refinement, a process of trial and error that cannot be accomplished by adherence to an inflexible protocol.¹⁰⁶ Indeed, it has been suggested that the randomized study can be rendered obsolete by advances in surgical technology.¹⁰⁷ In contrast, it is argued that drug studies assess an unchanging chemical entity.¹⁰⁸ These qualities of innovative surgery have been cited by some as factors that should distinguish it from other areas that require more standardized, rigorous testing before introduction into patients.

One prominent surgeon has highlighted the lack of financial support for surgical trials, in comparison to drug trials, as one reason that surgeons have “lagged behind” other medical disciplines in conducting clinical trials, further noting that many surgeons lack the appropriate training and experience to conduct clinical trials.¹⁰⁹

The previous discussion is not intended to suggest that surgeons and others do not believe that surgical techniques should not be evaluated and compared to standard treatments. The American College of Surgeons, for example, issued a 1995 opinion that stressed the importance of evaluation and comparison of new surgical technologies against existing and proven technologies.¹¹⁰ And, a former president

¹⁰⁴ See, e.g., FOX & SWAZEY, *supra* note 71, at 338-39; GAWANDE, *supra* note 103, at 25-31. See generally M. Leonard et al., *The Human Factor: The Critical Importance of Effective Teamwork and Communication in Providing Safe Care*, 13 QUALITY & SAFETY HEALTH CARE 85 (2004).

¹⁰⁵ Love, *supra* note 89, at 38. But see Robert J. Levine, *The Boundaries Between Biomedical or Behavioral Research and the Accepted and Routine Practice of Medicine*, in NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH, APPENDIX I, 1-1 (1979) (“[I]t should be noted that personal skills and experience greatly influence the outcome of the use of drugs. . . . [T]hus, for example, the use of methotrexate by an experienced oncologist may yield salutary effects with minimal risk while its use by many other physicians may be deadly.”).

¹⁰⁶ See Frader & Caniano, *supra* note 11, at 221.

¹⁰⁷ Bonchek, *supra* note 2, at 44.

¹⁰⁸ *Id.*

¹⁰⁹ R. Scott Jones, *Requiem and Renewal*, 240 ANNALS OF SURGERY 395, 401-04 (2004).

¹¹⁰ Editorial, *Statement on Issues to Be Considered Before New Surgical Technology Is Applied to the Care of Patients*, 80 BULL. AM. C. SURGEONS 46 (1995).

of the American College of Surgeons has publicly stressed the importance of moving towards a system that acknowledges the value of evidence-based practice and outcomes assessment.¹¹¹ Also, some have advocated for the consideration of RCTs, and cases in the surgical literature have documented specific instances where retrospective review indicated that patient outcomes would have been improved with earlier use of RCTs.¹¹² What is at issue is how such an evaluation and comparison should be conducted and overseen in light of the fact that decisions on the appropriate methodology for assessing the safety and efficacy of a particular innovation ultimately are vested in the individual surgeon.¹¹³

II. MEDICAL PRACTICE OR HUMAN SUBJECTS RESEARCH? THE CHOICE OF LEGAL PATHWAY

The law recognizes that a physician must adapt treatments, including surgical approaches, to the diverse presentations and varying needs of individual patients. At the same time, the law imposes conditions and limits on deviations from standard medical and surgical practices. Surgical innovations will follow one of two established, alternative legal pathways described herein as (1) the medical practice pathway (The Practice Pathway), which allows for retrospective redress of patient injury through tort liability,¹¹⁴ or (2) the human sub-

See also Gruen et al., *supra* note 17, at 607 (stating the stance of the American College of Surgeons Task Force on Professionalism: "We have a professional responsibility to ensure that our interventions are more effective than alternatives and, for this reason, outcomes-based research must be supported.").

¹¹¹ Jones, *supra* note 109, at 401.

¹¹² *E.g.*, shunt surgery for portal hypertension. Bunker et al., *supra* note 5, at 938 (advocating clinical surveillance as well as RCTs). King and Henderson describe the first time a surgical procedure underwent a controlled comparison:

Internal mammary artery ligation was a simple, safe and easily applicable procedure—requiring only local anesthesia—first used in 1939 to reduce angina related to coronary artery disease. It was widely employed between 1953 and 1958, at which time reports began to emerge questioning its efficacy. In 1959 two studies were carried out on patients with angina, randomly assigning patients to either a treatment group or a group that received a sham operation. The results demonstrated conclusively the existence of a placebo effect of surgery and established the need for controlled studies to evaluate surgical and medical procedures.

King & Henderson, *supra* note 72, at 1020 (footnotes omitted).

¹¹³ Margo, *supra* note 67, at 41 (quoting Gary B. Ellis, former head of the government oversight agency for human subject's protection: "... the process of protecting human study subjects essentially begins with a process of prospective self referral by investigators of themselves and their research to IRBs ...").

¹¹⁴ Other potential but less common bases for legal action in the practice

jects research pathway (The Research Pathway), which involves prospective review and oversight and also allows for retrospective redress of injury through federal sanctions and tort liability.

As will be discussed herein, innovative surgery does not fit comfortably in either the Practice Pathway or the Research Pathway. The Practice Pathway views innovations retrospectively through the lens of malpractice,¹¹⁵ examining and judging deviations from standards of care that are generally accepted by the medical community. Innovative surgery is by definition on the cutting edge of accepted practice and thus challenges this understanding. Likewise, the federal regulations governing human subjects research and the testing of medical drugs and devices that require prospective review of research protocols were not explicitly designed to regulate innovative surgeries. For example, future patients are the intended beneficiaries of research, but one could argue that innovative surgery is research based on an "N of One,"¹¹⁶ providing primary benefit to the individual patient and then a possible secondary benefit to future patients depending on the outcome in one patient.

The pathway followed affects the legal analysis and has implications for judicial decision-making. It affects the liability exposure of the surgeon and the institution where the surgery is conducted and the potential sanctions applied to the surgeon and/or the affiliated institution. It also affects the legal rights of the patient, including the right to consent to experimental procedures and a patient's ability to seek reimbursement of medical expenses.¹¹⁷

Since the pathway selected may have significant implications for surgeons and their affiliated institutions and patients, how is that pathway selected? At what point does an innovative surgical approach become more than just individualized patient care and worthy of com-

pathway include: express promise, battery, disciplinary action, review of institutional privileges and certificates, peer review, and constitutional claims. Those other bases of legal action are beyond the scope of this article.

¹¹⁵ The use of the term "malpractice" should not be construed to mean that practices that are not subject to prospective review constitute a form of malpractice. Indeed, the practice pathway is only prompted when a patient alleges injury resulting from the surgery, and the plaintiff may ultimately fail in his allegation.

¹¹⁶ See, e.g., King, *supra* note 42, at 577 (citing Jerome Groupman, *Dr. Fair's Tumor*, NEW YORKER, Oct. 26, 1998, at 78). For an argument that n-of-1 trials do not need regulatory approval, see, e.g., Les Erwig et al., *Ethics of n-of-1 Trials*, 345 LANCET 469 (1995).

¹¹⁷ For discussion of reimbursement implications of research classification, see *supra* Part I.B. See generally King & Henderson, *supra* note 72, at 1024 (describing medicine as a "dynamic discipline, whose every encounter has been described as a clinical trial, an experiment of one.") (footnote omitted).

parative evaluation or even the surgical equivalent of the clinical trial, the gold standard of research? Previous parts of this article have highlighted some of the policy issues and challenges in determining whether an innovative surgical approach constitutes research.¹¹⁸ An examination of the legal considerations follows, focusing particularly on tort liability and prospective regulation as moderators balancing between medical progress and protection of the rights and welfare of patients.

From a legal perspective, surgical innovation was historically either treated as malpractice derived from a surgeon's harmful experimentation or as a decision of medical judgment exercised as a surgeon's right.¹¹⁹ Dating back to at least 1871, the courts expressed a willingness to defer to the judgment of a surgeon where no established mode of treatment existed for the condition or injury.¹²⁰ In other circumstances, however, the legal risk associated with surgical innovations was placed squarely on the surgeon and was characterized as dangerous experimentation and a deviation from the standard of care.¹²¹ As the New York court in *Carpenter v. Blake* stated:

If the case is a new one, the patient must trust to the skill and experience of the surgeon he calls; so must he if the injury or the disease is attended with injury to other parts, or the diseases have developed themselves, for which there is no established mode of treatment. But when the case is one as to which a system of treatment has been followed for a long time, there should be no departure from it, unless the surgeon who does it is prepared to take the risk of establishing by his success, the propriety and safety of his experiment.¹²²

¹¹⁸ See *supra* Part I.A.

¹¹⁹ For a detailed examination of the historical relationship between medical innovation generally and malpractice litigation, see Kenneth A. De Ville, *Medical Malpractice in Twentieth Century United States: The Interaction of Technology, Law and Culture*, 14 INT'L J. TECH. ASSESSMENT HEALTH CARE 197 (1998).

¹²⁰ *Carpenter v. Blake*, 60 Barb. 488 (N.Y. Sup. Ct. 1871).

¹²¹ *Id.* (defendant physician claimed that he used his best judgment in treatment of dislocated elbow). See also *Slater v. Baker*, 95 Eng. Rep. 860, 863 (K.B. 1767) (innovation viewed negatively as experimentation where surgeon and apothecary re-broke plaintiff's leg and used metal frame during healing to lengthen it "contrary to the known rule and usage of surgeons.").

¹²² *Carpenter*, 60 Barb. at 523-24. The court continued:

The rule protects the community against reckless experiments, while it admits the adoption of new remedies and modes of treatment only when their benefits have been demonstrated, or when, from the necessity of the case,

The context of these decisions made clear that judicial concern was focused on reigning in fraudulent practices of medicine, i.e., quackery, and protecting its victims by implementing “standards of strict liability for deviations from accepted practice.”¹²³ As King and Henderson have documented, this notion of strict liability has eased considerably over time.¹²⁴ Judicial acknowledgement of the importance of the physician’s best medical judgment in the advancement of medical science emerged in the 1930s, i.e., that some deviation from the standard of care might be deemed acceptable and even important in order to allow medicine to progress.¹²⁵ In the 1935 case *Fortner v. Koch*,¹²⁶ a Michigan court appears to ease the negative treatment of novel treatments, permitting some departures from the standard of care that were considered to be therapeutically beneficial for the patient¹²⁷ and requiring the consent of the patient.¹²⁸ This standard thus permitted some innovation even where standard treatments were available. It also evidenced an early adoption of some of the regulatory requirements that apply to human subjects research today, i.e., valid consent and an acceptable risk-benefit balance.¹²⁹

The legal pathway today is essentially dictated by the surgeon;¹³⁰ the two pathways are ultimately defined by an affirmative decision to subject the surgical innovation to the regulatory review and oversight of the human subjects protection system associated with the Research Pathway. Innovations that are not processed under this regulatory system either escape prospective or retrospective review altogether (e.g., because the innovation did not result in injury or was undetected), or

the surgeon or physician must be left to the exercise of his own skill and experience.

Id.

¹²³ King & Henderson, *supra* note 72, at 1024.

¹²⁴ For a more detailed historical discussion of the evolution of experimentation and the law, see *id.* at 1024-27.

¹²⁵ See, e.g., *Brown v. Hughes*, 30 P.2d 259 (Colo. 1934); *Fortner v. Koch*, 261 N.W. 762 (Mich. 1935).

¹²⁶ *Fortner*, 261 N.E. at 762.

¹²⁷ King & Henderson, *supra* note 72, at 1026.

¹²⁸ *Fortner*, 261 N.E. at 765.

We recognize the fact that, if the general practice of medicine and surgery is to progress, there must be a certain amount of experimentation carried on; but such experiments must be done with the knowledge and consent of the patient or those responsible for him, and must not vary too radically from the accepted method of procedure.

Id.; King & Henderson, *supra* note 72, at 1027 (citing *Fortner*, 261 N.E. at 765).

¹²⁹ King & Henderson, *supra* note 72, at 1027. For discussion of current regulations see *infra* Part IV.A-C.

¹³⁰ Margo, *supra* note 67, at 41.

are judged under the state statutory and common law tort doctrines of medical malpractice (the Practice Pathway). The surgeon's decision, of course, is made within the context of his or her respective institution's organizational and legal culture.

Practically speaking, few surgeons appear to submit their innovative surgical procedures to the review process of the federal regulations.¹³¹ Thus, relatively few innovative surgical procedures formally receive prospective review and approval associated with the Research Pathway that is envisioned by the federal regulations for human subjects research. Such review and approval affords the opportunity to prevent potential injury to patients. In contrast, the default pathway is the Practice Pathway, which is prompted by patient injury.

Each pathway is examined below, beginning with the Practice Pathway, and each concludes with an assessment of the pathway's implications for the treatment of innovative surgery.

III. THE MEDICAL PRACTICE PATHWAY

Compared to other areas of medical practice, the conduct of surgery is by its very nature a risk factor in the prediction of medical malpractice claims. The number of surgical procedures conducted by physicians has been shown to be a statistically significant factor related to malpractice claim frequency and award size.¹³² One legal

¹³¹ Jones, *supra* note 109, at 401. No data have been collected that would explicitly indicate the numbers of surgical innovations subjected to the IRB process. Because the regulations are implemented at the level of the institution, only that particular institution would have any possibility of assessing how many surgical innovations had been subjected to the IRB process. But there is no checkbox for surgical innovation on IRB submission forms, and no requirement that such data be collected. Further, because surgeons or departments self-identify, the IRB would not have an independent way of identifying particular innovations that should have been forwarded for review. Empirical research by Reitsma and Moreno on surgeon uncertainty about the distinction between research and therapy and the applicability of human subjects regulations supports the claim that few surgeons submit their innovations to the Research Pathway. Surveys of surgeons indicate that surgeons disagree or are uncertain about whether innovative surgical techniques fall within the realm of acceptable variations of daily practice or are human subjects research warranting prospective regulation and oversight. Reitsma & Moreno, *supra* note 28. This is further supported by another survey which reported surgeons' lack of familiarity with human subjects regulations. Rutan et al., *supra* note 47.

¹³² Patricia M. Danzon, *The Effects of Tort Reforms on the Frequency and Severity of Medical Malpractice Claims*, 48 OHIO ST. L.J. 413, 414-15 (1987) (Danzon's study was designed to "assess the impact of tort reforms and other factors on malpractice claim frequency and severity," using statistical methods to

analyze the average experience of physicians in different states, some with and some without tort reforms, over the years 1975 through 1984. The unit

commentator has opined that “unregulated dissemination of new technologies and techniques has resulted in a general propensity to stimulate malpractice liability litigation.”¹³³ Indeed, De Ville has described the “ebb and flow” life cycle of malpractice suits growing out of new technologies, and decreasing over time:¹³⁴

After a technological innovation first becomes a conventional and widely used procedure, the profession does not fully realize the degree of caution required to use it. . . . Through clinical experience, the profession collectively discovers the types of problems associated with a new procedure and institutes precautions to deal with the newly discovered dangers. . . . As these precautions are introduced, successes increase and iatrogenic injuries decrease. As a result the intensity of the suits associated with that procedure may abate. . . . In addition, physicians may institute mechanical precautions to deal with inherent dangers that were not evident when the procedure entered widespread use. . . . These precautions decrease the number of untoward incidents and the resulting suits even further. . . . Just as significantly, widespread and common use of some procedures frequently moderate expectations, making them more accurate. As the limits of the procedure become more apparent through long-term use, both the profession, through outcomes data and clinical experience, and laypersons, through informed consent, develop more realistic views of the benefits and dangers of the procedure. As they do so, failure, complications, and less than perfect results will be less likely to incite dissatisfaction and lawsuits.¹³⁵

of analysis is not the individual physician or individual claim, but the average frequency of claims per 100 physicians and average severity per paid claim in each state. . . . Most consistently significant was the number of surgical procedures per capita, which is positively related to the frequency of claims filed per physician. Claim severity is significantly higher in states with a high ratio of surgical specialists, relative to medical specialists. These variables may capture the general effect of more complex medical practice, as well as the likelihood that surgical mishaps involve more serious errors and are easier to prove.

Id.

¹³³ JACOBSON, *supra* note 68, at 20. Other legal scholars have also explored the relationship between medical innovation and malpractice liability. See generally De Ville, *supra* note 119.

¹³⁴ De Ville, *supra* note 119, at 204.

¹³⁵ *Id.* at 204-05.

The increasing complexity of innovations means that their successful implementation requires greater surgical skill.¹³⁶ This complexity also increases the likelihood of “knowledge-based, skill-based, and attention-based mistakes,”¹³⁷ e.g., that “momentary lapses of concentration” in the use of a new procedure can have significant consequences for patients, even where adverse events are thought to be infrequent.¹³⁸ This environment surrounding innovations thus raises the prospect of potential litigation.¹³⁹

The Practice Pathway is only prompted when a patient alleges injury resulting from the surgery. In the United States, legal actions for injuries are generally based in tort law, the branch of the law that allows injured persons to seek monetary compensation from those responsible for the injury.¹⁴⁰ Tort law is the province of state law, created through state legislation and state judicial decisions, known as the “common law.”¹⁴¹ Variations exist among the states, but state tort rules are similar enough that generalized statements of liability can be made for the purposes of this examination.¹⁴²

A. Overview of Medical Malpractice Law

Most medical malpractice actions are based in negligence, or “conduct which falls below the standard established by law for the protection of others against unreasonable risk of harm.”¹⁴³ The plaintiff in these cases is the patient who is injured in the course of medical practice. The patient’s family may also bring a claim on his or her behalf in the event of the patient’s incompetency or death.¹⁴⁴ The defendant is typically the physician who allegedly caused the injury, but may also include the institution with which the physician is affili-

¹³⁶ JACOBSON, *supra* note 68, at 22.

¹³⁷ De Ville, *supra* note 119, at 203.

¹³⁸ *Id.*

¹³⁹ *Id.* at 206 (“[N]ew technologies . . . are likely to contribute to an overall increase in the number of medical malpractice cases in the system.”).

¹⁴⁰ See ROBERT E. KEETON ET AL., TORT AND ACCIDENT LAW: CASES AND MATERIALS 1 (3d ed. 1998).

¹⁴¹ See W. PAGE KEETON ET AL., PROSSER AND KEETON ON TORTS 1-32 (5th ed. 1984) (discussing background and history of tort law).

¹⁴² For example, many states, through their courts and state legislatures have adopted portions of the RESTATEMENT (SECOND) OF TORTS (1994) and the RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY (1998), the American Law Institute’s synthesis of the major principles of contemporary tort law (ALI 1997).

¹⁴³ RESTATEMENT (SECOND) OF TORTS § 282.

¹⁴⁴ Third parties may also be able to recover monetary damages for injury to a patient caused by negligence. For example, a spouse or child may claim loss of consortium, the legal term for the loss of the society and affection of the injured person.

ated.¹⁴⁵ A plaintiff may allege that the defendant institution is directly liable for its own actions or vicariously liable for the actions of the physician.¹⁴⁶

Negligence cannot be presumed merely by the existence of a patient's injury, but must meet particular legal requirements of proof. To succeed in a negligence case, the plaintiff (in this case the patient) must prove by a preponderance of the evidence each of four elements.¹⁴⁷ First, he or she must prove that the defendant had a legal duty to the plaintiff.¹⁴⁸ The duty owed in the medical malpractice context can include any one of a number of obligations that health professionals or institutions incur upon entering into a professional relationship with the patient.¹⁴⁹ It includes the duty to communicate certain information to the patient before treating the patient.¹⁵⁰ A duty may be mandated or implied by statutes, regulations, or guidelines.¹⁵¹ A duty may be shaped by whether the defendant reasonably could have foreseen the injury to the plaintiff.¹⁵²

Second, the existence of a duty will in turn create responsibilities on the part of the defendant to exercise due care, and the plaintiff must prove that the defendant breached the standard of care.¹⁵³ This element is discussed in significant detail later in this part.

Third, the plaintiff must prove that he or she suffered a compensable injury. In most negligence cases, only compensatory damages¹⁵⁴ (to compensate the plaintiff for the actual harm suffered, including pain and suffering) are awarded. In cases where the

¹⁴⁵ MARK A. HALL ET AL., *MEDICAL LIABILITY AND TREATMENT RELATIONSHIPS* 447-48 (Aspen Publishers 2005).

¹⁴⁶ *Id.* at 448.

¹⁴⁷ KEETON ET AL., *supra* note 141, at 4.

¹⁴⁸ DOUGLAS DANNER ET AL., *MEDICAL MALPRACTICE CHECKLISTS AND DISCOVERY* § 2:3 (Thomson/West 2004).

¹⁴⁹ HALL ET AL., *supra* note 145, at 80-85.

¹⁵⁰ *See, e.g., Canterbury v. Spence*, 464 F.2d 772, 787 (D.C. Cir. 1972) (the principle of informed consent requires a physician to disclose information a reasonable patient would wish to know in making treatment decisions); *Truman v. Thomas*, 611 P.2d 902, 906-07 (Cal. 1980) (patient must be apprised of risks of not undergoing treatment, even if she has refused treatment).

¹⁵¹ *See* HALL ET AL., *supra* note 145, at 81-85.

¹⁵² KEETON ET AL., *supra* note 140, at 393.

¹⁵³ *See, e.g., Locke v. Pachtman*, 521 N.W.2d 786, 789 (Mich. 1994).

¹⁵⁴ Compensatory damages include (1) economic damages, which are objectively verifiable monetary losses, include items such as medical expenses (past, present and future), lost wages, lost earning capacity, and burial costs, and (2) non-economic damages, which are subjective non-monetary losses, include items such as pain, suffering, and emotional distress. *See* VICTOR E. SCHWARTZ ET AL., *PROSSER, WADE AND SCHWARTZ'S TORTS* 531-38 (11th ed. 2005).

defendant's behavior was reckless or an extreme departure from the standard of care, commonly known as gross negligence, some states allow a plaintiff to recover punitive damages as well.¹⁵⁵ Also, while it is necessary that there be some injury in order to recover damages, the injury need not necessarily be tangible. In some cases, for example, patients have recovered damages for emotional distress or anxiety caused by a fear of getting cancer.

Lastly, the plaintiff must also prove that the defendant's actions caused the injury.¹⁵⁶ Causation can be a difficult concept: the plaintiff must show that "but for" the actions of the defendant the injury would not have occurred. This is "cause in fact." But the plaintiff must also establish legal cause, or proximate cause; the defendant is only responsible for the damages that are a foreseeable consequence of his or her behavior.¹⁵⁷ It may be particularly challenging for a plaintiff to prove that a defendant (instead of the underlying medical condition) was the legal cause of the patient's death in cases where the patient's condition initially presents itself as terminal or life-threatening, no standard therapy exists, and the patient dies following a medical or surgical intervention.¹⁵⁸

In a medical malpractice action involving the use of an innovative surgical procedure, an injured patient (the plaintiff) would allege, within the framework described above, that the surgeon (the defendant) breached, or rather failed to meet, the standard of care in the selection of the surgical approach and/or performance of the surgery.¹⁵⁹ The patient might also, or only, again within the basic framework described above, allege a failure of informed consent, i.e., that the defendant failed to adequately inform the plaintiff regarding the surgical procedure.¹⁶⁰ The plaintiff will likely allege that the institution where the surgery was conducted is either directly or vicariously liable.¹⁶¹ Each of these two applications of negligence is discussed separately below.

¹⁵⁵ KEETON ET AL., *supra* note 141, at 9 (punitive damages).

¹⁵⁶ *See, e.g.*, Locke, 446 N.W.2d at 789.

¹⁵⁷ BLACK'S LAW DICTIONARY 971 (7th ed. 1999) ("[t]o succeed in a malpractice claim, a plaintiff must also prove proximate cause").

¹⁵⁸ HALL ET AL., *supra* note 145, at 407.

¹⁵⁹ *See, e.g.*, Jones v. Chidester, 610 A.2d 964 (Pa. 1992) (plaintiff sued doctor alleging that injuries sustained were due to method utilized during surgery); Locke, 446 N.W.2d at 786 (plaintiff sued surgeon for injuries sustained during surgical procedure).

¹⁶⁰ *See, e.g.*, Culbertson v. Mernitz, 602 N.E.2d 98 (Ind. 1992) (plaintiff brought action against doctor alleging that he failed to inform her of risks and complications of the surgery).

¹⁶¹ *See, e.g.*, Browning v. Burt, 613 N.E.2d 993, 1010 n.16 (Ohio 1993).

B. Breach of the Standard of Care

In a medical malpractice claim for surgical innovation based on a breach of the standard of care, the plaintiff must prove through expert testimony (which will be countered by testimony of expert witnesses for the defense) that the surgeon failed to meet either of two aspects of the standard of care: whether it was proper to do the innovative procedure in the first place, and whether the chosen innovative procedure was performed properly. A surgeon whose actions are consistent with the standard of care will be shielded from liability for negligence, regardless of the treatment's outcome (although the surgeon will of course still incur the financial and emotional costs of defending against such a claim). Innovative surgery, which by definition involves novel procedures that have not been widely used, subjects the surgeon (and potentially the institution where the surgery was performed) to potential liability exposure because the novelty of the innovation by definition is essentially a deviation from the standard of care.

The standard of care is determined by what the reasonable practitioner would do in like circumstances.¹⁶² The circumstances to be considered include, for example, the patient's health, the surgeon's expertise, and the state of medical knowledge. The defendant-surgeon will be found to have breached a duty if his or her behavior fell below the standard of care.¹⁶³ Surgeons are generally required to exercise that degree of knowledge or skill ordinarily exercised by practitioners within their medical specialty. Most jurisdictions have moved from basing the standard of care on practices within a specific community (the locality rule) to a national standard for all physicians, or in this case, surgeons within a given specialty.¹⁶⁴

In general, medical standards of care emerge through a complex interplay of professional leaders, journals, peer discussions, and meetings.¹⁶⁵ Over time, these separate professional sources may evolve into clinical policies, and once generally accepted they become standard practice.¹⁶⁶ In medical malpractice litigation, the plaintiff and the defendant hire members of the medical profession to serve as experts who will testify as to the appropriate standard of care.

¹⁶² See, e.g., *Pederson v. Dumouchel*, 431 P.2d 973, 978 (Wash. 1967).

¹⁶³ *KEETON ET AL.*, *supra* note 141, at 137 (standard of care).

¹⁶⁴ See generally Jay M. Zitter, Annotation, *Standard of Care Owed to Patient by Medical Specialist as Determined by Local, "Like Community," State, National, or Other Standards*, 18 A.L.R. 4th 603 (1982).

¹⁶⁵ See *FURROW ET AL.*, *supra* note 81, at 266.

¹⁶⁶ *Id.* at 266-67.

As discussed *supra*, there is no standard pathway for the diffusion of new surgical techniques. Without systematic evaluation and publication of the risks and benefits of a new approach, the reputation, personality, and efforts of the innovator to share the innovation with peers may become very important influences on expert testimony and the procedure's acceptance as the standard of care.

The defendant surgeon can avoid liability by effectively denying any element of the plaintiff's *prima facie* case.¹⁶⁷ For example, the defense may (1) assert that the patient's distinct or atypical anatomical presentation made the surgery more difficult and that the plaintiff did not meet the burden of proving proximate causation¹⁶⁸ or (2) argue that the surgeon acted with reasonable care under the circumstances where the patient's injury is established as a known complication in the performance of the surgery that may occur without negligence.¹⁶⁹ Expert testimony is critical in establishing or responding to any such defenses. Where testimony of a defense expert is able to support that the surgeon's conduct was not negligent in direct contradiction to the testimony of the plaintiff's experts, courts will likely conclude that the plaintiff's burden of proof is not met, and find in favor of the defendant.¹⁷⁰

One might assume that the first-time use of a surgical procedure that results in patient injury (or even early adoption of a technique with uncertain risks or undocumented benefits in comparison to the standard approach) might be characterized as negligent experimentation and thus be easily characterized as an unacceptable deviation from the standard of care. However, the law provides considerable deference to a physician's medical judgment in individual cases and acknowledges that physicians must tailor treatments to the individual needs of their patients. Indeed, a deviation from the standard of care may be legally justified by the surgeon's assertion of various additional defenses. One defense that may be available is the defense of "therapeutic innovation" or "clinical innovation:"

¹⁶⁷ See discussion *supra* Part III regarding elements of a medical malpractice claim.

¹⁶⁸ Phyllis M. Gillespie, *Cause of Action Against a Physician for Laparoscopic Negligence Resulting in Injury or Death to a Patient*, 18 CAUSES OF ACTION 2d 43, § 12 (2004).

¹⁶⁹ See James Duff, Jr., Annotation, *Malpractice: Surgeon's Liability for Inadvertently Injuring Organ Other than that Intended to Be Operated on*, 37 A.L.R. 3d 464, § 2 (1971) (referencing several cases that have discussed a surgeon's liability for injuring another organ during surgery). See also Gillespie, *supra* note 168, § 11.

¹⁷⁰ Duff, *supra* note 169, § 2 (citing as an example *Roberts v. Wood*, 206 F. Supp 579 (Ala. 1962)).

Therapeutic innovation has long been recognized as permissible to avoid serious consequences. The everyday practice of medicine involves constant judgmental decisions by physicians as they move from one patient to another in the conscious institution of procedures, special tests, trials and observations recognized generally by their profession as effective in treating the patient or providing a diagnosis of a diseased condition. Each patient presents a slightly different problem to the doctor. A physician is presumed to have the knowledge and skill necessary to use some innovation to fit the peculiar circumstances of each case.¹⁷¹

Decisions to innovate therefore may potentially be characterized as physician "judgment" in favor of the defendant.¹⁷² However, a physician still runs the risk of being held liable if his or her therapeutic preference is ultimately determined to fall outside the standard of care.¹⁷³

Case law supports that an innovative surgical approach may be used for the first time with no other performance standard to serve as a comparison, even with a bad outcome, at least under the following circumstances: the patient is suffering from a life-threatening condition, no alternative therapies are available, and the patient understood that the treatment was unproven and the risks unknown. A well-known example is *Karp v. Cooley*,¹⁷⁴ which was a medical malpractice action against a chief surgeon and assistant surgeon following the

¹⁷¹ *Brook v. St. John's Hickey Mem'l Hosp.*, 380 N.E.2d 72, 76 (Ind. 1978) (a radiologist was found not negligent in his selection of a child's calves to inject contrast medium, a site which differed from that recommended in the manufacturer's directions and that resulted in injury to the child).

¹⁷² This judicial deference to physician judgment is consistent with the legal treatment of what is commonly referred to as "off-label" uses of drugs and medical devices. From a regulatory standpoint, the U.S. Food and Drug Administration (FDA - the regulatory agency that oversees and approves drugs, biologics, and medical devices in the United States) does not prohibit or discourage physicians from using approved drugs and devices for unapproved purposes. This is because the FDA regulates suppliers and not prescribers, and oversees and restricts marketing practices, not the actual uses of the drugs or devices. 21 U.S.C. §§ 351(f)(1)(B), 352(f), and 331(a-c, g) (2001). Indeed, like surgical innovation, a novel use of a drug or device in an off-label manner may creep into use without rigorous comparative studies and in litigation be recognized as the standard of care even though the drug or device has not been approved by the FDA for such use. Further examination of this issue is beyond the scope of this article.

¹⁷³ *Edenfield v. Vahid*, 621 So. 2d 1192 (La. Ct. App. 1993) (surgeon's decision to use non-absorbable suture, instead of long term absorbable suture, fell below applicable standard of care).

¹⁷⁴ 493 F.2d 408 (5th Cir. 1974).

first-ever use of a mechanical heart implant. In this case the mechanical heart was implanted after the standard approach (ventriculoplasty) was unsuccessful, and served as a temporary life-prolonging device while waiting for a donor heart to become available for heart transplant. The patient died thirty-two hours after transplant surgery. The case was ultimately decided in favor of the defendant-surgeons.¹⁷⁵

The tort system also acknowledges that more than one medically acceptable treatment alternative may be appropriate to address a patient's medical condition. It is unlikely that a physician will be held liable for selecting one acceptable procedure over another, i.e., one that is supported by a minority within the professional group.¹⁷⁶ Specifically, in some jurisdictions, a physician or surgeon is permitted to prove through expert testimony that he or she used a method that was accepted by at least a "respectable minority" of physicians or surgeons.¹⁷⁷ To escape liability, of course, the selected procedure must

¹⁷⁵ In *Karp*, the 5th Circuit affirmed a district court holding that, *inter alia*, the evidence did not warrant submission to the jury on issues of negligence in the performance of the surgical procedure, negligence based on human experimentation, or lack of informed consent with respect to the innovative mechanical heart implant. *Id.* at 408.

¹⁷⁶ *Di Filippo v. Preston*, 173 A.2d 333, 337 (Del. 1961); *Miller v. Scholl*, 594 S.W.2d 324, 329 (Mo. Ct. App. 1980); *Ball v. Mallinkrodt Chemical Works*, 381 S.W.2d 563, 566 (Tenn. Ct. App. 1964) (surgeon had the right to use best judgment in selecting contrast solution used in half of all similar heart imaging procedures, which was more toxic than the alternative and caused patient injury); *Bellomy v. United States*, 888 F. Supp. 760, 765-66 (D. W. Va. 1995).

¹⁷⁷ *See, e.g., Velazquez v. Portadin*, 751 A.2d 102, 107-10 (N.J. 2000) (stating that a physician's professional conduct does not involve the exercise of medical judgment in selecting among acceptable and medically reasonable courses of treatment, but only implicates the exercise of reasonable care in the performance of a medical procedure). *See also Versteeg v. Mowery*, 435 P.2d 540, 543 (Wash. 1967) ("The testimony of other physicians that they would have followed a different course of treatment than that followed by the defendant, or a disagreement of doctors of equal skill and learning as to what the treatment should have been, does not establish negligence" (quoting *Richison v. Nunn*, 340 P.2d 793 (Wash. 1959))). Similarly, the Florida Supreme Court adopted the respectable minority defense in *Baldor v. Rogers*, 81 So. 2d 658, 660 (Fla. 1954) (holding that "[i]f the treatment used is approved by a 'respectable minority of the medical profession' that would relieve the defendant of the charge of malpractice. The doctor is obligated only to use reasonable skill and he fulfills his obligation if he uses methods approved by others of the profession who are reasonably skilled."). *Baldor* has been cited positively by a long line of cases. *See, e.g., Campbell v. United States*, 325 F. Supp. 207, 210 (Fla. 1971) (citing *Baldor* for the proposition that "a disagreement among doctors of equal skill and learning as to what the diagnosis and treatment should have been, does not establish negligence as a matter of law"). The Court of Appeals of Arizona held that jury instructions allowing the respectable minority defense were proper, concluding that "[s]o long as a respectable minority of physicians approve the disputed technique and so long as the defending doctor properly employed that technique, he has not fallen below the standard of

also have been performed non-negligently. The respectable minority defense thus allows for a certain amount of variation in clinical judgment among respected modalities. Just how many physicians or surgeons qualify as a respectable minority? The number is not specified, and jurisdictions vary in their standards. Most require that a respectable minority include "a considerable number of reputable and respected physicians."¹⁷⁸ Thus, a defendant will attempt to utilize this defense by establishing that a respectable minority supports the practice in contention.¹⁷⁹

States that have rejected the respectable minority defense have critiqued the standard, noting that the accepted standard of medical practice cannot be ascertained by "counting how many physicians follow a particular practice."¹⁸⁰ These jurisdictions rely on a more traditional evaluation of the standard of care, e.g., that the "mode or form of treatment [must be one] which a reasonable and prudent member of the medical profession would undertake under the same or similar circumstances."¹⁸¹

If a specific medical or surgical approach, such as an innovative surgical technique, has already been tried and discredited, then the plaintiff will use expert testimony to prove that the defendant failed to comply with the standard of care.¹⁸² It is less clear whether a discredited innovation breaches the standard of care if the surgeon continues modifying it in an attempt to improve it.

The leeway afforded surgeons in exercising their professional judgment and the limits afforded by the application of the standard of care were explored in a 1977 case involving a novel and controversial surgical treatment for emphysema.¹⁸³ The surgeon first used the tech-

care." *Borja v. Phoenix Gen. Hosp. Inc.*, 727 P.2d 355, 357-58 (Ariz. Ct. App. 1986). *Borja* was cited positively on this point in *Nunsuch v. United States*, 221 F. Supp. 2d 1027, 1034 (D. Ariz. 2001). The respectable minority defense developed as early as 1915, and was well-established by the 1920s and 1930s. *See, e.g.*, *Dahl v. Wagner*, 151 P. 1079, 1079 (Wash. 1915); *Ennis v. Banks*, 164 P. 58, 60 (Wash. 1917); *Dishman v. N. Pac. Beneficial Ass'n*, 164 P. 943, 950 (Wash. 1917); *Swanson v. Hood*, 170 P. 135, 137 (Wash. 1918); *Reeves v. Wilson*, 177 P. 825, 826 (Wash. 1919); *Schumaker v. Murray Hosp.*, 193 P. 397, 403 (Mont. 1920); *Gerarty v. Kaufman*, 162 A. 33, 36 (Conn. 1932); *Sims v. Weeks*, 45 P.2d 350, 354-5 (Cal. 1935).

¹⁷⁸ *See, e.g.*, *Jones v. Chidester*, 610 A.2d 964, 969 (Pa. 1992).

¹⁷⁹ In fact, once proven, a judge may direct a verdict in favor of the defendant, deciding in favor of the defendant and removing the opportunity for a jury to make the determination.

¹⁸⁰ *State Bd. of Med. Examiners v. McCroskey*, 880 P.2d 1188, 1194-95 (Colo. 1994).

¹⁸¹ *Hood v. Phillips*, 554 S.W.2d 160, 165 (Tex. 1977).

¹⁸² 15 AM. JUR. 2D *Proof of Facts* 711, § 9 (2005) [hereinafter *Proof of Facts*].

¹⁸³ *Hood*, 554 S.W.2d at 166 (the technique involved removal of a carotid

nique in 1962, and in the ensuing four years had performed it over a thousand times.¹⁸⁴ He claimed that 85 percent of his patients were helped by the surgery,¹⁸⁵ while plaintiff's experts condemned the procedure.¹⁸⁶ Indeed, one expert for the plaintiff stated that the procedure was developed "without much scientific rationale, tried by a number of physicians worldwide; found ineffectual and abandoned."¹⁸⁷ In arriving at the appropriate standard to be applied in this case, the Supreme Court of Texas stated as follows:

[M]ost courts have not attempted to articulate a distinction among "experimental," "outmoded," "rejected," and "accepted" surgical procedures. Instead, the majority of courts have attempted to draw a line between the reasonable and prudent physician who, as a last resort, turns to an "experimental" or a "rejected" treatment in the hope of assisting the patient and the individual practitioner who attempts to beguile his patient with false or distorted promises. These courts have recognized, as we do, that physicians should be allowed to exercise their professional judgment in selecting a mode or form of treatment. Further, physicians should be allowed to experiment in order that medical science can provide greater benefits for humankind.¹⁸⁸

In general, it appears that courts will allow greater deviation from accepted practice without finding negligence for more severe illnesses.¹⁸⁹ In addition, innovative therapies are less likely to be found negligent where there is no effective standard therapy¹⁹⁰ or the disease is considered terminal with the use of standard therapy, as long as there is a reasonable basis for a rational physician to try it, and as discussed below, the patient is informed of the innovative nature of the surgery.¹⁹¹ One legal commentator suggests that for terminal medical

body from the neck, while the accepted treatment involved drugs and machines to aid breathing).

¹⁸⁴ *Id.* at 162.

¹⁸⁵ *Id.* at 167.

¹⁸⁶ *Id.* at 160.

¹⁸⁷ *Id.* at 163.

¹⁸⁸ *Id.* at 165.

¹⁸⁹ See *Baldor v. Rogers*, 81 So. 2d 658 (Fla. 1954) (cancer); *Proof of Facts*, *supra* note 182, § 7 n.48.

¹⁹⁰ See *Proof of Facts*, *supra* note 182, at § 7.

¹⁹¹ As early as 1954, courts found that there is "no clearcut issue whether [a surgeon] committed malpractice when he used a certain method [for treatment of terminal cancer], for no infallible cure has been discovered." See *Proof of Facts*, *supra* note 182, § 1 (citing *Baldor*, 81 So. 2d at 658).

conditions that do not have effective standard treatments, such as some cancers, it might even be negligent not to attempt innovation in order to save a patient's life.¹⁹² In contrast, at least one court has rejected a plaintiff's novel claim that the standard of care *required* that the defendant surgeon innovate rather than apply the "textbook theory" to the patient's condition. In *Pernia v. Trail*,¹⁹³ the court observed that plaintiff's expert apparently "suggest[ed] that [the surgeon] was using bad judgment in not going through with an experimental horizontal incision . . . , as the patient lay on the operating table."¹⁹⁴ The court rejected this attempt by plaintiff to turn the "clinical innovation" defense on its head finding instead that the doctor "performed the surgery in this case well above the standards required by the law."¹⁹⁵

C. Failure to Provide Adequate Informed Consent¹⁹⁶

Under common law or by state statute, a physician has a duty to obtain a patient's informed consent before providing medical treatment.¹⁹⁷ One generally recognized exception to this duty is where the urgency of the patient's medical condition does not permit the time necessary to obtain the patient's informed consent (or that of his or her designated representative).¹⁹⁸

A plaintiff may raise a claim based on the failure to provide informed consent alone or concurrently with a claim that the defendant

¹⁹² See *Proof of Facts*, *supra* note 182, §7.

¹⁹³ 519 So. 2d 231 (La. Ct. App. 1988).

¹⁹⁴ *Id.* at 233.

¹⁹⁵ *Id.* at 234.

¹⁹⁶ For a comprehensive legal analysis of informed consent, including discussion of informed consent and medical innovation, see generally Lars Noah, *Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy*, 28 AM. J.L. & MED. 361, 377 n.82 (2002) (in addition to facing tort liability, failure to provide adequate informed consent may result in disciplinary sanctions); *Proof of Facts*, *supra* note 182.

¹⁹⁷ See generally *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, 317 P.2d 170 (Cal. Ct. App. 1957); *Schloendorff v. Soc'y of New York Hosp.*, 105 N.E. 92 (N.Y. 1914). For a discussion of the evolution and ethical and legal underpinnings of informed consent, see generally RUTH R. FADEN ET AL., A HISTORY AND THEORY OF INFORMED CONSENT (1986).

¹⁹⁸ See, e.g., LA. REV. STAT. ANN. § 40:1299.54 (2001) (recognizing that consent to emergency procedures is generally implied); *Stafford v. La. State Univ.*, 448 So. 2d 852, 855 (La. Ct. App. 1984) (emergency exception applied in situation where competent medical judgment would conclude that the patient was in a life threatening situation, a person authorized to consent was not readily available, and delay could reasonably have been expected to jeopardize the patient's life and health).

failed to meet the standard of care.¹⁹⁹ An informed consent claim can succeed irrespective of whether the defendant deviated from the standard of care in performing the medical treatment.²⁰⁰

In order to establish negligence for failure to provide informed consent, generally a plaintiff must prove the following elements: (1) that the medical procedure carried a specific risk that was not disclosed, (2) that the physician violated the applicable standard of disclosure, (3) that the undisclosed risk materialized, and (4) that the failure to disclose the information caused the patient's injury.²⁰¹ The physician's negligence thus lies in the inadequate disclosure itself, and the damage claimed is derived from nondisclosure of risks incidental to treatment that would have resulted in the patient's deciding against the treatment.

The physician has a duty to communicate "material" information.²⁰² The courts have devised two different approaches to establish the appropriate standard for such disclosures. The physician-based or professional practice standard, adopted in approximately half of the states, requires expert testimony to establish what a reasonable practitioner would have disclosed in a similar situation, in essence treating the disclosure as a medical question.²⁰³ The patient-oriented standard is becoming increasingly popular, and addresses criticisms that the professional practice standard offered an overly favorable advantage to physician-defendants.²⁰⁴ The "reasonable patient" or objective patient standard allows the trier-of-fact (the judge or the jury, as applicable) to determine whether a physician disclosed risks that a reasonable person would find material, regardless of professional practice standards.²⁰⁵ Only a few courts have applied a subjective patient-

¹⁹⁹ See Hall et al., *supra* note 145, at 206 (claims for failure of informed consent are rarely raised alone because of the limited damages that are generally recoverable).

²⁰⁰ See *id.* at 223; Backlund v. Univ. of Wash., 975 P.2d 950, 950 (Wash. 1999) (jury's finding that physician followed standard of care "did not preclude trier of fact from finding liability under the informed consent statute").

²⁰¹ HALL ET AL., *supra* note 145, at 217.

²⁰² See *Canterbury v. Spence*, 464 F.2d 772, 786 (D.C. Cir. 1972) ("The scope of the physician's communications to the patient . . . must be measured by the patient's need, and that need is the information material to the decision"); Noah, *supra* note 196, at 367 n.26 (citing *Henderson v. Milobsky*, 595 F.2d 654, 658 (D.C. Cir. 1978) ("holding that a surgeon did not need to disclose a 0.001% risk of permanent loss of sensation in a small section of the plaintiff's face").

²⁰³ Noah, *supra* note 196, at 368; FURROW ET AL., *supra* note 81, at 267-68.

²⁰⁴ Noah, *supra* note 196, at 367 (the "'professional standard' came under criticism for excessive paternalism and the effective immunity that it granted to defendants in medical malpractice cases").

²⁰⁵ *Id.* at 368. The seminal case in this area is in fact a surgical case, *Canter-*

oriented standard, focusing on the specific preferences of a particular patient.²⁰⁶ Expert testimony is still required when applying the patient standard in order to characterize risks and alternative treatments, or to establish that the physician should have been aware of the risk.²⁰⁷

In the consent process, at a minimum, the disclosure must include the nature and purpose of the treatment or procedure, expected benefits, foreseeable risks of treatment, reasonable alternatives, and foreseeable risks of forgoing treatment.²⁰⁸ Indeed, these elements of proper disclosure have been litigated in informed consent actions involving surgery.²⁰⁹ It is always necessary to prove that the undisclosed risk actually materialized, and that the patient would not have chosen to proceed with the procedure had he or she been informed of the risks and nature of the procedure.²¹⁰ Regardless of the materiality standard applied, causation is a necessary element in an informed consent claim. Most courts require proof that a reasonable patient would have declined treatment had the physician disclosed the additional information (i.e., applying an objective standard), while a few courts have

bury v. Spence, 464 F.2d 772, 787 (D.C. 1972) (“A risk is thus material when a reasonable person, in what the physician knows or should know to be the patient’s position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy”).

²⁰⁶ Noah, *supra* note 196, at 368 n.31 (citing *Korman v. Mallin*, 858 P.2d 1145 (Alaska 1993); *Hartke v. McKelway*, 707 F.2d 1544 (D.C. Cir. 1983); *Lugebuhl v. Dowling*, 676 So. 2d 602 (La. Ct. App. 1996); *Macy v. Blatchford*, 8 P.3d 204 (Or. 2000)).

²⁰⁷ *Id.* at 368.

²⁰⁸ See generally John H. Derrick, Annotation, *Medical Malpractice: Liability for Failure of Physician to Inform Patient of Alternative Modes of Diagnosis or Treatment*, 38 A.L.R. 4th 900 (1985); W.M. Moldoff, Annotation, *Malpractice: Physician’s Duty to Inform Patient of Nature and Hazards of Disease or Treatment*, 79 A.L.R. 2d 1028 (1961).

²⁰⁹ See, e.g., *Dawes v. Kinnett*, 779 So. 2d 978, 984 (La. Ct. App. 2001) (holding that physician failed to inform patient of material risks of shoulder surgery); *Goleman v. Orgler*, 771 So. 2d 374 (Miss. Ct. App. 2000) (involving a patient who was informed of particular risks associated with surgery while under the influence of sedation, and holding that this failure to obtain valid consent supported a claim of assault but not lack of informed consent); *Gouse v. Cassel*, 615 A.2d 331, 331 (Pa. 1992) (holding that surgeons need not disclose all known information about a potential surgery to obtain informed consent, but are required to advise patient of those material facts, risks, complications, and alternatives to surgery that a reasonable person in the patient’s position would consider significant in deciding whether to have the operation).

²¹⁰ See *Backlund v. Univ. of Wash.*, 975 P.2d 950, 958-59 (Wash. 1999) (“the plaintiff must establish that ‘a reasonably prudent patient under similar circumstances would not have consented to the treatment if informed of such material fact or facts’”). See also FURROW ET AL., *supra* note 81, at 333.

viewed causation from the perspective of the plaintiff-patient (i.e., applying a subjective standard).²¹¹

At least two areas of disclosure are of particular interest in informed consent claims involving surgical innovation: the therapy's innovative nature and the surgeon's experience with the procedure.

1. Disclosure of the Therapy's Innovative Nature

There are relatively few medical malpractice cases involving disclosure of the innovative nature of a medical or surgical therapy.²¹² A review of available cases indicates that the innovative nature of a practice or procedure and the attendant lack of knowledge about risks constitute information that should be revealed to the patient during the informed consent process (enhanced disclosure).²¹³ This holds true in

²¹¹ Noah, *supra* note 196, at 368-69 nn.31-41.

²¹² In fact, as Holder notes, "there are very few malpractice case dealing with research procedures or with "innovative therapy." She further opines on the reasons:

The paucity of case law on this subject may be indicative of one or both of two factors: (1) That a patient in a clinical research center in a major medical center who is a participant in a well-designed, properly administered research study is probably receiving better medical care than he would if he were in the hands of a private physician administering standard therapy; in short, there *may* be very few injuries in the course of true innovative therapy; and (2) The plaintiff's attorneys may be unaware that the injury, in fact, resulted from a research trial or innovative therapy, and that the treatment was not the standard one for the patient's condition. Thus, the malpractice suit may be brought and adjudicated on the basis of ordinary negligence principles without reference to any innovative elements.

Proof of Facts, *supra* note 182, § 4.

²¹³ See *Gaston v. Hunter*, 588 P.2d 326, 351 (Ariz. Ct. App. 1978) ("Thus, we also hold that when a physician contemplates a novel or investigational procedure he must inform his patient of the novel or investigational nature of the procedure. Absent this, he has committed a battery."); *Ahern v. Veterans Admin.*, 537 F.2d 1098 (10th Cir. 1976); *Estrada v. Jaques*, 321 S.E.2d 240 (N.C. Ct. App. 1984) (holding that the consent obtained by surgeons failed to satisfy statutory requirements); *Fiorentino v. Wenger*, 272 N.Y.S.2d 557 (N.Y. App. Div. 1966), *rev'd on other grounds*, 227 N.E.2d 296 (N.Y. 1967). See also *Fortner v. Koch*, 261 N.E. 762 (Mich. 1935).

Clemens v. Regents of the University of California, 87 Cal. Rptr. 108, 114 (Cal. Ct. App. 1970), involved juror conduct that resulted in an order for a new trial. *Clemens v. Regents of the Univ. of Cal.*, 97 Cal. Rptr. 589 (Cal. Ct. App. 1971). Nonetheless, the facts of the case and the court's comments are worthy of mention. In *Clemens*, the trial court issued a jury instruction that stated

a physician seeking consent to a 'new or experimental' procedure should inform the patient that it is new or experimental when seeking consent to it," and the jury found in favor of the physician. The physician testified that he told the plaintiff that the "procedure was a 'new' one and described it in detail [and] specifically informed appellant of the possibility of the precise complication upon which [the patient] base[d] his lawsuit.

Clemens, 87 Cal. Rptr. at 114. It is interesting to note that in this case, the appeals

jurisdictions applying the professional and patient-oriented disclosure standards. A brief review of three of these cases reflects a range of origins for the innovations: refinement of a surgeon's own inventive technique despite the availability of standard therapy, surgery conducted in reliance on one medical journal article, and surgery conducted with very little information on risk.

In *Fiorentino v. Wenger*,²¹⁴ a fourteen-year-old patient died following an orthopedic surgical procedure intended to treat scoliosis (spinal curvature).²¹⁵ The child's mother successfully alleged that the surgeon failed to disclose the experimental nature of the procedure: the surgeon was the inventor of the procedure (the "spinal-jack" operation); the surgeon had performed it thirty-five times before and improved it over time; the surgery had resulted in one case of paralysis, four cases of serious complications, and arguably one death; and the technique was only used in this country by this one surgeon and was not used commonly outside the United States.²¹⁶ Other standard therapies were available. The appeals court upheld the jury verdict finding the surgeon²¹⁷ liable on this basis.²¹⁸

In *Ahern v. Veterans Administration*,²¹⁹ a surgeon used an experimental pre-operative radiation therapy without informing the patient and was found liable for lack of informed consent.²²⁰ The patient was admitted with carcinoma of the rectum, and the surgeon testified that the increased radiation dosage (substantially above the recommended dosage) used was based on a paper that a member of the sur-

court described the procedure as "new" but no longer "experimental," basing its distinction on the fact that it had been in use for three years at the institution where the surgery was conducted. *Id.* at 112. Note that more than one plaintiff has attempted unsuccessfully to treat a claim for failure to inform of the innovative nature of a surgery as a fraudulent concealment claim to avoid the application of the shorter statutory limitation period applicable to medical malpractice claims. *See, e.g., Johnson v. Arthur*, 986 S.W.2d 874, 874-75 (Ark. Ct. App. 1999); *Adams v. Arthur*, 969 S.W.2d 598, 598, 608 (Ark. 1998) (consolidation of twelve similar claims).

²¹⁴ 272 N.Y.S.2d at 557.

²¹⁵ *Id.* at 557-58.

²¹⁶ *Id.*

²¹⁷ The focus of the case on appeal concerned the hospital's liability for the surgeon's failure to inform. The Court of Appeals of New York found that the hospital in this case did not have an independent duty to assure adequate informed consent, nor was it vicariously liable where the surgeon was an independent contractor. *Fiorentino v. Wenger*, 227 N.E.2d 296, 298 (N.Y. 1967).

²¹⁸ *Fiorentino*, 272 N.Y.S.2d at 559 ("We are of the opinion that, . . . the defendant physician was obligated to mark a disclosure to the parents of his . . . [patient] that the procedure he proposed was novel and unorthodox and that there were risks incident to or possible in its use.").

²¹⁹ 537 F.2d 1098 (10th Cir. 1976).

²²⁰ *Id.* at 1098, 1102.

gical team had heard at a medical conference.²²¹ The experimental dosage resulted in severe burns requiring removal of the patient's bladder, testicles, lower sacrum, and coccyx, and the trial court awarded \$150,000 to the patient for lack of informed consent and negligent treatment. Although the defendants tried to argue that they tailored the treatment to this patient's individual presentation,²²² the Tenth Circuit affirmed the holding of the trial court, concluding that "in order for a physician to avoid liability by engaging in drastic or experimental treatment, which exceeds the bounds of established medical standards, his patient must always be fully informed of the experimental nature of the treatment and of the foreseeable consequences of that treatment."²²³

A later case, *Estrada v. Jacques*²²⁴ concluded similarly. In *Estrada*, two radiologists and two surgeons were involved in the performance of a "relatively new" procedure (known as percutaneous steel coil embolization)²²⁵ on a patient who was diagnosed with a false aneurysm²²⁶ arising out of a bullet wound to his knee.²²⁷ Although the

²²¹ *Id.* at 1100 n.2.

²²² The patient's primary treating physician stated: "[W]e felt we had a limited time in which to treat Mr. Ahern. We wanted to give him as much radiation as the board and our consultants felt could be given with reasonable safety, realizing increased risk, with the faster therapy dose, but still, to get it done as quickly as possible, because of his pending obstruction." *Id.* at 1099 (internal citation omitted).

²²³ *Id.* at 1102. In surgery involving FDA regulated products, some courts have found that the lack of FDA-approval constitutes material information that should be disclosed to the patient. See Noah, *supra* note 196, at 371-72. However, several cases involving surgery using "off-label" or experimental use of FDA-approved devices, have found that surgeons and hospitals are not required to disclose that FDA-approved devices are being used for "off-label" purposes, where FDA status is not determined to be a material risk. See, e.g., *Alvarez v. Smith*, 714 So. 2d 652, 653 (Fla. Dist. Ct. App. 1998) (physicians were not required to inform patient that metallic pedicle screws to be implanted in patient's spine had not been approved by the FDA for the procedure in question, and that the FDA classified such screws as "experimental or investigational"); *Southward v. Temple Univ. Hosp.*, 781 A.2d 101 (Pa. 2001) (physician not required to disclose that screws used in spinal surgery were classified by the FDA as experimental); *Bryant v. HCA Health Servs. of N. Tenn., Inc.*, 15 S.W.3d 804 (Tenn. 2000) (hospital was not required to disclose that pedicle screws were experimental devices, where screws were approved for off-label uses prior to surgery, and patient did not demonstrate that off-label use was subject to federal study or mandatory monitoring).

²²⁴ 321 S.E.2d 240 (N.C. Ct. App. 1984).

²²⁵ The procedures "involved insertion of a small steel coil into the weakened artery upstream from the false aneurysm, thereby cutting off the flow of blood and preventing a rupture." *Id.* at 243.

²²⁶ The opinion describes a false aneurysm as "a weakened spot in an arterial wall." *Id.*

²²⁷ *Id.*

surgeons discussed the procedure with the patient prior to its performance, the radiologists performed the actual procedure. It was unsuccessful, resulting in hours of corrective surgery, and ultimately resulted in the amputation of the patient's leg. The injured patient brought, *inter alia*, an informed consent claim against the surgeons on the basis that they had not informed him of the "highly experimental nature" of the procedure.²²⁸ The court found that the patient received incomplete information about the risks of the procedure, noting that few people involved in the patient's care understood the risks associated with this type of intervention.²²⁹ Apparently the description of the surgery's risks was based on one article in a medical journal and the limited experience of one of the radiologists, who had performed this type of procedure only once before.²³⁰ In addition, although evidence existed that the risk of the procedure was low when used in certain parts of the body, no evidence existed to suggest that this risk would apply to the location where the procedure was performed on this particular patient.²³¹ Ultimately the court held that the experimental nature of a treatment must be revealed during the informed consent process,²³² expressing its concurrence with "the majority of courts and commentators which have considered the problem."²³³

The disclosure of the innovative nature of a procedure, thus, is in addition to all of the other disclosures required for all medical procedures.²³⁴ This higher standard of disclosure can be justified when the procedure is "new and untested"²³⁵ because of the additional

²²⁸ *Id.*

²²⁹ *Id.* at 253.

²³⁰ *Id.* The court also noted that there was little indication that the radiologist had communicated this information to the surgeons who were involved in obtaining the patient's informed consent. *Id.*

²³¹ *Id.* ("This omission is critical in light of the evidence that such arteries presented additional difficult problems of size and accessibility.")

²³² *Id.* at 254 ("[W]here the health care provider offers an experimental procedure or treatment to a patient, the health care provider has a duty, in exercising reasonable care under the circumstances, to inform the patient of the experimental nature of the proposed procedure."). One of the justifications provided by the *Estrada* court for disclosure of the experimental nature of the procedure was the potential conflict of interest that may arise when an experimental procedure is performed: "[t]he psychology of the doctor-patient relation, and the rewards, financial and professional, attendant upon recognition of experimental success, increase the potential for abuse and strengthen the rationale for uniform disclosure." *Id.* at 255. The *Estrada* court, however, did not require specific disclosure of potential conflicts of interest. *Id.*

²³³ *Id.* at 254. See also *Karp v. Cooley*, 493 F.2d 408, 419-20 (5th Cir. 1974).

²³⁴ For example, a surgeon offering to use an innovative technique must not only describe the risks and benefits of such technique, but must also explain the alternative, standard therapy, if one exists. *Proof of Facts*, *supra* note 182, § 2.

²³⁵ *Estrada*, 321 S.E.2d at 255.

element of “unknown risks” that should be disclosed in addition to the “known risks” that are normally disclosed.²³⁶ Note, however, a surgeon is generally not required to disclose *unchosen* alternatives that are experimental or innovative, as long as these alternatives are not performed.²³⁷

Courts may distinguish failure to inform patients of the innovative nature of a procedure from the intentional concealment of the innovative nature. If determined to involve intentional concealment by a physician or institution, the statutory period of time in which a patient can bring a claim (statute of limitation) may be extended.²³⁸ An intentional concealment requires something more than inadequate informed consent, and the plaintiff would have to show that the defendant made affirmative misrepresentations about the treatment.²³⁹ An example of a misrepresentation in the context of innovation could be a surgeon’s assertion to the patient that the procedure was “not experimental.”²⁴⁰

²³⁶ *Id.* at 254.

With experimental procedures the ‘most frequent risks and hazards’ will remain unknown until the procedure becomes established. If the health care provider has a duty to inform of *known* risks for *established* procedures, common sense and the purposes of the statute equally require that the health care provider inform the patient of any *uncertainty* regarding the risks associated with *experimental* procedures. This includes the experimental nature of the procedure and the *known or projected most likely risks*.

Id.

²³⁷ See, e.g., *Moore v. Baker*, 989 F.2d 1129, 1133 (11th Cir. 1993) (finding that physician is not liable for failure to inform patient of ethylene diamine tetra acetic acid chelation therapy (EDTA) as alternative to carotid endarterectomy surgery, where evidence overwhelmingly suggested that mainstream medical community did not recognize or accept EDTA as a practical alternative).

²³⁸ See, e.g., WASH. REV. CODE ANN. § 4.16.350(3) (West 2006). The Washington statute states:

[T]he time for commencement of an action is tolled upon proof of fraud, intentional concealment, or the presence of a foreign body not intended to have a therapeutic or diagnostic purpose or effect, until the date the patient or the patient’s representative has actual knowledge of the act of fraud or concealment, or of the presence of the foreign body; the patient or the patient’s representative has one year from the date of the actual knowledge in which to commence a civil action for damages.

Id.

²³⁹ See, e.g., *Trantafello v. Med. Ctr. of Tarzana*, 227 Cal. Rptr. 84, 87 (Cal. Ct. App. 1986) (holding that intentional concealment requires more than inadequate informed consent in the instant case, where surgeon failed to tell a patient of use of an innovative and experimental procedure involving an acrylic implant); *Adams v. Arthur*, 969 S.W.2d 598, 598, 608 (Ark. 1998) (consolidation of twelve cases where surgeon inserted innovative implant in orthopedic procedure without the knowledge or consent of patients as to the innovation).

²⁴⁰ *Adams*, 969 S.W.2d at 612 (“The alleged representation that the material was ‘not experimental’ goes beyond a mere opinion as to [the innovation’s] efficacy,

Although informing patients of the innovative nature of surgery may provide a defendant with some protection from malpractice claims, the surgeon can still be found negligent for medical malpractice in the decision to perform the surgery or in the actual performance of the surgery.²⁴¹

2. Disclosure of Surgeon's Experience with Procedure.

The number of times the surgeon has performed the procedure may be a potential indicator of innovation.²⁴² Most jurisdictions have declined to take an expansive view of the duty to inform that would include disclosure of a surgeon's experience. For example, in *Whiteside v. Lukson*,²⁴³ a surgeon attended a two-day training course in which he learned a new surgical procedure to remove the gall bladder (laparoscopic cholecystectomy),²⁴⁴ practicing the procedure on three pigs.²⁴⁵ The plaintiff-patient was subsequently injured by the surgeon's first performance of the procedure, sustaining injuries to her bile duct.²⁴⁶ The Washington appeals court applied the "reasonable patient" standard and declined to find that the surgeon's professional experience should have been revealed to the patient as part of the informed consent process.²⁴⁷ In a different case, a surgeon inaccurately stated his experience in response to a patient query. The Pennsylvania Supreme Court still found that "evidence of a physician's personal characteristics and experience is irrelevant to an informed consent claim,"²⁴⁸ but would allow an injured patient to pursue other remedies at law, including damages for misrepresentation.²⁴⁹

e.g., they had 'good results,' and is arguably a false representation concerning the surgery."²⁴¹

²⁴¹ See generally *Burnet v. Spokane Ambulance*, 772 P.2d 1027, 1030 (Wash. Ct. App. 1989) (agreeing that "informed consent is an alternative method to impose liability" and one may be present without the existence of the other); *Bays v. St. Luke's Hosp.*, 825 P.2d 319, 320 (Wash. Ct. App. 1992) (holding that where physician has not diagnosed condition there is no duty to disclose risks associated with it, but they may still be liable for medical negligence based upon a failure to diagnose).

²⁴² It may also be evidence of an individual surgeon's lack of experience in performing an established procedure or indicate a lack of training which may support conduct falling below the standard of care.

²⁴³ 947 P.2d 1263 (Wash. Ct. App. 1997).

²⁴⁴ The surgery was conducted in 1990, during early adoption of the innovative procedure. See discussion of laparoscopic cholecystectomy, *infra* Part V.

²⁴⁵ *Whiteside*, 947 P.2d at 1264.

²⁴⁶ *Id.*

²⁴⁷ *Id.* at 1265 ("[W]e conclude 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.").

²⁴⁸ *Duttry v. Patterson*, 771 A.2d 1255, 1259 (Pa. 2001) (In a case involving

One jurisdiction, however, has interpreted the materiality requirement for informed consent to require disclosure of the surgeon's experience with a procedure. In *Johnson by Adler v. Kokemoor*,²⁵⁰ the plaintiff was rendered a partial quadriplegic following surgery to clip an aneurysm in her brain. The Supreme Court of Wisconsin applied the "reasonable patient" standard and held that a neurosurgeon should have disclosed that his success rate with the surgery was substantially different from other surgeons pursuant to a statutory requirement that required disclosure of "'all of the viable alternatives and risks of the treatment proposed' which would be material to a patient's decision."²⁵¹ A close reading of the case arguably suggests that this is a case specific to the facts and interpretation of the relevant Wisconsin statute.²⁵² Here the defendant surgeon elected to explain the morbidity and mortality risks from surgery to the plaintiff in statistical terms, and dramatically understated them (at 2 percent versus nearly 30 percent estimated by experts if the surgery were performed by this inexperienced surgeon, and close to 11 percent even if performed by the most skilled neurosurgeon); further, he substantially "overstated" his experience in performing the surgery in response to the patient's specific inquiries.²⁵³ The surgeon's misleading introduction of statistics allowed the statistics to enter into consideration in the final verdict.

surgical treatment for esophageal cancer, the court applied a reasonable patient standard, and reasoned that an injured patient has other avenues to pursue claims against the surgeon, including breach of the standard of care and misrepresentation).

²⁴⁹ *Id.*

²⁵⁰ 545 N.W. 2d 495 (Wis. 1996).

²⁵¹ *Id.* at 507.

²⁵² *See id.*

[W]hen different physicians have substantially different success rates with the same procedure and a reasonable person in the patients position would consider such information material, the . . . court may admit this statistical evidence. . . . [O]ur decision will not always require physicians to give patients comparative risk evidence in statistical terms to obtain informed consent. Rather we hold that evidence of the morbidity and mortality outcomes of different physicians was admissible under the circumstances of this case.

Id. (citations omitted).

²⁵³ "[W]hen the plaintiff questioned the defendant regarding his experience, he replied that he had performed the surgery . . . 'several' times; asked what he meant by 'several,' the defendant said 'dozens' and 'lots of times.' In fact, however, the defendant had relatively limited experience with aneurysm surgery." *Id.* at 499. The court stated further:

The plaintiff also presented evidence that the defendant understated the morbidity and mortality rate associated with basilar bifurcation aneurysm surgery. According to the plaintiff's witnesses, the defendant had told the plaintiff that her surgery carried a two percent risk of death or serious impairment and that it was less risky than the angiogram procedure she

D. Institutional Liability

Many of the cases involving surgical innovation reviewed *supra* involved allegations of malpractice against surgeons, but some also included allegations of institutional liability as well. Under medical malpractice law, generally an institution may be held vicariously liable for the acts of an employee-surgeon, including residents and interns, under the doctrine of *respondeat superior*.²⁵⁴ A grant of staff privileges is not in itself sufficient to hold an institution vicariously liable.²⁵⁵ Although traditionally an institution will not be held liable for the acts of independent contractors, courts have found health care institutions vicariously liable for such acts under various exceptions, including ostensible agency or agency by estoppel, inherent function, and non delegable duties.²⁵⁶ In addition, courts have found health care institutions independently liable under general negligence²⁵⁷ and cor-

would have to undergo in preparation for surgery. The plaintiff's witnesses also testified that the defendant had compared the risks associated with the plaintiff's surgery to those associated with routine procedures such as tonsillectomies, appendectomies and gall bladder surgeries.

Id. The court commented on the plaintiff's expert testimony and evidence:

The plaintiff's neurosurgical experts testified that even the physician considered to be one of the world's best aneurysm surgeons, who had performed hundreds of posterior circulation aneurysm surgeries, had reported a morbidity and mortality rate of ten-and-seven-tenths percent when operating upon basilar bifurcation aneurysms comparable in size to the plaintiff's aneurysm. Furthermore, information in treatises and articles which the defendant reviewed in preparation for the plaintiff's surgery set the morbidity and mortality rate at approximately fifteen percent for a basilar bifurcation aneurysm. The plaintiff also introduced expert testimony that the morbidity and mortality rate for basilar bifurcation aneurysm operations performed by one with the defendant's relatively limited experience would be between twenty and thirty percent, and 'closer to the thirty percent range.'

Id. Cf. Duttry, 771 A.2d at 1259.

²⁵⁴ See FURROW ET AL., *supra* note 81, at 376 (citing Shands Teaching Hosp. & Clinics, Inc. v. Pendley, 577 So. 2d 632 (Fla. App. 1991)). The acts must be within the "scope of employment." *Lisa M. v. Henry Mayo Newhall Mem'l Hosp.*, 907 P.2d 358 (Cal. 1995).

²⁵⁵ See FURROW ET AL., *supra* note 81, at 376 (citing Albain v. Flower Hosp., 553 N.E.2d 1038 (Ohio 1990)).

²⁵⁶ See *id.* at 376-81. For a detailed examination of liability of specific types of health care institutions for the acts of a health care provider, see generally John D. Hodson, Annotation, *Liability of Hospital or Sanitarium for Negligence of Physician or Surgeon*, 51 A.L.R. 4th 235 (1985) (providing a detailed examination of liability of specific types of health care institutions for the acts of a health care provider), and William E. Milks, Annotation, *Liability of Health Maintenance Organizations (HMOs) for Negligence of Member Physicians*, 51 A.L.R. 5th 271 (1997) (providing a detailed examination of liability of HMOs).

²⁵⁷ See FURROW ET AL., *supra* note 81, at 381. Hospitals have a duty to pa-

porate negligence theories.²⁵⁸ Hospital duties have been held to include monitoring informed consent, supervising medical staff, and properly selecting and retaining medical staff.²⁵⁹ Examples of cases involving institutional liability for surgical innovation have included a claim involving respondeat superior,²⁶⁰ a claim for negligent credentialing of an independent contractor surgeon,²⁶¹ an unsuccessful claim of vicarious and independent duties to inform of the surgery's experimental nature,²⁶² and an unsuccessful claim of negligent supervision of an independent contractor surgeon.²⁶³ Nonetheless, subject to applications of state law, one can assume that vicarious liability and corporate negligence theories may potentially be applied to surgical innovation cases in the same manner that they are applied in other malpractice cases.

tients to maintain facilities, provide and maintain medical equipment, hire, supervise and retain nurses and other employees, and maintain proper procedures to protect patients.

²⁵⁸ See *id.* at 391.

²⁵⁹ *Id.* at 389-91 (citing *Doctors Mem. Hosp. v. Evans*, 543 So. 2d 809 (Fla. App. 1989) (duty on hospital to ensure patient consent is properly obtained); *Darling v. Charleston Comm. Mem'l Hosp.*, 211 N.E.2d 253 (Ill. 1965) (duty to supervise medical staff); *Welsh v. Bulger*, 698 A.2d 582 (Pa. 1997) (duty to take reasonable steps to insure the competence of members of its medical staff)). *But see, e.g.*, *Kelly v. Methodist Hosp.*, 664 A.2d 148 (Pa. Super Ct. 1995) (declining to impose duty of obtaining informed consent on hospitals).

²⁶⁰ *Ahern v. Veterans Admin.*, 537 F.2d 1098 (10th Cir. 1976) (government employer liable for acts of employee physicians).

²⁶¹ In *Browning v. Burt*, 613 N.E.2d 993, 994 (Ohio 1993), the court permitted a claim to proceed against a hospital for negligent credentialing of an independent contractor surgeon. The case involved an extreme case of surgical malpractice for vaginal reconstruction surgeries which the court labeled as "atrocities." *Id.* at 1009. The plaintiff was prompted to sue when she saw a television news program documenting the injuries and experiences of other women who had undergone the same surgeries. At the same time, the court cautioned that "nothing in [the] opinion should be read to stand in the way of the proper performance of progressive medicine." *Id.* The dissent argued that the statute of limitations had expired because the cause of action had accrued against the hospital when it advised the patient by form letter delivered before surgery that the procedure was not "generally accepted" and was not yet "duplicated by other investigators." *Id.* at 1012 (Moyer, C.J., concurring in part and dissenting in part).

²⁶² *Fiorentino v. Wenger*, 227 N.E.2d 296 (N.Y. 1967) (where surgeon was an independent contractor, hospital did not have an independent duty to assure adequate informed consent, nor was it vicariously liable for surgeon's failure to inform).

²⁶³ *Gaston v. Hunter*, 588 P.2d 326, 331-32 (Ariz. Ct. App. 1978) (directed verdict upheld in favor of defendant hospital where plaintiff's negligence claims included negligent supervision of the "conduct of the investigational procedure of chemonucleolysis").

E. Lessons for Surgical Innovation from Review of the Medical Practice Pathway

What lessons can innovative surgery take from this review of the Practice Pathway? First, the route down this pathway is only taken in the event of a bad surgical outcome. Innovations that are successful or are unknown to patients do not provoke legal scrutiny under this approach. Second, there may be judicial deference to physician judgment to innovate in order to tailor a therapy to an individual clinical presentation, even though an innovation is arguably by its very nature a deviation from the generally accepted standard of care. The success of the defense of clinical or therapeutic innovation is of course not guaranteed, and depends on the facts and circumstances of the case.

However, at some point after the first performance of the innovation, it may have a greater likelihood of being characterized as an unacceptable deviation from the standard of care (or “breach” of the standard of care). Some of the variables that appear to affect the acceptability of the deviation from standard practice are the severity of illness or underlying condition in combination with the availability of a standard therapy,²⁶⁴ and the surgeon’s success and failure rate.²⁶⁵ It is also relevant to note that in practice the reputation of the surgeon will influence expert testimony.

When more than one surgical approach may be appropriate to address a patient’s medical condition, a surgeon may be able to use the “respectable minority” defense in some jurisdictions. In this situation, the surgeon will not be held liable for selecting one acceptable procedure over another. The acceptability of the procedure is not proven by surveying those who use the procedure, but rather obtained through expert testimony supporting the plaintiff and the defendant regarding standard practices under like circumstances. One can imagine that

²⁶⁴ *Baldor v. Rogers*, 81 So. 2d 658 (Fla. 1954). *Baldor* involved a patient with a cancerous growth on his lip who was treated with certain injections rather than radiation or surgery, where there was considerable conflict among the experts as to whether the treatment was acceptable. The court took note that in this case there was “no certain cure and . . . the physician did not indulge in quackery by representing he had one.” *Id.* at 659-60. Holder contrasts two orthopedic fracture cases, *Davis v. Wilmerding*, 24 S.E.2d 337, n.50 (N.C. 1943) (where innovation held to be negligence where it was a departure from a treatment known to be effective) and *Miller v. Toles*, 150 N.W. 118 (Mich. 1914) (where innovation held to be non-negligent where standard treatment was attempted and ineffective). *Proof of Facts*, *supra* note 182, § 9.

²⁶⁵ *Adler ex rel. Johnson v. Kokemoor*, 545 N.W.2d 495, 507 (Wis. 1996) (“When different physicians have substantially different success rates, whether surgery is performed by one rather than another represents a choice between ‘alternate, viable medical modes of treatment.’”).

where the surgical specialty area consists of only a handful of specialists this number could be quite small. Also, the availability of this defense would seem to imply that rapid diffusion of the innovation through the profession, regardless of the adequacy of its testing for clinical effectiveness and safety, could work to the legal advantage of surgeons who adopt the innovation: a rapidly adopted innovation could become standard practice as attested by defense experts, thus acting as a potential shield against liability. However, variation in jurisdictional adoption also indicates that reliance on such a defense generally deserves caution and close scrutiny.

The examination of informed consent underscores that surgeons working in innovative areas, especially in nonemergency situations, should be informing patients of the innovative nature of the surgery, the foreseeable risks, and an acknowledgment that some risks are unknown. This is particularly important in light of Reitsma and Moreno's findings from their survey of surgeons. They state:

Most respondents to the full questionnaire (75 [percent]) claimed that their patients had been aware of the fact that they underwent an innovative procedure, but in only one-third of the cases (7 of 21) had this been specifically mentioned in the informed consent form. This result raises some concerns about the adequacy of consent forms used in these procedures.²⁶⁶

The informed consent examination also underscores the differences in jurisdictional consideration of these issues, and the need for surgeons and institutions to be aware of jurisdictional requirements affecting informed consent practices, such as when the surgeon's learning curve is considered material information. It is also important to recognize that enhanced disclosure during informed consent will not necessarily be exculpatory, as informed consent claims and due care claims are separate bases of liability.

IV. THE RESEARCH PATHWAY

An innovative surgical approach that is characterized as research instead of medical practice may encounter the legal system at two points: (1) prior to its performance pursuant to federal human subjects protection regulations (if the surgeon's affiliated institution or the research project itself is subject to the pertinent regulations), and (2) after its performance in the event that a human subject alleges injury

²⁶⁶ Reitsma & Moreno, *supra* note 28, at 795.

resulting from participation in an approved research project. In contrast to the Practice Pathway, participation in prospective review requires an affirmative act by the researcher or the researcher's institution to subject it to such review. The two entry points are discussed sequentially below following a discussion of the evolution of research regulations and its implications for surgical innovation.

A. The Evolution of Federal Regulation of Human Subjects Research in the United States

Regardless of the pathway chosen, all medical interventions will ultimately be tested, whether formally or informally, on humans.²⁶⁷ The impetus for regulatory controls on research has its roots in the Nuremberg war crimes trials and the responses to Nazi experimentation on prisoners of war during World War II. The Nuremberg Code, issued in 1949, set forth ten ethical directives for the conduct of experimentation on humans.²⁶⁸ Primary among them is the Code's requirement of voluntary consent and informed decision-making.²⁶⁹ The Code further addresses appropriate risks and benefits, dictating, *inter alia*, that the experiment yield "fruitful results for the good of society,"²⁷⁰ that the risk to the individual not exceed the importance of the problem intended to be solved by the experiment,²⁷¹ and that the ex-

²⁶⁷ "[N]o matter what steps may come first, medical investigations must ultimately be put to the test with human subjects." Frader & Caniano, *supra* note 11, at 217.

²⁶⁸ 2 TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10, at 181-82 (1949), available at <http://history.nih.gov/laws/pdf/nuremberg.pdf> (outlining an international code of ethics concerning human subject research).

²⁶⁹ The first directive of the Nuremberg Code states:

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

Id. ¶ 1.

²⁷⁰ *Id.* ¶ 2.

²⁷¹ *Id.* ¶ 6.

periment avoid “unnecessary . . . suffering and injury.”²⁷² In 1964, the World Medical Association promulgated similar principles that were more specific to the conduct of medical research by physicians, known as the Declaration of Helsinki.²⁷³

In the United States, the policy response to the Nuremberg Code was not immediate,²⁷⁴ and decisions about research continued to be vested in individual researchers without government intervention or oversight.²⁷⁵ Two years after the National Institutes of Health (NIH) opened its campus research hospital, the Clinical Center, the NIH issued federal guidelines for research on humans.²⁷⁶ Those 1953 guidelines contained the first official requirement of committee review of research studies, but only applied to research conducted at the Clinical Center.²⁷⁷

Later revelations of research abuses would prompt policy attention at the highest levels, and indicate a need for explicit enforcement provisions rather than general pronouncements.²⁷⁸ Indeed, the “development of human subject protection policy in the United States was driven by a history of exploitation of subjects, most notably by re-

²⁷² *Id.* ¶ 4.

²⁷³ The Declaration of Helsinki was first adopted in 1964, and subsequently revised four more times, most recently in 2000, with the addition of notes of clarification in 2002 and 2004. World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (1964), available at <http://www.wma.net/E/POLICY/PDF/17c.pdf> (providing the amended 2000 Declaration, and the subsequent clarifications added in 2002 and 2004).

²⁷⁴ For a detailed discussion of the reaction of the U.S. medical community to the Nuremberg Code and its impact on medical practice, see ACHRE, *supra* note 40, at 74-96.

²⁷⁵ “[A]ccording to one historian, ‘. . . the events [including Beecher’s publication] accomplished what the Nuremberg trials had not: to bring the ethics of medical experimentation into the public domain and to make apparent the consequences of leaving decisions about clinical research exclusively to the individual investigator.’” Frader & Caniano, *supra* note 11, at 217 (citing David J. Rothman, *Human Experimentation and the Origins of Bioethics in the United States*, in SOC. SCI. PERSP. ON MED. ETHICS (George Weisz ed., 1990)).

²⁷⁶ NAT’L INST. OF HEALTH, U.S. DEP’T OF HEALTH & HUMAN SERVS., GUIDELINES FOR THE CONDUCT OF RESEARCH INVOLVING HUMAN SUBJECTS 15 (5th ed. 2004), available at <http://ohsr.od.nih.gov/guidelines/GrayBooklet82404.pdf> (summarizing the foundations for NIH’s policies and procedures, including relevant historical background).

²⁷⁷ *Id.*

²⁷⁸ For a detailed policy history of the protection of human subjects from the 1940s through the present, see ACHRE, *supra* note 40. For an analysis of the evolution of federal policies from the 1960s through early 2000s, see Anna Mastroianni & Jeffrey Kahn, *Swinging on the Pendulum: Shifting Views of Justice in Human Subjects Research*, HASTINGS CENTER REP., May – June 2001, at 21 [hereinafter Mastroianni & Kahn, *Swinging on the Pendulum*].

search on 'vulnerable' subject populations that came to light between the mid-1960s and the early 1970s."²⁷⁹ In 1966, Henry Beecher published an influential article in a preeminent medical journal documenting ethical lapses in clinical research (some of which involved surgery),²⁸⁰ including failures of consent.²⁸¹ And it was later in 1966 that the Public Health Service issued a policy requiring institutional review of all funded research.²⁸² Other examples of unethical research at that time included hepatitis vaccine research conducted on institutionalized children at the Willowbrook State School²⁸³ and the injection of cancer cells into elderly nursing home residents at the Jewish Chronic Disease Hospital.²⁸⁴ Most infamous was the so-called Tuskegee Syphilis Study, a forty-year study begun in 1932 that tracked the effects of untreated syphilis in a large group of impoverished African-American men in rural Alabama.²⁸⁵ Not only were the men unaware of their participation in a study, but extensive measures were taken to ensure that these men did not receive treatment for the disease.²⁸⁶ A scathing indictment of the study by an independent review panel appointed by the Department of Health, Education and Welfare (DHEW),²⁸⁷ set against the backdrop of the aforementioned studies, ultimately resulted in Congressional passage of the National Research Act of 1974.²⁸⁸ This Act created the National Commission²⁸⁹ and laid

²⁷⁹ *Id.* at 21-22.

²⁸⁰ Frader & Caniano, *supra* note 11, at 217.

²⁸¹ Henry K. Beecher, *Ethics and Clinical Research*, 274 NEW ENG. J. MED. 1354, 1355 (1966) (critiquing prior medical studies that placed patients at risk of harm, often without the patients' consent for the experimentation).

²⁸² ACHRE, *supra* note 40, at 100.

²⁸³ *Id.* at 101-03.

²⁸⁴ 3 ENCYCLOPEDIA OF BIOETHICS 1271, 1274 (3d ed. 2004) (explaining the origins of the legal term "informed consent"); *Hyman v. Jewish Chronic Disease Hosp.*, 206 N.E.2d 338, 339 (N.Y. 1965) (holding as a matter of law, the director of the hospital corporation could inspect hospital records to investigate possible, or alleged, illegal or improper treatment of patients, specifically experimentation).

²⁸⁵ JAMES H. JONES, *BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT* 1-15 (2d ed. 1993) (providing an overview of the Tuskegee Study, and its lasting negative impact).

²⁸⁶ *Id.* at 5-10. See also Vanessa Northington Gamble, *Under the Shadow of Tuskegee: African Americans and Health Care* 87 AM. J. PUB. HEALTH 1773 (1997) (analyzing how the Tuskegee experiments, as well as prior medical history, created negative attitudes among African Americans towards the integrity of health care).

²⁸⁷ DHEW is the predecessor agency to the current U.S. Department of Health and Human Services and the Department of Education. DHEW was the parent organization of the public health service, the sponsor of the Tuskegee Syphilis Study.

²⁸⁸ National Research Act, Pub. L. No. 93-348, 88 Stat. 342 (1974); 4 ENCYCLOPEDIA OF BIOETHICS 2357 (3d ed. 2004) (documenting the initial regulations created by Congress concerning research on human subjects).

the foundation for formal regulatory oversight of federally sponsored research involving human subjects.²⁹⁰ The National Commission published a series of highly influential reports, including the aforementioned *Belmont Report*, whose findings and recommendations were incorporated into or influenced the drafting of many of the federal human subjects regulations that are in place today.

Although Congress in 1974 had an opportunity to institute a formal oversight mechanism for the protection of human subjects involved in *all* government-supported research, it was forced to compromise with a requirement of federal oversight of research sponsored by DHEW, the largest government supporter of research at that time.²⁹¹ The DHEW regulations promulgated in 1974 included requirements for ethics review of research protocols at the institutional level and detailed procedural and substantive requirements for informed consent.²⁹² DHEW later included additional protections for fetuses, pregnant women, children and prisoners, that included, *inter alia*, enhanced disclosure requirements and limitations on the risks imposed on the subjects in light of the potential benefits of the research.²⁹³ In 1981, a high-level advisory body, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, recommended consolidation of all federal protections for human subjects.²⁹⁴ Once initiated, the process of hammering out agreement among all the federal agencies involved in human subjects research took nine years (1982–1991).²⁹⁵ In 1991, sixteen federal departments and agencies that support, conduct, or otherwise regulate human subjects research agreed to adopt one common set of regulations, the *Federal Policy for the Protection of Human Subjects*,²⁹⁶ which collectively are generally

²⁸⁹ See *infra discussion* on The Belmont Report in Part I.A; ENCYCLOPEDIA OF BIOETHICS, *supra* note 288.

²⁹⁰ ACHRE, *supra* note 40, at 104.

²⁹¹ *Id.* at 98, 103-04.

²⁹² See *id.* at 425-26 (providing a history of the Common Rule, which was the adopted regulation of procedures protecting the rights and interests of human subjects).

²⁹³ *Id.* at 425-26.

²⁹⁴ PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MED. & BIOMEDICAL & BEHAVIORAL RESEARCH, IMPLEMENTING HUMAN RESEARCH REGULATIONS 7-8, 132 (1983) (evaluating and summarizing the annual investigation into human research regulations); Frader & Caniano, *supra* note 11, at 218.

²⁹⁵ ACHRE, *supra* note 40, at 425.

²⁹⁶ Federal Policy for the Protection of Human Subjects, 56 Fed. Reg. 28,002 (June 18, 1991) (discussing acceptance of the Federal Policy for the Protection of Human Subjects, specifically notes and rules). See generally OFFICE FOR HUMAN RESEARCH PROTS., IRB GUIDEBOOK (1993), available at <http://www.hhs.gov/>

referred to as the “Common Rule.”²⁹⁷ The Food and Drug Administration (FDA), a subsidiary agency of the Department of Health and Human Services, did not adopt the Common Rule in its entirety because of the need for specific provisions related to the oversight of food, drugs, and medical devices, but made conforming changes to its informed consent and institutional review regulations.²⁹⁸ Regulatory drafters were keenly aware of the need to allay public suspicion of research resulting from the previously mentioned publicized examples, cases that highlighted failures of informed consent, reliance on vulnerable subject populations, exploitive subject recruitment, and exposing subjects to risks where there was little potential for direct medical benefit.²⁹⁹ Although innovation was discussed by the National Commission in the development of *The Belmont Report*, it was not explicitly referenced in the Common Rule. Thus, the determination as to whether innovative surgery is subject to the regulations rests on the regulatory definition of “research.”

For purposes of examining the current practice of innovative surgery, one important legacy of this history was the creation of a system of local social control over medical research . . . [leading] us to place a large share of the responsibility for the ethical conduct of clinical investigation on the shoulders of researchers’ close peers who sit on institutional review boards (IRBs) in hospitals, medical schools, universities, and independent research centers.³⁰⁰

The relevant regulatory provisions allow for interpretation in implementation, and such interpretations are frequently left to local judgment, which may vary among IRBs.³⁰¹ For example, the baseline deci-

ohrp/irb/irb_guidebook.htm [hereinafter IRB Guidebook]. Each department and agency adopting the Common Rule incorporates the regulation within its section of the Code of Federal Regulations. For example, the Department of Health and Human Services (DHHS) locates the Common Rule at 45 C.F.R. § 46, subpart A, and the Department of Energy locates the regulation at 10 C.F.R. § 745. DHHS has additional protections for subpopulations located in other subparts of 45 C.F.R. § 46: pregnant women, fetuses, and neonates (subpart B); prisoners (subpart C); and, children (subpart D).

²⁹⁷ ACHRE, *supra* note 40, at 425-33.

²⁹⁸ See Federal Policy for the Protection of Human Subjects, 56 Fed. Reg. 28,002; Protection of Human Subjects; Informed Consent, 60 Fed. Reg. 66,530 (Dec. 22, 1995); Standards for Institutional Review Boards for Clinical Investigations, 56 Fed. Reg. 28,025 (June 18, 1991) (to be codified at 21 C.F.R. pts. 50 & 56). See generally IRB Guidebook, *supra* note 296.

²⁹⁹ Mastroianni & Kahn, *Swinging on the Pendulum*, *supra* note 278, at 22-23.

³⁰⁰ Frader & Caniano, *supra* note 11, at 218-19.

³⁰¹ See, e.g., Barbara A. Noah, *Bioethical Malpractice: Risk and Responsibil-*

sion about whether an innovative practice meets the regulatory definition of research will be decided by the local IRB, and judgments about the very same practice may vary among IRBs.

This historical review also highlights that the reach of the current system of federal regulatory oversight of human subjects protection is limited—as discussed in more detail below, it has never applied to research conducted in private settings that lacks a federal nexus (contractual or otherwise), i.e., some private surgical clinics and other institutions where surgical innovation is performed are not subject to any federal oversight. Further, this review points out that as early as the Declaration of Helsinki, and in policies promoted at the National Institutes of Health Clinical Center and in federal regulations created in response to scandals, there was a recognition of the vulnerability of patients—a vulnerability that required, *inter alia*, the protections of external oversight and specific informed consent. This recognition and the articulation of the vulnerability of the ill³⁰² continues to be refined, both in understanding patients' desperation in light of the hope offered by surgical innovation and the identification of potential conflicts of commitment that arise when treating physicians also serve in the role of researcher (or innovator) offering solutions with unknown risks.³⁰³

B. Prospective Regulatory Review Today

As indicated in the previous part, the U.S. system of federal regulatory oversight and prospective ethics review and approval was established in response to well-documented abuses and misuses of human subjects in the past. The system was designed to prevent harm and injury to research subjects to the extent possible and ensure that the research is otherwise conducted in an ethical manner. The Office of Human Research Protections (OHRP) is the federal agency within the U.S. Department of Health and Human Services charged with interpreting, enforcing, and overseeing implementation of the Common Rule.³⁰⁴ The Common Rule applies to federally funded research and to

ity in Human Research, 7 J. HEALTH CARE L. & POL'Y 175, 185 (2004) (“[T]he regulations leave some of the most difficult scientific issues unresolved, and they leave important ethical questions to the discretion of IRBs, which may vary substantially in their interpretation and application of the regulatory requirements.”).

³⁰² Baruch A. Brody, *Research on the Vulnerable Sick*, in BEYOND CONSENT: SEEKING JUSTICE IN RESEARCH 32 (Jeffrey P. Kahn et al. eds., 1998).

³⁰³ See, e.g., *id.*; Mastroianni & Kahn, *Swinging on the Pendulum*, *supra* note 278, at 22; Jeffrey Kahn & Anna Mastroianni, *Moving from Compliance to Conscience: Why We Can and Should Improve on the Ethics of Clinical Research*, 161 ARCHIVES INTERNAL MED. 925 (2001); Nancy E. Kass et al., *supra* note 40.

³⁰⁴ See U.S. Dep't of Health & Human Servs., Office for Human Research

research conducted at institutions that have contractually agreed through a Federal Wide Assurance (FWA) to apply the Common Rule to all human subjects research regardless of the funding source.³⁰⁵ The FDA has promulgated similar human subjects protection regulations related to research involving experimental drugs, biological products, and medical devices that will be marketed in the United States regardless of funding source.³⁰⁶

The Common Rule does not apply to all research conducted in the United States: research that is conducted without the use of federal monies at a nongovernmental institution that does not hold a FWA will not be subject to the Common Rule.³⁰⁷ This gap in coverage may be particularly significant in the context of innovative surgery to the extent that such innovations take place in hospitals and surgical clinics that are unaffiliated with FWA institutions or the federal government (e.g., Veteran's Administration hospitals are examples of federal governmental institutions). Regardless, such privately conducted research may fall within the purview of state laws on human subjects protections.³⁰⁸

In addition to the federal nexus described above, in order for an innovative surgical technique to be covered by the federal human subjects protection regulations, it must meet the definition of research found in the regulations. Under the Common Rule, research "means a systematic investigation, including research development, testing and

Prots. (OHRP), <http://www.hhs.gov/ohrp/> [hereinafter OHRP website]. Prior to June, 2000, the oversight body was known as the Office of Protection from Research Risks (OPRR) and was situated within the National Institutes of Health, a constituent group of institutes within the DHHS. See Statement of Organization, Functions, and Delegations of Authority, 65 Fed. Reg. 37,136 (June 13, 2000).

³⁰⁵ See OHRP website, *supra* note 304.

³⁰⁶ FDA Protection of Human Subjects, 21 C.F.R. §§ 50.3(c), 56.102(c) (2005).

³⁰⁷ Note, however, federal legislative initiatives to make the rule apply to all research regardless of funding source or FWA. Human Research Subject Protections Act of 1997, S. 193, 105th Cong. (1997); Protection for Participants in Research Act of 2006, H.R. 5578, 109th Cong. (2006).

³⁰⁸ See, e.g., Protection of Human Subjects in Medical Experimentation Act, CAL. HEALTH & SAFETY CODE §§ 24170 – 24179.5 (West 1978) (attempting to codify the recommendations of the Nuremberg Code and the Declaration of Helsinki); and Protection of Human Subjects. N.Y. PUB. HEALTH LAW §§ 2440-2446. (McKinney 2002) (codifying protections specifically for human subjects used in medical and scientific research). See also, e.g., Kevin L.J. Oberdorfer, Note, *The Lessons of Greenberg: Informed Consent and the Protection of Tissue Sources' Research Interests*, 93 GEO. L.J. 365, 367-68 (2004) ("In addition [to the Common Rule], states have statutory and regulatory regimes based on and augmenting the federal regulations."); Alain Meisel & Lisa D. Kabnick, *Informed Consent to Medical Treatment: An Analysis of Recent Legislation*, 41 U. PITT. L. REV. 407 (1980).

evaluation, designed to develop or contribute to generalizable knowledge.”³⁰⁹ As noted in the introduction to this article, innovative surgery does not fit comfortably within this definition by its very nature of progressive changes over time and its emphasis on the best interests of the patient rather than future beneficiaries of the knowledge gained from innovative applications.³¹⁰ But for the definition of research, there is regulatory silence on the treatment of innovation. Indeed, Reitsma and Moreno have suggested that surgeons’ narrow interpretation of “research” as requiring a formal protocol has allowed surgeons to evade the additional scrutiny of outside review associated with human subjects protections.³¹¹

Research subject to the regulations must be independently reviewed and approved by an institutional review board (IRB) prior to the enrollment of human subjects. The criteria for IRB approval include, *inter alia*, a determination that risks to human subjects are minimized and are “reasonable in relation to anticipated benefits,” “selection of subjects is equitable,” informed consent will be sought and “appropriately documented,” and that there are “adequate provisions” for data monitoring and protections for subject privacy and data confidentiality.³¹² The regulations also provide for expedited review for certain kinds of research, i.e., research involving no more than minimal risk and where previously approved research is only proposing minor changes.³¹³ Research that is funded by the U.S. Department of Health and Human Services (DHHS) is also subject to additional regulatory protections related to risk and informed consent when the research involves pregnant women or prisoners.³¹⁴ Both

³⁰⁹ 45 C.F.R. § 46.102(d) (2004). The FDA regulations apply to “clinical investigations” and are not applicable to surgical innovation as defined in this article. The definition is narrower than that of the Common Rule, and encompasses activities that fall within the Common Rule’s definition of research. 21 C.F.R. §§ 50.3(c) & 56.102(c) (2005).

Clinical investigation means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration . . . or is not subject to requirements for prior submission to the Food and Drug Administration . . . , but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

21 C.F.R. §§ 50.3(c) & 56.102(c).

³¹⁰ See *supra* Part I.A.

³¹¹ Reitsma & Moreno, *supra* note 48, at 49.

³¹² 45 C.F.R. § 46.111.

³¹³ 45 C.F.R. § 46.110; 21 C.F.R. § 56.110.

³¹⁴ 45 C.F.R. §§ 46.201-.207, 46.301-.306.(titling the sections “Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Re-

DHHS-funded research and research involving FDA regulated products involving children are also subject to additional regulatory protections.³¹⁵

An IRB must perform continuing reviews of approved studies at least once a year, typically through paperwork reviews of adverse event reports.³¹⁶ IRBs may review protocols that are determined to be especially risky in light of the anticipated benefits on a more frequent basis.³¹⁷ In addition, investigators are required to submit adverse event reports, and the IRB determines whether the adverse event reports require changes in the conduct of the study, including suspension or termination of the study, revisions to the informed consent form, or protocol changes.³¹⁸ The responsibility for IRB submissions and adverse event reporting rests on the investigator; the IRB does not have the power or resources to monitor the conduct and implementation of each protocol in person.³¹⁹ As a practical matter, it would be nearly impossible for an IRB, especially one associated with a large institution or academic medical center, to identify work that should have been submitted to review unless it is specifically brought to the attention of the IRB administrators. In the context of innovative surgery intended to treat a medical condition or disease, in practice, the decision as to whether an innovation meets the definition of research thus rests on the surgeon (and perhaps the affiliated department or clinic) to submit a proposal to an IRB.³²⁰

While the federal regulations place the responsibility to review and approve human subjects research on IRBs, they place the responsibility to obtain informed consent directly on researchers.³²¹ The basic elements of informed consent specified in the regulations are comprehensively specified in the regulations and include, *inter alia*:

search” and “Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects”).

³¹⁵ 45 C.F.R. §§ 46.401-409 (titling the section “Additional Protections for Children Involved as Subjects in Research”); 21 C.F.R. §§ 50.50-56.

³¹⁶ 45 C.F.R. § 46.109(e). *See also* Noah, *supra* note 301, at 184.

³¹⁷ Noah, *supra* note 301, at 193. Also, the National Institutes of Health may also require that certain funded studies have ongoing supervision by a data safety monitoring board (DSMB). *Id.*

³¹⁸ *Id.* at 194 n.84.

³¹⁹ *Id.* at 194 (“The effectiveness of the adverse event monitoring system for human subjects depends heavily on voluntary compliance with IRB and federal regulatory reporting guidelines, but recent reports suggest that many researchers routinely fail to report injuries and deaths among their study patients.”).

³²⁰ Margo, *supra* note 67, at 41.

³²¹ 45 C.F.R. § 46.116; 21 C.F.R. § 50.20 (2005).

- “A statement that the study involves research, and explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental”³²²
- “A description of any reasonably foreseeable risks” and where appropriate, disclosure that some risks are “currently unforeseeable”³²³
- A description of “benefits to the subject or to others” that are reasonably expected³²⁴
- Disclosure of alternative procedures or courses of treatment³²⁵
- A description of applicable confidentiality procedures³²⁶
- A “description of whether any compensation and . . . medical treatments are available if injury occurs”³²⁷
- A “statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled”³²⁸
- A “statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation will be provided to the subject”³²⁹

It is worth highlighting that in both the Research Pathway and Practice Pathway, informed consent must acknowledge the experimental nature of the intervention and that risks are unknown.³³⁰

Federal regulations also set forth narrow circumstances where the requirements for informed consent can be altered or waived.³³¹ With respect to legal actions, the informed consent document may not

³²² 45 C.F.R. § 46.116(a)(1); 21 C.F.R. § 50.25(a)(1).

³²³ 45 C.F.R. §§ 46.116(a)(2) & (b)(1); 21 C.F.R. §§ 50.25(a)(2) & (b)(1).

³²⁴ 45 C.F.R. § 46.116(a)(3); 21 C.F.R. § 50.25(a)(3).

³²⁵ 45 C.F.R. § 46.116(a)(4); 21 C.F.R. § 50.25(a)(4).

³²⁶ 45 C.F.R. § 46.116(a)(5); 21 C.F.R. § 50.25(a)(5).

³²⁷ 45 C.F.R. § 46.116(a)(6); 21 C.F.R. § 50.25(a)(6).

³²⁸ 45 C.F.R. § 46.116(a)(8); 21 C.F.R. § 50.25(a)(8).

³²⁹ 45 C.F.R. § 46.116(b)(5); 21 C.F.R. § 50.25(b)(5).

³³⁰ See *supra* Part III.B.

³³¹ 45 C.F.R. §§ 46.116(c)-(d); 21 C.F.R. § 50.23; 21 C.F.R. § 50.24.

include exculpatory language that waives “any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.”³³² In addition, the federal regulatory requirements for informed consent do not preempt any federal, state, or local requirements for informed consent.³³³

Thus, in contrast to the Practice Pathway, subjecting innovative surgery to the human subjects protection system would offer the opportunity for independent prior review and approval of the ethics of such approaches, and the potential to provide greater accountability and prevent harm to patients. However, a significant barrier to accessing this system is the regulatory definition of “research.” It is doubtful that an already overburdened IRB system³³⁴ could or would voluntarily take on the practice of innovative surgery without guidance on the definition of research.

C. Retrospective Redress of Injury

When a human subject is injured in a research study, the regulatory system and the tort liability system offer some means of redress. Although the federal regulations do not expressly provide for a cause of action in negligence, OHRP (or the FDA in the case of a clinical trial of a drug, biologic or medical device) is empowered to impose sanctions on a regulated researcher and/or institution for failure to abide by the regulations.³³⁵ Sanctions may include loss of federal funding, restrictions or prohibitions on applying for future funding, a halt on the conduct of all or some research at the institution, or failure to obtain FDA approval.³³⁶ In addition, such sanctions may prompt

³³² 45 C.F.R. § 46.116; 21 C.F.R. § 50.20.

³³³ 45 C.F.R. § 46.116(e); 21 C.F.R. § 50.25(c).

³³⁴ See generally JAMES BELL ET AL., FINAL REPORT: EVALUATION OF NIH IMPLEMENTATION OF SECTION 491 OF THE PUBLIC HEALTH SERVICE ACT, MANDATING A PROGRAM OF PROTECTION FOR RESEARCH SUBJECTS (1998), available at http://www.hhs.gov/ohrp/policy/hsp_final_rpt.pdf; U.S. GEN. ACCOUNTING OFFICE, GAO/HEHS-96-72, SCIENTIFIC RESEARCH: CONTINUED VIGILANCE CRITICAL TO PROTECTING HUMAN SUBJECTS 17-20 (1996), available at <http://www.gao.gov/archive/1996/he96072.pdf> [hereinafter GAO, Continued Vigilance]; DEP’T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., INSTITUTIONAL REVIEW BOARDS: A TIME FOR REFORM 6 (1998), available at <http://oig.hhs.gov/oei/reports/oei-01-97-00193.pdf>.

³³⁵ See ACHRE, *supra* note 40, at 432; 45 C.F.R. §§ 46.113, 46.123; 21 C.F.R. § 50.113.

³³⁶ Indeed, such sanctions can have significant ramifications for an entire institution. For example, a twenty-four year old healthy volunteer died during an NIH funded study at Johns Hopkins University. An OHRP investigation revealed deficien-

federal prosecution of researchers and institutions for misuse of funds under the False Claims Act.³³⁷ Injured subjects may also be able to receive compensation through a sponsor's compensation program if any. The availability of such a program, if any exists, is required by regulation to be included in the informed consent form.³³⁸ Among U.S. academic research institutions, the University of Washington is one of the few to have a formal self-insured compensation program for research subjects.³³⁹

Surgical innovation is rarely the subject of federal funding,³⁴⁰ but if performed without IRB oversight at a FWA institution and subsequently determined to have met the regulatory definition of research, the investigator and the institution could be subject to some of the sanctions delineated above.

The discussion in Part III, *supra*, focused on cases involving injuries caused by innovation or alleged of experimentation in the medical treatment setting. As indicated, courts have generally applied a medical malpractice framework to such cases, but in many cases take into account some of the differences from standard medical practice offered by innovation, such as the need for enhanced disclosure during informed consent. This part will focus exclusively on the legal treatment of acts that involve formal research protocols that may or may not be proceeding with IRB approval.³⁴¹

When a human subject is injured during participation in a clinical research study, the injured person is likely to pursue a negligence claim.³⁴² Researchers,³⁴³ and potentially their affiliated institutions and

cies in the IRB review process and ultimately led to a temporary suspension of all federally funded research at the university. *Report on a Research Death Faults Review Board*, N.Y. TIMES, Aug. 31, 2001, at A16.

³³⁷ See, e.g., *United States ex rel. Cantekin v. Univ. of Pittsburgh*, 192 F.3d 402, 402 (3d Cir. 1999) (concerning a medical researcher who failed to disclose industry funding on grant applications submitted to NIH); *United States ex rel. Berge v. Bd. of Trustees of Univ. of Ala.*, 104 F.3d 1453 (4th Cir. 1997) (reversing a prior decision in favor of student, in which student claimed the university made false statements to the NIH in its annual progress reports under a particular grant).

³³⁸ 45 C.F.R. § 46.116(a)(6).

³³⁹ Larry D. Scott, *Research-Related Injury: Problems and Solutions*, 31 J.L. MED. & ETHICS 419, 420, 422 (2003).

³⁴⁰ See generally Reitsma & Moreno, *supra* note 28 (stating that "[t]here are no clear federal regulations governing innovative surgery, even though general guidelines regulating research with human subjects do exist"); Reitsma & Moreno, *supra* note 31.

³⁴¹ This focus is justified in light of recommendations in the literature that surgical innovation be subject to the federal regulations and review by an IRB.

³⁴² FAY A. ROZOVSKY & RODNEY K. ADAMS, *CLINICAL TRIALS AND HUMAN RESEARCH: A PRACTICAL GUIDE TO REGULATORY COMPLIANCE* 392 (2003). Other

IRB members,³⁴⁴ may be held liable for breach of standard of care and/or failure to obtain informed consent.³⁴⁵ There are relatively few reported cases involving research conducted as a formal clinical study (or IRB-approved study), although litigation in human subjects research is increasing.³⁴⁶

Courts have applied medical malpractice law to many of such cases alleging negligence,³⁴⁷ particularly where the facts involve patients (in contrast to healthy volunteers) in a clinical study. Those

theories that research subjects may use to recover damages may include: battery, breach of confidentiality, infliction of emotional distress, fraud, breach of contract, product liability (where the case involves use of marketed medications or medical devices), violations of civil rights, and vicarious liability. *Id.* at 392-93. See also Roger L. Jansson, *Researcher Liability for Negligence in Human Subject Research: Informed Consent and Researcher Malpractice Actions*, 78 WASH. L. REV. 229, 231 (2003) (establishing why researchers owe human subjects a duty of care based on informed consent and malpractice).

³⁴³ For a detailed examination of potential researcher liability, see generally *id.*

³⁴⁴ For a detailed examination of potential IRB liability, see generally Noah, *supra* note 301.

³⁴⁵ Michelle M. Mello et al., *The Rise of Litigation in Human Subjects Research*, 139 ANNALS INTERNAL MED. 40, 40-41 (2003).

³⁴⁶ *Id.* at 41-42 (historically, personal injury lawsuits by research subjects against researchers have been rare, however, both the frequency and stakes of these lawsuits are on the rise); Jansson, *supra* note 342, at 230. As discussed *infra*, however, courts have evaluated claims of experimentation outside of a protocol in terms of medical malpractice. Indeed, many of the actions filed in the last ten years or so have been well publicized in the news media and on law firm websites, and many of them have resulted in settlements. See, e.g., Robertson, Silverstein Kohl Rose and Podolsky Home Page, <http://www.sskrplaw.com> (news articles on the *Gelsing* lawsuit available at <http://www.sskrplaw.com/gene/gelsing.html>, and on the *Robertson v. McGee* case at <http://www.sskrplaw.com/gene/robertson/news.html>). From these filings it is clear that plaintiffs are expanding their claims beyond negligence: a lawsuit brought today may also include "allegations of defective products [where the clinical trial involved testing of a drug, device or biologic], fraud, negligent conduct and monitoring of the research, intentional infliction of emotional distress, breach of patients' rights protected by state law, violation of federal regulations, and violation of constitutional rights." Mello et al., *supra* note 345, at 41.

³⁴⁷ See *Burton v. Brooklyn Doctors Hosp.*, 452 N.Y.S.2d 875, 879-80 (N.Y. App. Div. 1982) (holding the trial jury received the proper charge for determining malpractice, and thus upheld the verdict against the physician and hospital); E. Haavi Morreim, *Medical Research Litigation and Malpractice Tort Doctrines: Courts on a Learning Curve*, 4 HOUS. J. HEALTH L. & POL'Y 1, 19-32 (2003) (discussing court treatment of clinical research cases as malpractice) (citing *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990), *cert. denied*, 504 U.S. 986 (1992); *Kernke v. Mennigier Clinic Inc.*, 172 F. Supp. 2d 1347 (Kan. 2001); and *Heinrich v. Sweet*, 308 F.3d 48 (1st Cir. 2002)).

cases include patient-subjects who are informed³⁴⁸ or uninformed³⁴⁹ of their research participation.

Some courts, in contrast, do recognize a distinction between medical practice and research.³⁵⁰ Some apply theories of ordinary negligence rather than medical malpractice,³⁵¹ and at least one of those cases involved patients undergoing medical care who became unwitting research subjects.³⁵² A few cases have explicitly distin-

³⁴⁸ *Heinrich*, 308 F.3d at 48. *Kernke*, 172 F. Supp. 2d at 1347, allowed application of Kansas medical malpractice law in a case where a patient-subject died during preparation period necessary for participation in investigational psychiatric drug trial (known as "wash out"). It further upheld summary judgment for defendants on claims of intentional infliction of emotional distress, fraudulent misrepresentation, misrepresentation and breach of fiduciary duty because they arose out of "the same series of events as the underlying malpractice claim." *Id.* at 1354.

³⁴⁹ *Moore*, 793 P.2d at 479 (involving an unwitting subject of research). In *Moore*, the court applied California medical malpractice law on informed consent and breach of fiduciary duty where the patient underwent surgical removal of spleen as treatment for hairy cell leukemia and physician-researcher used cells extracted during surgery in research without his knowledge and consent. The researchers also had the patient-subject return for further extraction of cells on many occasions solely for research-related reasons. *Id.* See also *Burton*, 452 N.Y.S.2d at 877, 880-81 (explaining how the research study concerning administration of oxygen to premature children began only days prior to the arrival of the premature child, and determining the physicians should have obtained consent from the parents for participation in the study).

³⁵⁰ For a comprehensive assessment of research litigation and negligence advocating distinct treatment of medical and research injury claims, see Morreim, *supra* note 347; E. Haavi Morreim, *Litigation in Clinical Research: Malpractice Doctrines Versus Research Realities*, 32 J.L. MED. & ETHICS 474, 384 (2004) (critiquing courts for "deeming research injuries as just a species of medical malpractice . . . [and] largely fail[ing] to recognize crucial differences between clinical trials and medical practice," and arguing that "human clinical trials need tort doctrines specifically adapted to the research setting").

³⁵¹ Morreim, *supra* note 347, at 28-30 (citing *Payette v. Rockefeller Univ.*, 643 N.Y.S.2d 79 (N.Y. App. Div. 1996) (rejecting application of New York's statute of limitations applicable to medical malpractice actions in action against research institution involving healthy volunteer's participation in nutrition study); *Ande v. Rock*, 647 N.W.2d 265 (Wis. Ct. App. 2002), *rev. denied*, 650 N.W.2d 840 (Wis. 2002), *cert. denied sub. nom.* *Ande v. Fost*, 537 U.S. 1107 (2003) (medical malpractice claims fail for lack of physician-patient relationship in research involving newborn screening for cystic fibrosis); *Craft v. Vanderbilt Univ.*, 18 F. Supp. 2d 786 (M.D. Tenn. 1998)). *Craft* was an action against research institutions in which the court held that the statute of repose applicable to medical malpractice did not apply to radioactive iron absorption studies conducted on pregnant patients with no therapeutic purpose and without their knowledge or consent. "The medical malpractice statutes only apply to a doctor's conduct where the challenged actions were taken in an effort to benefit or cure the patient." *Id.* at 796.

³⁵² See, e.g., *Craft*, 18 F. Supp. 2d at 786.

guished medical practice from research,³⁵³ and allowed constitutional and civil rights claims to proceed.

1. Research Malpractice—Breach of Standard of Care

Although traditional medical malpractice can draw on statutes and well-developed case law to define the standard of care in medical malpractice, there is little case law discussing a distinct standard of care applicable to a researcher in the context of a clinical study.³⁵⁴ In the absence of a physician-patient relationship, courts in at least two cases have characterized the researcher-subject relationship as a “special relationship,” a predicate for establishing a duty.³⁵⁵ Federal regulations have not been used to establish a unique standard of care for researcher malpractice,³⁵⁶ except in some informed consent claims.³⁵⁷ As revealed in the following two cases, where the research subject is also a patient (as in surgical innovation), courts have easily established the duty prong of negligence by implicit or explicit reference to the physician-patient relationship.

³⁵³ Morreim, *supra* note 347, at 30-31 (citing *Barrett v. United States*, 689 F.2d 324, 329 (1982) (reversal of the district court’s summary judgment for the defendants in an action against the U.S. government and others under the Federal Tort Claims Act and the civil rights provisions of 42 USC § 1983); *In re Cincinnati Radiation Litig.*, 874 F. Supp. 796, 832 (Ohio 1995) (allowing plaintiffs’ claims to proceed for “violations of constitutional rights of substantive due process, procedural due process, access to the courts, and equal protection as well as a claim for a violation of 42 U.S.C. § 1985”).

³⁵⁴ Jansson, *supra* note 342, at 238.

³⁵⁵ *Blaz v. Michael Reese Hosp. Found.*, 74 F. Supp. 2d 803, 806-07 (N.D. Ill. 1999) (finding a duty to warn research subject of research findings and holding that “Dr. Schneider’s position as the person in charge of the Program involved in researching the effects of the radiation treatments and contacting patients who had been subjected to them created the sort of ‘special relationship’ the Illinois Supreme Court requires for a finding of duty in the absence of a physician-patient relationship.”). See also Grimes, *supra* note 7, at 3030 (“[r]esponsibility for this medical malfeasance lies primarily with physicians”).

³⁵⁶ Jansson, *supra* note 342, at 251-252.

Although the federal regulations are intended to protect the rights and safety of human subjects, they do not impose specific requirements on researchers beyond obtaining the subjects’ informed consent and IRB approval. The federal regulations place the responsibility of weighing risks and approving research on IRBs, not on researchers. Thus, unlike in informed consent, the federal regulations do not provide a specific standard of care for researcher malpractice actions.

Id. at 251-52 (citations omitted).

³⁵⁷ See discussion on Research Malpractice—Failure of Informed Consent *infra* Part IV.C.2.

*Burton v. Brooklyn Doctors Hospital*³⁵⁸ involved the application of medical malpractice law to a research study that had been designed to challenge a long-standing medically accepted practice. In the early 1950s, many physicians believed that increased oxygen was important in preventing brain damage and even death in premature newborns. At the same time, some in the medical community believed that this approach contributed to a condition that caused blindness known as retrolental fibroplasia. In 1953, one of the defendant physicians and the hospital undertook a study to examine these conclusions, randomizing prematurely born newborns into a research study without parental consent. The plaintiff was in a group receiving increased oxygen and suffered blindness. The physician-investigator's argument that increased oxygenation was standard practice failed. The court took note of the fact that an earlier study by the investigator had concluded that oxygenation was not recommended. The court also found convincing that a two-to-one randomization decision (two patients receiving decreased oxygen for every one patient receiving increased oxygen) disfavored a practice that the defense had argued was standard of care.³⁵⁹ In addition, the court duly noted that the defendants had failed to remove the plaintiff-patient from the study when he first showed signs of eye damage and that the attending physician, who had ordered a reduction in oxygen, had not been consulted before the infant was entered into the clinical study. The court ultimately found that the physician-investigator was accountable for the actual superior knowledge that she had gained from her previous study concerning the risk of injury that might result from the study.³⁶⁰ This case could potentially be interpreted to suggest that physician-researchers may be held to a higher standard of care based on actual knowledge of clinical study results. Indeed, it is worthy of note that at least one jurisdiction has imposed a duty on "nontreating physicians in charge of . . . research programs . . . to warn the former patients of risks discovered in . . . research."³⁶¹

³⁵⁸ 452 N.Y.S.2d 875 (N.Y. App. Div. 1982).

³⁵⁹ "[W]e find it difficult to believe that any reputable institution would permit two out of three of its patients to receive unusual treatment, which might result in death or brain damage, unless it was fairly convinced that the conventional wisdom no longer applied." *Id.* at 880.

³⁶⁰ "A physician should use his best judgment and whatever superior knowledge, skill and intelligence he has." *Id.* at 880.

³⁶¹ *Blaz v. Michael Reese Hosp. Found.*, 74 F. Supp. 2d 803, 807 (N.D. Ill. 1999).

*Heinrich v. Sweet*³⁶² raises issues arguably analogous to surgical innovation, but in the context of a research protocol: use of patients to benefit future patients but also presumably with some prospect of medical benefit to the patient-subject as well,³⁶³ and refinement of therapy over time. The case was brought by families of two deceased patients who were treated in the early 1960s in a clinical trial of an experimental therapy known as Boron Neutron Capture Therapy (BNCT), a post surgical combination of chemotherapy and radiation. The research was conducted in leading medical institutions by prominent surgeons and other medical personnel and funded by the U.S. Government's Atomic Energy Commission. Earlier trials on patients in the 1950s had proved unsuccessful, but researchers continued attempts to further improve BNCT, resulting in the clinical trial at issue, which involved nineteen patients. One of the patient-plaintiffs underwent BNCT in what appears to be "last resort" circumstances: after surgical removal of the tumor and conventional treatment failed to prevent the recurrence of the malignancy. The other patient-subject was treated with BNCT a short time following surgery. The court applied state malpractice law and allowed expert testimony to establish the standard of care applicable to a researcher,³⁶⁴ finding that the physicians did not breach the standard of care.³⁶⁵ The court found that prior approval of the research by four committees was "very compelling evidence" that the research was conducted in compliance with the standard of care at that time.³⁶⁶

Heinrich involved research performed before federal regulatory requirements for IRB approval were implemented. But *Heinrich* suggests that independent review by an IRB or similar committee may offer a potential partial defense to malpractice, at least in the context of research.³⁶⁷ Such approval may be used to demonstrate that an independent group determined that the research met regulatory require-

³⁶² *Heinrich v. Sweet*, 308 F.3d 48-49 (1st Cir. 2002) (discussing the "use of experimental boron neutron capture therapy (BNCT) to treat patients' terminal brain cancer").

³⁶³ Earlier decisions that formed the basis for this appeal had concluded that there was no potential for therapeutic benefit to the patient subjects. *Id.* at 69-70. The case on appeal found instead that the physician-investigators and other defendants did not know at the time that the procedure offered no prospect of medical benefit. *Id.*

³⁶⁴ *Id.* at 63 (applying a malpractice standard, stating "[t]he standard of care for medical doctors is not static or rigid. It is a standard that changes depending on many factors, including a doctor's specialty, the resources available, and the advances of the medical profession at the time of the alleged negligent act.").

³⁶⁵ *Id.* at 65-67.

³⁶⁶ *Id.* at 69.

³⁶⁷ Jansson, *supra* note 342, at 254.

ments, including appropriate balancing of risks and benefits, informed consent, and equitable subject selection.³⁶⁸ Nonetheless, such review is not dispositive, however, as at least one court has allowed negligence actions against researchers and the research institution to proceed even though the researchers obtained IRB approval, and indeed was scathing in its critique of the IRB's judgment.³⁶⁹

2. Research Malpractice—Failure of Informed Consent

There are a number of reported cases involving research studies dating back to the 1950s that involve the use of human subjects without their knowledge or consent.³⁷⁰ Some of those research studies were supported with federal funding, including funding from the military,³⁷¹ and some involved patients receiving care that they believed was standard medical treatment.³⁷² In the cases involving military research funding, courts have generally relied on constitutionally-guaranteed interests in the right to bodily integrity in order to advance the informed consent claims.³⁷³ In other contexts, courts have reached

³⁶⁸ See *supra* Part IV.B.

³⁶⁹ See *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 813 (Md. 2001).

³⁷⁰ *Morreim, supra* note 347, at 6-13.

³⁷¹ Military sponsored studies include: *Barrett v. United States*, 689 F.2d 324 (2d Cir. 1982) (the U.S. Army used individuals as test subjects for a chemical warfare experiment without their consent); *In re Cincinnati Radiation Litig.*, 874 F. Supp. 796 (S.D. Ohio 1995) (plaintiffs alleged they were unknowingly exposed to large amounts of radiation as a part of Human Radiation Experiments conducted at Cincinnati General Hospital with funding and authorization from the U.S. Department of Defense's Nuclear Agency); *Stadt v. Univ. of Rochester*, 921 F. Supp. 1023 (W.D.N.Y. 1996) (a military doctor allegedly injected plaintiff's decedent with plutonium without her consent in order to study its effects). In all three of these cases, informed consent was an issue addressed by the court. However, the court evaluated these claims by asserting the right to bodily integrity rather than using the informed consent analysis seen in traditional medical malpractice cases. *Barrett*, 689 F.2d at 331; *In re Cincinnati Radiation Litig.*, 874 F. Supp. at 819; *Stadt*, 921 F. Supp. at 1027.

³⁷² See, e.g., *Mink v. Univ. of Chicago*, 460 F. Supp. 713 (N.D. Ill. 1978) (physicians gave DES to pregnant women for prevention of miscarriage alleging daughters were at increased risk of cancer); *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990), *cert. denied*, 504 U.S. 986 (1992) (physician uses patient's cells from therapeutically removed spleen to develop potentially lucrative cell line and removes tissue samples for research purposes only during follow up visits); *Burton v. Brooklyn Doctors Hosp.*, 452 N.Y.S.2d 875 (N.Y. App. Div. 1982) (physicians treated premature infants with high levels of oxygen causing blindness); *Friter v. IOLAB Corp.*, 607 A.2d 1111 (Pa. Super. Ct. 1992) (physician, under approval of the hospital's Institutional Review Board, implanted an intraocular lens into patient's eye as a part of an experimental study without obtaining his consent).

³⁷³ See, e.g., *Barrett*, 689 F.2d at 331; *In re Cincinnati Radiation Litig.*, 874 F. Supp. at 819; *Stadt*, 921 F. Supp. at 1027. *Contra, e.g.*, *Wright v. Fred Hutchinson Cancer Research Ctr.*, 269 F. Supp. 2d 1286, 1295 (W.D. Wash. 2002) (explicitly

various conclusions on the application of a cause of action for lack of informed consent for research. For example, some courts have held that if a patient is completely unaware of their participation in the study, the proper cause of action is battery rather than informed consent.³⁷⁴ Other courts, however, have upheld such a cause of action even though the law at the time had not recognized the duty to obtain informed consent from research subjects.³⁷⁵ This duty has even been extended to hospitals under the theory that they assume such a duty by participating in a research study due to the requirements of the federal regulations.³⁷⁶ Some courts have extended the duty to one where a physician must disclose even personal interests unrelated to the patient's health, whether research or economic, that may affect the physician's medical judgment.³⁷⁷ Thus in cases where a patient, such as one undergoing innovative surgery, is not aware that he or she is in a research study, that patient may either have a cause of action for violation of his or her constitutional rights (if the experiment is funded by the government) or for lack of informed consent for any injury caused by their participation in the study.

An informed consent claim in the Research Pathway will proceed similarly to that of traditional medical malpractice, with the need to establish all the elements of such a cause of action. However, some accommodation for research circumstances has been acknowledged in case law. For example, the Maryland Court of Appeals took another approach, tailoring the duty prong to research circumstances in an action involving allegations of inadequate informed consent in so-called "nontherapeutic" research. Specifically, the court found that researchers may owe research subjects a distinct duty of care based on a special relationship that can be derived from various sources, including the informed consent agreement and implied duties arising out of the federal human subjects protection regulations.³⁷⁸ However, multiple courts have used the federal regulations to set the standard against which informed consent in human subjects research will be compared where the case involved inadequate informed consent. For example, *Whitlock v. Duke University*³⁷⁹ adopted the Common Rule's

rejecting constitutional claims in the research context and distinguishing the foregoing cases in which the "true nature of the experiments" were hidden by the defendants).

³⁷⁴ *E.g.*, *Mink*, 460 F. Supp at 717.

³⁷⁵ *E.g.*, *Burton*, 452 N.Y.S.2d at 880-81.

³⁷⁶ *E.g.*, *Friter*, 607 A.2d at 1114, 1116 (applying 21 C.F.R. § 813.66(a)(6)).

³⁷⁷ *Moore*, 793 P.2d at 485.

³⁷⁸ *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 858 (Md. 2001).

³⁷⁹ *Whitlock v. Duke Univ.*, 637 F. Supp. 1463 (M.D. N.C. 1986), *aff'd*, 829 F.2d 1340 (4th Cir. 1987) (involving an experiment researching high pressure nervous

informed consent requirements as the standard and held that there is a heightened duty for disclosure of foreseeable risks as compared to the medical context.³⁸⁰ More recently, the 1997 case *Daum v. SpineCare Medical Group*³⁸¹ held that the FDA regulations provided the standard for informed consent in spinal surgery using an experimental device. The *Daum* court held that violation of the regulatory requirements for informed consent could support a jury instruction for negligence *per se*.³⁸² Other courts have held that the FDA regulations set the standard for informed consent in cases involving the implantation of experimental medical devices.³⁸³ Note further that at least one court reviewing an informed consent claim in the context of a research protocol has declined to follow the lead of the *Moore* court, discussed *supra*, holding that there is no duty to disclose a researcher's economic interest.³⁸⁴

In one recent experimental surgery case, however, the court in its review of the deceased plaintiff's informed consent claim applied the informed consent requirements delineated in state malpractice law rather than relying on those set forth in the federal regulations. In *Goodman v. United States*,³⁸⁵ the Ninth Circuit held that the federal regulations do not apply to the liability of the United States in actions by human subjects against the United States under the Federal Tort Claims Act (FTCA).³⁸⁶ In *Goodman*, an experimental surgical procedure was performed at the NIH for liver cancer.³⁸⁷ The husband of the deceased patient sued under the FTCA, alleging that his wife died

syndrome in deep sea diving).

³⁸⁰ *Id.* at 1471.

³⁸¹ *Daum v. SpineCare Med. Group, Inc.*, 61 Cal. Rptr. 2d 260 (Cal. Ct. App. 1997).

³⁸² *Id.* at 271.

³⁸³ *See, e.g.*, *Chambers v. Osteonics Corp.*, 917 F. Supp. 624, 626 (S.D. Ind. 1996); *Kus v. Sherman Hosp.*, 644 N.E.2d 1214, 1221 (Ill. App. Ct. 1995) (suit against hospital for faulty medically implanted lenses); *Southard v. Temple Univ. Hosp.*, 781 A.2d 101, 107-08 (Pa. 2001) (declining to apply FDA disclosure requirements and the revelation of the investigational nature of a surgically implanted device where the surgeon was *not* participating in a formal clinical investigation subject to FDA regulation).

³⁸⁴ *Greenberg v. Miami Children's Hosp. Research Inst.*, 264 F. Supp. 2d 1064, 1070-71 (S.D. Fla. 2003). Indeed, it is interesting to note that the court distinguished *Moore* because of the *Moore* physician's therapeutic relationship with the patient. *Id.* at 1070 (In *Moore*, "[t]he doctors did not inform their patient that they were using his blood and tissue for medical research." "The allegations in the Complaint are clearly distinguishable as Defendants here are solely medical researchers and there was no therapeutic relationship as in *Moore*." (citations omitted).

³⁸⁵ *Goodman v. United States*, 298 F.3d 1048 (9th Cir. 2002).

³⁸⁶ *Id.* at 1054 n.6.

³⁸⁷ *Id.* at 1050-51.

from a toxic reaction to the medicine used in surgery, and asserting a claim for failure to obtain informed consent.³⁸⁸ The court declined to apply the federal human subjects regulations stating that “[u]nder the FTCA, the liability of the United States is determined ‘in accordance with the law of the place where the [allegedly tortious] act or omission occurred,’ 28 U.S.C. § 1346(b),” and applied Maryland malpractice law on informed consent.³⁸⁹ The court further noted that:

[I]n the battle against deadly diseases, progress often will be made only when medical experimentation is permitted. Doctors must give fair warnings of risks that are known or that reasonably should have been known by them. However, here, the NIH doctors were not required to warn JoAnn Goodman, as she embarked bravely on an experimental procedure that might have helped her and others, of an unperceived risk of which they reasonably were not aware.³⁹⁰

The *Goodman* court held that the physicians adequately informed the patient of known material risks associated with the experimental surgery (which included the possibility of death), basing its conclusion on undisputed expert testimony at the trial level. The court also determined that the informed consent form did not need to be supplemented to explain that three earlier NIH patients had experienced complications when they underwent the same procedure, stating, “[t]o hold that the signed consent form was inadequate would require the NIH to update its already detailed consent form every time a patient experiences any sort of complication from an experimental procedure.”³⁹¹ This is a potentially surprising result in light of federal regulations that require that informed consent includes, where appropriate, “a statement that new findings developed during the course of the research which may relate to the subject’s willingness to continue

³⁸⁸ *Id.* at 1048.

³⁸⁹ *Id.* at 1054 n.6.

³⁹⁰ *Id.* at 1058.

³⁹¹ *Id.* See also the findings of the FDA regarding the 1999 death of Jesse Gelsinger in a gene transfer research trial. An FDA compliance letter to Penn included the accusation that the researchers did not amend the informed consent document following adverse effects experienced by test subjects. The letter states that “[t]hese were ‘significant’ adverse events. . . . Nevertheless, despite this important evidence of increased risk, [the researchers] failed to provide potential subjects . . . with information about this possible risk of participation.” Letter from Steven A. Masiello, Dir., Office of Compliance & Biologics Quality, Ctr. for Biologics Evaluation & Research to Mark L. Batshaw, Children’s Nat’l Med. Ctr. (Nov. 30, 2000), available at <http://www.fda.gov/foi/nidpoe/n141.pdf>.

participation will be provided to the subject.”³⁹² The tone of the opinion, yet again, may be interpreted as judicial accommodation to physician innovation in the face of a serious and life-threatening medical condition (liver cancer).

Because of the comprehensiveness and specificity of the regulatory requirements for informed consent, discussed earlier, a higher standard of disclosure would appear to apply to research than to medical practice. At the same time, the medical malpractice framework discussed *supra* generally requires disclosure in the informed consent process that a particular therapy is innovative and carries unknown risks. Thus it appears that in retrospective redress of injury, the Practice Pathway appears to, at least partially, use a comparable standard of disclosure in the area of medical or surgical innovation. Indeed, at least one recent legal commentator has highlighted innovative therapies in particular to support his argument that the medical practice-research dichotomy in informed consent is indeed a distinction without a difference.³⁹³

D. Institutional Liability and Sanctions

Based on the examination of malpractice law, discussed *supra* at Part III.D, institutional liability claims arising in research where medical malpractice law is applied are likely to be viable on the same bases.³⁹⁴ In *Burton*, discussed *supra*, where malpractice law was applied, the hospital was held liable, but the basis for liability (vicarious liability or breach of an independent duty) was not expressly articulated.³⁹⁵ In *Goodman*, discussed *supra*, the researchers were NIH employees, and thus the law implicitly applied respondeat superior to the informed consent claim.³⁹⁶ Courts have also found independent institutional duties to research subjects.³⁹⁷ As noted *supra*, at least one

³⁹² 45 C.F.R. § 46.116(b)(5).

³⁹³ Noah, *supra* note 196, at 407-08 (challenging the distinct applications of informed consent rules in experimental and standard therapies, and arguing that the area of clinical innovation, in particular, deserves careful attention in this area).

³⁹⁴ See discussion *supra* Part III.D regarding institutional liability of health care institutions.

³⁹⁵ It is unclear whether it was an independent or vicarious basis for liability. The hospital was unsuccessful in its attempt to claim exemption from liability based on charitable immunity, a theory which was eliminated in the seminal case of *Bing v. Thunig*, 143 N.Y.2d 3 (N.Y. 1957).

³⁹⁶ See generally *Goodman v. United States*, 298 F.3d 1048 (9th Cir. 2002).

³⁹⁷ *Mink v. Univ. of Chicago*, 460 F. Supp. 713, 720 (N.D. Ill. 1978), involved patients who had taken DES as part of a clinical study without their knowledge or consent and alleged increased risk of cancer to themselves and their children. The court held that the university hospital had a

court has held that the federal regulations (i.e., the FDA regulations) impose a duty of informed consent on a research hospital in the context of a research study.³⁹⁸ Researcher or institutional failure to apply relevant federal research regulations may also result in sanctions against the institution.

E. Lessons for Surgical Innovation from Review of the Research Pathway

There are some general observations that can be derived from review of the Research Pathway. The federal regulations, where applicable, require IRB review and approval before the research protocol proceeds. In this sense, the federal regulations are prospective in nature, and unlike the retrospective remedies offered by the Practice Pathway, the review mandated by the regulations offers the opportunity to prevent unreasonably risky or unwise innovative surgical procedures, thereby protecting patient-subjects and promoting greater

duty to notify the plaintiff patients of the risk inherent in DES treatment when they became aware of should have become aware of the relationship between DES and cancer . . . The University's duty to notify is simply an extension of duty of physician to warn their patients of the risk inherent in treatment. . . . When the University hospital became aware or should have become aware of facts which would induce a reasonable physician under the same circumstances to warn patients of the risk involved in treatment, a duty to notify arose. The fact the knowledge of the risk was obtained after the patient was treated does not alter the obligation. If the defendant fails to notify the patient when the risk becomes known, he has breached this duty.

Id. at 720. In *Blaz v. Michael Reese Hospital Foundation*, F. Supp. 2d 803, 806 (N.D. Ill. 1999), the court followed *Mink* and found that the hospital had a duty based on agency theory. *Id.* at 806 ("The agent to whom the hospital delegates the direction of such research has an obligation to inform the patients subjected to such treatments of the results of that research if it indicates that there is a foreseeable risk."). In *Payette v. Rockefeller Univ.*, 643 N.Y.S.2d 79, 80 (N.Y. App. Div. 1996), a previously healthy volunteer in a nutrition study was not barred from bringing a cause of action against a research institution alleging "the careless, unskillful and negligent design, prescription, supervision and control of a dietary regimen" in a research study. The court held that the statute of limitations for ordinary negligence applied rather than the limitation applicable to medical malpractice actions. *Id.* at 80.

³⁹⁸ *E.g.*, *Friter v. IOLAB Corp.*, 607 A.2d 1111, 1113-14 (Pa. Super. Ct. 1992) (referencing 21 C.F.R. § 813.66(a)(6)).

[T]he hospital, as a participant in a clinical investigation for the FDA, specifically assumed a duty to ensure that an informed consent was obtained by any patient participating in the study. In particular, under applicable federal regulations, *Wills Eye Hospital had an affirmative duty to '[a]ssure that the rights of human subjects are properly protected, that legally effective informed consent is obtained, and that the methods of obtaining consent properly informs the human subject of the significant aspects of the study.'*

21 C.F.R. § 813.66(a)(6) (2005).

accountability. At the same time, subjecting surgical innovation to the formal regulatory process raises challenges. A central problem is defining the situations in which surgical innovation meets the regulatory definition of research. No guidance currently exists. With reliance on individual investigators to bring these events to the attention of the IRB and review taking place at the local level, such guidance is not currently forthcoming.³⁹⁹

As in the Practice Pathway, retrospective legal scrutiny initiates when a patient-subject is injured. From an institutional standpoint, a FWA institution will be subject to scrutiny from federal regulators, and negative findings may result in sanctions that affect the future career of a federally-funded investigator, the reputation of the institution, and potentially the conduct of all unrelated research at the institution. Although the stakes are high from an institutional perspective, the intention is to protect the rights and welfare of human subjects. A benefit however may accrue to the institution and innovator through IRB review. This review process provides an opportunity for independent parties to evaluate the risks and benefits of the research, and otherwise ensure that the research is ethical and that informed consent is appropriate. Indeed, the independent review offered by an IRB may provide some protection against potential liability. As one legal commentator has noted:

Peer review cannot be substituted for proof of standard practice where innovation is used, but well-documented peer review of a written research protocol is, at least, evidence that other physicians and community representatives found the in-

³⁹⁹ Note however that there is some federal precedent for creating powerful programs that subject activities with a therapeutic intention to federal regulatory oversight but otherwise do not meet the precise definition of research. The FDA's Parallel Track program "is intended to make promising investigational agents available as quickly as possible to patients with AIDS and other HIV-related diseases." ROZOVSKY & ADAMS, *supra* note 342, at 358 (citing 57 Fed. Reg. 13,250 (Apr. 15, 1992)).

A Treatment IND/IDE is a procedure whereby the FDA allows investigational drugs or devices to be administered to very ill patients earlier in the development process. . . . 'The purpose . . . is to facilitate the availability of promising new drugs to desperately ill patients as early in the drug development process as possible (before marketing begins) and to obtain additional data on the drug's safety and effectiveness'. . . . Treatment IND studies require prospective IRB approval. . . .

Id. at 354 (citations omitted).

novation to be reasonable to use on patients with a specific type of problem in terms of risk-benefit ratio.⁴⁰⁰

A review of the case law related to alleged injuries occurring in the context of research protocols reveals far fewer cases than in medical malpractice generally. There have been relatively few reported cases since the institution of IRB review requirements pursuant to the federal regulations, but at the same time there have been well publicized reports of case filings and related settlements, so case law still may be developing in this area.⁴⁰¹

From the reported case law, there appears to be a tendency to apply medical malpractice principles to research malpractice claims, but some courts and commentators are recognizing distinct differences between research and therapy. One case in particular arguably holds physician-investigators to a higher standard of knowledge and skill.⁴⁰²

In the area of informed consent, there appears to be a general tendency to rely on the regulatory requirements where applicable. As noted earlier, however, the specificity of the elements of informed consent in research are drawing closer to that required in medical practice, particularly in the area of medical innovation, so this may be a distinction without a difference.

V. A CASE STUDY IN INNOVATION AND MALPRACTICE LIABILITY: LAPAROSCOPIC CHOLECYSTECTOMY

This part examines one example of surgical innovation in depth in an attempt to understand its legal treatment during its evolution and diffusion into standard practice. This particular innovation stimulated a wave of surgical malpractice claims in the 1990s.⁴⁰³ Laparoscopic cholecystectomy is the use of a minimally invasive technique to treat gallstones by removing the gall bladder.⁴⁰⁴ This innovation combines

⁴⁰⁰ *Proof of Facts*, *supra* note 182, § 1.

⁴⁰¹ Mello et al., *supra* note 345, at 40.

⁴⁰² *Burton v. Brooklyn Doctors Hospital*, 452 N.Y.S.2d 875, 880-81 (N.Y. App. Div. 1982).

⁴⁰³ JACOBSON, *supra* note 68, at 23-27. Trial lawyers are well aware of the injuries that may result from laparoscopic surgical techniques. See, e.g., Association of Trial Lawyers of America, Laparoscopy Litigation Group, *Pretrial Issues in Laparoscopic Negligence Cases*, 1 ATLA Ann. Convention Reference Materials 685 (2001), (available on Westlaw as "1 Ann.2001 ATLA-CLE 685 (2001)").

⁴⁰⁴ "[The laparoscopic approach to surgery] has been around since the early fifties, in use primarily by gynecologic surgeons. Laparoscopic surgery allows the surgeon to make a very small incision right below the navel and introduce an instrument called a laparoscope. The laparoscope is a long tube with a lens at one end and a

a technique that had been accepted in other surgical areas (laparoscope) with an established treatment (gall bladder removal). Previously, the standard approach for gall bladder removal (known generally as "open cholecystectomy") required major abdominal surgery, with a large incision and significant healing time,⁴⁰⁵ but had a low risk of complications.⁴⁰⁶ In comparison, the innovative technique offered the opportunity for smaller incisions and quicker recovery times.⁴⁰⁷ The introduction of this technique also increased the rate of surgical removals of the gall bladder as a treatment for gallstones.⁴⁰⁸ Indeed, patients readily acquiesced to the innovation, with a 15–20 percent refusal rate for open cholecystectomy dropping to 1 percent with the laparoscopic version.⁴⁰⁹

The procedure was first performed in the United States in 1988 by Dr. J. Barry McKernan,⁴¹⁰ and rapidly diffused into practice.⁴¹¹ Unfortunately, a number of surgeons unaccustomed to working with "less visibility and unfamiliar instruments"⁴¹² caused secondary injuries to patients during their initial adoption of the technique. These injuries included, *inter alia*, damage to the common bile duct, liver, bowel, iliac artery,⁴¹³ and renal aorta.⁴¹⁴

miniature video camera at the other. The laparoscope enables the physician to see the desired organ. Several more tiny incisions are made to allow for the passage of instruments to be used to cut and clamp off the operative organ." Gillespie, *supra* note 168, § 1.

⁴⁰⁵ JACOBSON, *supra* note 68, at 28.

⁴⁰⁶ De Ville, *supra* note 119, at 205.

⁴⁰⁷ JACOBSON, *supra* note 68, at 23, 27.

⁴⁰⁸ See A.P. Legorreta et al., *Increased Cholecystectomy Rate After the Introduction of Laparoscopic Cholecystectomy*, 270 JAMA 1429 (1993).

⁴⁰⁹ Strasberg & Ludbrook, *supra* note 10, at 938.

⁴¹⁰ J. Barry McKernan, *Origin of Laparoscopic Cholecystectomy in the USA: Personal Experience*, 23 WORLD J. SURGERY 332 (1999). J. Barry McKernan performed the first laparoscopic cholecystectomy in the U.S. on June 22, 1988. Dr. McKernan's account of his first performance of this procedure indicates that he was aware of potential medicolegal issues. He further states that "industry played a major role in pushing laparoscopic cholecystectomy. . . . We surgeons initially played a distant role. . . . Without the participation and encouragement of industry the revolution would have taken decades. It also had to be multinational." *Id.* at 333. The procedure was first performed outside of the United States in 1985 by Erich Muhe in Germany. It is interesting to note that Dr. Muhe's license was "revoked shortly thereafter." *Id.* at 333. Note, however, that another author states that the surgery originated in France. Strasberg & Ludbrook, *supra* note 10, at 938.

⁴¹¹ Strasberg & Ludbrook, *supra* note 10, 938.

⁴¹² JACOBSON, *supra* note 68, at 28.

⁴¹³ *Id.* at 28–29.

⁴¹⁴ Fusilier v. Dauterive, 779 So. 2d 950, 952 (La. Ct. App. 2001) (case on remand for reassessment of damages).

A. IRB Review and Informed Consent

Dr. McKernan's first performance of this procedure did not undergo IRB review.⁴¹⁵ In a personal account, he discusses his informed consent encounter with the patient:

We found a patient, and I told her we had a 10 [percent] chance of removing the gallbladder the first time. She got a second opinion from a surgeon who told her she was "out of her mind." She conferred again with me, and I told her he was probably right but she was going to have to have it removed by an open procedure anyway. She decided to try the laparoscopic approach.⁴¹⁶

The early adoption of this procedure by surgeons did not stimulate IRB oversight in most instances.⁴¹⁷ This reportedly was because surgeons did not characterize it as research.⁴¹⁸ It also may have been attributable, at least in part, to the fact that surgeons in private practice constituted the vast majority of the early adopters,⁴¹⁹ and research conducted in these settings is not necessarily subject to the reach of the federal regulatory regime. As mentioned *supra*, even insurers did not consider the procedure to be research: while the surgical approach was novel, the procedures themselves had known risk and benefits.⁴²⁰ Later randomized controlled trials comparing open cholecystectomy to laparoscopic cholecystectomy clearly met the definition of research and underwent IRB review.⁴²¹

Strasberg and Ludbrook undertook a review of this procedure and two other innovative procedures⁴²² in part to assess whether injuries could have been detected earlier and whether preventive measures could have been taken to prevent patient injuries. As part of this assessment, they evaluated the value of IRB review. The randomized

⁴¹⁵ See McKernan, *supra* note 406.

⁴¹⁶ See *id.*

⁴¹⁷ See Strasberg & Ludbrook, *supra* note 10, at 938-39 ("The performance of cholecystectomy by laparoscopy in patients who had clear indications for cholecystectomy did not seem to many surgeons to fit the definition of research. To these practitioners, there was no indication or compulsion to seek approval from a regulatory body such as an IRB.").

⁴¹⁸ *Id.* at 938.

⁴¹⁹ McKernan, *supra* note 402.

⁴²⁰ Gleeson, *supra* note 82.

⁴²¹ *Id.*

⁴²² The other two innovative procedures they examined were radiofrequency ablation of metastatic colorectal tumors in the liver and live donor right hemiliver transplantation. *Id.* at 939.

trials, reported as early as 1992, were conducted at single institutions and lacked the statistical power to detect the differences in "relatively infrequent events," such as the injuries mentioned above.⁴²³ The profession instead was alerted to these events by a registry operated by the state board of medicine, a registry run by a surgical association, and journal publication of case series that reported increased referrals for complications resulting from laparoscopic cholecystectomy.⁴²⁴ Retrospective review indicated that injuries were caused by two factors: (1) "inadequate training and credentialing," and (2) "fundamental flaws in the procedure as it was initially conceived and practiced."⁴²⁵ In their comprehensive review of this and two other innovative procedures, Strasberg and Ludbrook concluded that patients are not assured of adequate protection from the inherent uncertainties of significant innovative procedures "by any formal compulsory regulatory system."⁴²⁶

B. Malpractice Claims

Injuries from laparoscopic cholecystectomy were amplified by the large number of procedures performed and resulted in a significant increase in malpractice claims and awards compared to the time period before the innovation was available.⁴²⁷ Indeed, one insurance association documented such an increase in a survey of its member companies as follows:

From 1990 to 1994, before minimally invasive techniques entered widespread use, [the Physician Insurers Association of America (PIAA)] received 750 claims relating to gallstone surgery, and made indemnity payments of approximately \$42 million. In 1995-1999, the number of claims rose to 1,426, with indemnity payments of around \$104 million. In the latter period, 60 [percent] of claims involved allegations of improperly performed cholecystectomies, which PIAA attributes to both higher numbers of cholecystectomies being performed and a greater risk of complications from the laparoscopic technique. Tellingly, the rate of paid claims involving cholecystectomy (50 [percent]) vastly exceeds PIAA's overall rate

⁴²³ *Id.* at 939.

⁴²⁴ *Id.*

⁴²⁵ *Id.*

⁴²⁶ *Id.* at 943.

⁴²⁷ JACOBSON, *supra* note 68, at 29. De Ville reports a 500 percent increase in medical malpractice suits arising out of surgical gallbladder removal. De Ville, *supra* note 119, at 205.

of paid claims (31 [percent]), and the average indemnity payment is 26 [percent] higher.⁴²⁸

The injuries and litigation that resulted from the performance of laparoscopic cholecystectomies attracted the attention of surgeons as well. In one study, reported in a 1997 medical journal article, researchers affiliated with a major department of surgery examined medical records associated with forty-six malpractice cases involving common bile duct⁴²⁹ injuries related to procedures performed between 1990 and 1996.⁴³⁰ The purpose of their study was to “increase awareness” among surgeons about this particular type of injury and “educate surgeons about the consequences of these injuries.”⁴³¹ The researchers characterized the medical factors that appeared to affect decisions to litigate. The most significant factors were health complications resulting from delays in identifying injuries and poor treatment of immediately identified injuries.⁴³² The researchers also examined and dismissed previously published assertions that the injuries were the result of the “learning curve,” concluding instead that “no surgeon is immune from the risk of bile duct injury, and no case is simply routine.”⁴³³ In their study, plaintiffs prevailed by verdict or

⁴²⁸ JACOBSON, *supra* note 68, at 29-30 (citing PIAA, LAPAROSCOPIC PROCEDURE STUDY (1994) & PIAA, LAPAROSCOPIC INJURY STUDY (2000)). Jacobson concludes:

One reason for these results is that the procedure has a higher severity index than the conventional procedure (4.25 to 3.94 in the 1994 survey, rising to 4.9 for all claims in the 2000 report, rising to 5.19 for all paid claims). The National Association of Insurance Commissioners (NAIC) publishes the severity index, with codes from 1 (emotional injury) to 9 (death). A severity index of 4 is classified as a major temporary injury without permanent effects. In the laparoscopic studies, the severity index means that many injured patients require an additional surgical procedure that results in no life-long debilitation.

Id.

⁴²⁹ The “common bile duct . . . is the common excretory duct of the liver and gallbladder. It is about three inches in length, of the diameter of a goose-quill, and formed by the junction of the cystic and hepatic ducts.” GRAY’S ANATOMY 926 (15th ed. 1995).

⁴³⁰ B.J. Carroll et al., *Common Bile Duct Injuries During Laparoscopic Cholecystectomy that Result in Litigation*, 12 SURGICAL ENDOSCOPY: ULTRASOUND & INTERVENTIONAL TECHNIQUES 310, 310 (1998).

⁴³¹ *Id.*

⁴³² *Id.*

⁴³³ *Id.* at 312 (“[O]ther investigators have noted an ongoing problem well past the learning period. Nine injuries in this study occurred after the surgeon’s 50th case, and five of these were after the 100th case. . . .”) (citations omitted).

settlement in 86 percent of the cases examined, with an average award of \$214,000.⁴³⁴

C. Reported Legal Cases

There have been at least fifty reported legal cases involving surgical malpractice claims for injuries arising during performance of a laparoscopic cholecystectomy.⁴³⁵ Cases include claims for failure of inadequate informed consent as well as claims of substandard care. For example, *Whiteside v. Lukson*, discussed *supra*, was an informed consent claim based on one of the earliest performances of the procedure reported in a legal case, 1990. The basis of the claim was the materiality of the surgeon's nondisclosure of his experience where he had never performed the procedure on a patient before. The availability of alternatives, particularly the more established procedure of open cholecystectomy, was not a litigated issue.⁴³⁶

An examination of three cases from one jurisdiction provides some insight regarding the diffusion of a surgical innovation from a legal perspective, particularly the impact on the standard of care and on informed consent. It also underscores the fact-specific nature of malpractice cases, and highlights the critical role expert witnesses play in malpractice cases involving surgical innovation.⁴³⁷

*Fusilier v. Dauterive*⁴³⁸ involved one of the earliest performances of the surgery that resulted in a reported legal case.⁴³⁹ The surgery was

⁴³⁴ *Id.*

⁴³⁵ Searches conducted in Westlaw: LAPROSCOP! /p (MALPRACTICE INJUR!) /p CHOLECYSTECTOMY (July 21, 2005). Search conducted in Westlaw: GALL /p BLADDER /p SURG! /p (MALPRACTICE INJUR!) & ((STANDARD /s CARE) ("INFORMED CONSENT")) (July 22, 2005). I eliminated duplicate cases, unpublished cases, and cases where surgical malpractice was not the direct subject of litigation (e.g., malpractice of anesthesiologist; malpractice as basis for state disciplinary action) (July 21, 2005) (results on file with author). *Whiteside v. Lukson*, discussed *supra*, for example, was an informed consent claim based on surgery performed in 1990. The experience of the surgeon was at issue, while the availability of alternatives, particularly the more established procedure of open cholecystectomy, was not at issue. *Whiteside v. Lukson*, 947 P.2d 1263 (Wash. Ct. App. 1997).

⁴³⁶ *Whiteside*, 947 P.2d at 1265.

⁴³⁷ Indeed, the testimony of expert witnesses is central in all medical malpractice cases. *See, e.g.*, *Jones v. Hernandez*, 880 So. 2d 245, 248 (La. Ct. App. 2004) ("The assistance of expert testimony is needed to establish the applicable standard of care, whether the standard of care was breached by the defendant doctor's conduct, and whether that breach resulted in injury to the plaintiff.") (citing *Edwards v. Raines*, 799 So. 2d 1184 (La. Ct. App. 2003); *Pugh v. Beach*, 722 So. 2d 442 (La. Ct. App. 1998)).

⁴³⁸ *Fusilier v. Dauterive*, 764 So. 2d 74 (La. 2000).

⁴³⁹ *Id.*

conducted in 1990 when the technique was in the early stages of adoption.⁴⁴⁰ The case was brought in Louisiana and ultimately reviewed by the Louisiana Supreme Court, which issued its opinion in 2000.⁴⁴¹ In *Fusilier*, the patient brought a malpractice claim alleging that the surgeon had breached the standard of care when he injured three organs during the gall bladder surgery, and two more in his attempts to treat the original injuries.⁴⁴² The original complaint included allegations that that surgeon had “deviated from the accepted standards of medical practice” by breaching the standard of care, lacking appropriate training and experience, and failing to provide appropriate informed consent.⁴⁴³ The Louisiana Supreme Court acknowledged that expert testimony had established that no national standards existed in 1990 for the performance of laparoscopic cholecystectomies.⁴⁴⁴ The court thus implicitly acknowledged the innovative nature of the surgery, and, overturning a jury verdict in favor of the surgeon, found that the lack of an established standard of care under the particular circumstances of the case did not excuse the surgeon from liability for malpractice.⁴⁴⁵ In this case, testimony from plaintiff and defense witnesses directly conflicted on whether the patient’s injuries would have occurred “in the absence of substandard care” by the surgeon.⁴⁴⁶ Significantly, the court found that none of the defendant’s experts offered an adequate explanation for the injuries; the assertion by defense experts that the injuries were “unfortunate ‘complications’” was deemed insufficient.⁴⁴⁷ In addition, the court rejected the defense’s un-

⁴⁴⁰ See discussion of PIAA report *supra* Part V.A.

⁴⁴¹ *Fusilier*, 764 So. 2d at 74.

⁴⁴² *Id.* at 77.

⁴⁴³ *Id.* Allegations in the original complaint included assertions that the surgeon “deviated from the accepted standards of medical practice . . .’ [having, *inter alia*] [f]ailed to comply with the appropriate standard of care; [f]ailed to have the proper training and experience . . . ; [f]ailed to secure informed consent; [f]ailed to warn of, recognize or properly treat medical risks and emergencies.” *Id.* at 77.

⁴⁴⁴ *Id.* at 81.

⁴⁴⁵ *Id.*

⁴⁴⁶ *Id.* at 79.

⁴⁴⁷ *Id.* at 81.

None of the experts testifying at the trial offered any plausible explanation for the injuries plaintiff suffered. The perforations of plaintiff’s aorta, duodenum, and mesentery were all dismissed as unfortunate ‘complications’ of the procedure. The only explanation offered by defendant for perforating plaintiff’s aorta, duodenum, and mesentery, is an unsupported allegation that plaintiff’s aorta must have been displaced. However, the operative report does not reflect that observation, and none of plaintiff’s medical records support defendant’s contention that plaintiff had any anatomic abnormality or variation. The only logical conclusion is that

ported claim that the patient's unique anatomical configuration was the reason for the injuries.⁴⁴⁸

A factor that one would expect to be raised in claims arising during the diffusion period is the quality and extent of the surgeon's training. The court noted that the adequacy of training was the subject of conflicting expert testimony at trial: six months before attempting the surgery, the surgeon participated in a two-day training course and had only used the technique on pigs.⁴⁴⁹ The court explicitly rejected the defense argument that a surgeon comports with the standard of care if he recognizes and addresses complications that arise during the course of surgery.⁴⁵⁰ Clearly, if that contention had been accepted, it would have aided any defense of a standard of care breach related to a newly introduced surgical technique.

*Jones v. Hernandez*⁴⁵¹ involved the performance of the same surgical technique nine years later in 1999.⁴⁵² This case was also brought in Louisiana and reviewed by the Louisiana Court of Appeals (Second Circuit), which issued its opinion in 2004, four years after *Fusilier*. Here, the plaintiff had suffered injury to the common hepatic duct. The court distinguished *Jones* from *Fusilier* by explicitly acknowledging that a national standard for performance of laparoscopic cholecystectomy had emerged in the nine years since the plaintiff in *Fusilier* had undergone the procedure.⁴⁵³ Five of the six experts agreed upon

Dr. Fusilier negligently inserted the needles, either by location or angle, and perforated Mrs. Fusilier's aorta, duodenum, and mesentery.

Id.

⁴⁴⁸ *Id.*

⁴⁴⁹ The defense expert, Dr. J. Barry McKernan, had performed the first laparoscopic cholecystectomy in the United States, and "stated that the training the defendant [surgeon] had received prior to performing the surgery was probably more extensive than most doctors received at that time." *Id.* at 80. The defense expert appeared to contradict his own published opinion that a surgeon's preparation prior to the first performance of the procedure should include, *inter alia*, twenty-five to fifty supervised procedures, a position supported by the plaintiff's expert. *Id.* at 79-81.

⁴⁵⁰ *Id.* at 81 ("We repudiate the contention that the standard of care is met when a physician, who negligently causes injuries, takes measures to correct them.").

⁴⁵¹ 880 So. 2d 245 (La. Ct. App. 2004), *writ denied*, 888 So. 2d 203 (La. 2004).

⁴⁵² *Id.*

⁴⁵³ *Id.* at 254-55.

In *Fusilier*, the claimant underwent laparoscopic cholecystectomy surgery in 1990. The expert testimony was unequivocal that, *at that time*, there were no national standards for physicians to follow regarding the performance of a laparoscopic cholecystectomy. . . . [The surgeon] performed laparoscopic surgery on Jones more than nine years after the surgery in *Fusilier*. During that period of time [expert medical testimony showed that] national standards for surgeons to follow in performing laparoscopic cholecystectomies

and articulated the standard of care.⁴⁵⁴ Here, the plaintiff's injury was considered to be a "known and accepted risk of the procedure."⁴⁵⁵ The decision was rendered in favor of the surgeon despite expert testimony that the surgeon had performed the surgery incorrectly: "[T]he intentional placement of a surgical clip on the common hepatic duct is not within the applicable standard of care; however, injury to the common duct, whether by an inadvertently placed clip or subsequent scar tissue formation, is a known and accepted risk of the procedure."

In contrast to *Jones*, in 2005 the Louisiana Appeals Court (Fifth Circuit) in *Walker v. Corsetti*⁴⁵⁶ also considered *Fusilier* in a case involving surgery performed in 1998. However, the court drew express analogies between the facts of *Fusilier* and *Walker*, overturned the jury verdict in favor of the defendant, and found the surgeon liable for injuries to the patient's common hepatic duct, common bile duct, and hepatic artery.⁴⁵⁷ The court refused to accept the defense argument that it was "simply a case of a recognized complication."⁴⁵⁸ The court was particularly persuaded by the admission by the surgeon that "he [had] made a series of misidentifications during the [procedure]."⁴⁵⁹ Like *Fusilier*, the court also noted the lack of support from experts regarding the surgeon's belief that the patient's anatomy was a reason for the misplacement of certain surgical clips (including clips on the common hepatic duct, as in *Jones*).⁴⁶⁰ It also took into account expert testimony concerning the surgeon's lack of response to the patient's excessive blood loss.⁴⁶¹

From the previous two cases, it certainly can be argued from a defense perspective that there may be a potential benefit for surgeons and their affiliated institutions if known complications are rapidly identified.⁴⁶² Indeed, this would support a policy recommendation for the development of policy mechanisms that can identify early complications arising in surgical innovation.

were developed. . . . [The court finds that there was] sufficient evidence presented [to] show[] that Jones' injuries could have occurred without any negligence on the part of [the surgeon].

Id.

⁴⁵⁴ *Id.*

⁴⁵⁵ *Id.*

⁴⁵⁶ 900 So. 2d 991 (La. Ct. App. 2005), *writ denied*, 904 So. 2d 700 (La. 2005).

⁴⁵⁷ *See id.*

⁴⁵⁸ *Id.* at 996.

⁴⁵⁹ *Id.*

⁴⁶⁰ *See id.*

⁴⁶¹ *Id.* at 94-95.

⁴⁶² *See supra* Part III.A. *See also* Duff, *supra* note 169, § 2[b].

D. Lessons for Surgical Innovation from Case Study Review

This brief review of the evolution and diffusion of one surgical innovation indicates that registries may be a useful strategy for detecting problems with a surgical procedure during its development and refinement. This is especially true for those innovations like laparoscopic cholecystectomy that are rapidly diffused into practice and applied to large numbers of patients in diverse settings. Such registries can help spot issues that may be inherent in the procedure as well as issues that may originate from corresponding training. From a patient safety standpoint as well as a defense perspective, case law supports the need for rapid identification of potential injuries once the procedure emerges out of early development and is introduced to the surgical community. For patients, such a need is vital to prevent injury. From a defense perspective, a surgeon may benefit from the acknowledgment among peers that a particular injury is a known or accepted risk of the procedure.⁴⁶³ Such a need can be addressed with registries and a system of coordination among them.

But this review does not reveal any guidance on how to properly address the very early development of a surgical technique, and how to ensure that patients are properly protected and informed of their participation in the development of a surgical innovation. This procedure evaded IRB review from the outset because the innovating surgeon and early adopters did not characterize it as research, or were not within the reach of federal regulatory requirements. Randomized controlled studies conducted with IRB review missed detecting the critical injuries. Also, study results were not reported until four years after the procedure's first performance, when the procedure was already being performed by many and already stimulating legal claims.

The medical literature surrounding laparoscopic cholecystectomy reveals accolades and honors for the surgical innovator, Dr. McKernan.⁴⁶⁴ Although Dr. McKernan's claims record is not publicly available, there are no reported legal cases involving him or his performance of this procedure.⁴⁶⁵ Further, there is an approximate two-year delay between his first performance of the surgery and the procedure's

⁴⁶³ See JONES, *supra* note 285, at 7; discussion on known or accepted risk of the procedure *infra* Part VI.

⁴⁶⁴ See, e.g., W. Peter Geis, *J. Barry McKernan, MD, PhD—A Profile*, 8 J. SOC'Y LAPAROENDOSCOPIC SURGEONS 399 (2004); Michael S. Kavic, Editorial, *A Decade of Laparoscopic Cholecystectomy*, 2 J. SOC'Y LAPAROENDOSCOPIC SURGEONS 319 (1998).

⁴⁶⁵ Indeed, at least one early case indicates his appearance as an expert for the defense. See, e.g., *Fusilier v. Dauterive*, 764 So. 2d 74 (La. 2000).

performance by another surgeon that prompted a reported legal case. All that is readily available for any assessment during this two-year void is the doctor's personal accounting of the informed consent process for the first time attempt of the procedure. From that account, one can sense the trust of patients in the expertise of a well-regarded surgical innovator and the willingness of some patients to try new approaches even in the face of contrary medical opinions. Thus, for this early critical period before diffusion into the broader surgical community, for the benefit of patient safety, one must consider other solutions, which are introduced below.

RECOMMENDATIONS AND CONCLUSIONS

An ideal system of oversight and control for surgical innovation would ensure an appropriate balance between two goals: (1) the protection of the rights and welfare of patients, including protection from both unintentional or unconsented harm, and (2) encouragement of innovation to enhance the possibility of the best health outcomes for individual patients and the advancement of medicine for the benefit of all patients.⁴⁶⁶ Currently, surgical innovation will follow one of two pathways through the legal system, treated either as research or practice. Each pathway is supported by historical roots that clearly indicate an intention to address the aforementioned goals, but in practice have been found deficient in adequately balancing them. Each pathway, however, has certain commendable qualities that are worthy of replication in some form in efforts to achieve such a balance. For example, at a minimum, one can conclude from both legal pathways that prior review of scientific merit and ethical concerns, including informed consent that acknowledges the innovative nature of the therapy and associated unknown risks, not only meets the requirements of federally regulated research, but may potentially provide a partial defense in an action for research or medical malpractice action. At their core, these actions have the effect of enhancing patient safety and encouraging innovation while safeguarding the trust of patients in medicine and research.

What is the appropriate policy response to surgical innovation? Many commentators in the medical and ethics literature have advocated for increased attention to and oversight of innovative surgery.⁴⁶⁷ Below, I briefly summarize from a legal perspective first

⁴⁶⁶ Inherent within these goals are many sub-goals, including ensuring the financial viability of institutions to continue support for the development of innovations designed to advance human health.

⁴⁶⁷ *E.g.*, Reitsma & Moreno, *supra* note 31, at 107; Gillett, *supra* note 96, at

the challenges of retaining the current approach and second, the challenges of subjecting surgical innovation to the federal research oversight system. I conclude with a recommendation for an approach tailored to surgical innovation, which includes three components: (1) monitoring through registries designed to evaluate surgical outcomes, (2) institutional oversight and review, and (3) educational initiatives for surgeons.

A. Maintaining the Status Quo⁴⁶⁸

If no changes are sought in the current approach to surgical innovation, from a legal perspective innovative surgery will in most cases default to the Practice Pathway and the malpractice system. As discussed *supra*, this may be attributed to, *inter alia*, the following circumstances: decisions to subject an innovation to regulatory oversight are made by the surgeons who perform the innovative surgery in the context of the institutional and legal culture in which they practice; the ambiguity surrounding the definition of research, both in the federal regulations themselves and the understanding of surgeons; and the inherent limitations in reach of the federal research regulations, specifically the failure to cover some research that is privately funded and conducted.

There are significant problems associated with reliance on the Practice Pathway (the malpractice system) to prevent injuries and protect the rights and welfare of patients. First, any review of the procedure for safety or effectiveness is *post hoc*, and there is little opportunity for prevention of injury and protection of patient interests. Litigation is not a good substitute for the scrutiny of scientific review by

898; Casler, *supra* note 29; Jones, *supra* note 109, at 399-400; Lyon, *supra* note 34; Ward, *supra* note 1; Editorial, *supra* note 22; Bunker et al., *supra* note 5; Strasberg & Ludbrook, *supra* note 10; Scott, *supra* note 339, at 425; Dossetor, *supra* note 4; Spodick, *supra* note 20; Margo, *supra* note 67; Rutan et al., *supra* note 47; Francis D. Moore, *Ethical Problems Special to Surgery: Surgical Teaching, Surgical Innovation, and the Surgeon in Managed Care*, 135 ARCHIVES SURGERY 14 (2000); Martin F. McKneally, *Ethical Problems in Surgery: Innovation Leading to Unforeseen Complications*, 23 WORLD J. SURGERY 786 (1999); *Statements on Emerging Surgical Technologies and the Evaluation of Credentials*, AM. C. SURGEONS BULL., June 1994, at 40; Rosamond Rhodes, *An Innovative Paradigm for Clinical Research*, 3 AM. J. BIOETHICS 59 (2003); Michael D. Sussman, *Ethical Requirements that Must Be Met Before the Introduction of New Procedures*, 378 CLINICAL ORTHOPAEDICS & RELATED RESEARCH 15 (2000).

⁴⁶⁸ A small number of medical commentators have defended the current approach to surgical innovation typically in response to published articles advocating change. See, e.g., Gates, *supra* note 25, at 1353; Bonchek, *supra* note 2, at 45 ("The referring physician is thus the surgeon's Food and Drug Administration.").

peers. Also, the Practice Pathway offers no opportunity for outcomes evaluation beyond the individual result that is the subject of litigation. Indeed, the Practice Pathway can only address the alleged bad outcomes that have reached the level of legal scrutiny, and the deterrent effect of malpractice litigation on physician behavior and negligence prevention is generally thought to be questionable.⁴⁶⁹

Second, the malpractice system essentially rests on a standard of care which is established by peers. The history described herein supports that reliance on this level of review could result in the propagation of unvalidated procedures. Third, and maybe most important, to leave innovative surgery in the realm of practice or routine health care does not reflect reality, i.e., such innovations are treated as routine health care, but in reality it may instead be health care with less certainty about the outcome and benefits, and significant unknown risks. The legal review herein has shown that as a matter of legal risk management, informed consent should routinely reveal the procedure's innovative nature and the possibility of unknown risks where appropriate. This is especially important where the innovation constitutes a significant departure from standard practice and is not simply a justified adaptation to the individual's anatomical configuration. Empirical data support that this disclosure has not been integrated into practice, which provides more evidence of the inability of the tort system to rectify professional practice standards. Fourth, it has been well-documented that the medical malpractice system is an inefficient tool for adverse event compensation.⁴⁷⁰

B. Subjecting Surgical Innovation to the Research Pathway⁴⁷¹

Relatively few surgical innovations currently undergo review pursuant to the federal regulations. The benefits of subjecting innovative surgery to the Research Pathway are relatively straightforward: the Research Pathway provides opportunities for the collection of com-

⁴⁶⁹ See Michelle M. Mello et al., *Fostering Rational Regulation of Patient Safety*, 30 J. HEALTH POL. POL'Y & L. 375, 388 (2005).

⁴⁷⁰ David M. Studdert et al., *Medical Malpractice*, 350 NEW ENG. J. MED. 283 (2004) ("Commentators lament the 'lawsuit lottery,' which provides windfalls for some patients, but no compensation for the vast majority of patients injured by medical care."); Mello et al., *supra* note 469, at 388 ("Although a number of studies have concluded that the system does a fairly good job of directing compensation to plaintiffs with valid claims, other studies have determined that many cases in which compensation is awarded lack evidence of negligence, a cognizable injury, or both.").

⁴⁷¹ Some commentators have pointed out benefits of treating surgical innovation as research. See, e.g., Margo, *supra* note 67; Strasberg & Ludbrook, *supra* note 10.

parative information; it offers clearer direction on the quality of informed consent; and, it generally provides opportunities to prevent unvalidated procedures from proceeding without appropriate patient protections by using processes such as prospective review and fully informed consent. These actions increase the likelihood that harm to patients will be prevented and potentially decrease liability exposure for providers and their respective institutions.⁴⁷²

Numerous legal and practical challenges arise in attempts to apply the federal research framework to surgical innovation. Surgical innovation would have to clearly meet the regulatory definition of “research” to fall within the purview of federal oversight. When and if it does is not clear, and such determinations are made on a case-by-case basis at the local level. At that level, like all research, participation in prospective review requires an affirmative act by an investigator as IRBs have no way to monitor compliance directly. In surgical innovation, the surgeon or the surgeon’s institution has this decision-making authority. The numerous complaints about the functioning of the prospective review system by those who are required through federal regulation to submit their research projects to such reviews—complaints such as timeliness of approval, lack of expertise, and variability in implementation of the regulations among IRBs⁴⁷³—are likely to discourage surgeons from submitting their projects to such review unless it is clearly an institutional or regulatory requirement.

Arriving at an appropriate mechanism to compel surgeons to submit surgical innovation into the Research Pathway is an onerous task. Broadening the Common Rule’s definition of research, for example, is daunting, especially in light of the nine-year process involved in the regulation’s creation. It may also have unintended effects in other areas of medicine, the assessment of which are beyond the scope of this article. More practically, the regulatory definition of research could be interpreted more expeditiously in OHRP guidance documents to encompass surgical innovation or aspects thereof, but would suffer the deficiency in legal force of informal administrative action. Such an official interpretation would likely be respected by

⁴⁷² Practically speaking, any attempt to further refine the definition of research to include surgical innovation (or particular aspects) may not affect a court’s interpretation as research or practice. Legal decisions show that many courts, especially in actions involving patients, may ignore such definitions and apply medical malpractice law. However, the increase in litigation involving research and the willingness of judges to second guess the decisions of IRBs, such as in *Grimes v. Kennedy Krieger Institute, Inc.*, 782 A.2d 807, 813 (Md. 2001), may limit the impact of this approach on liability exposure.

⁴⁷³ See, e.g., GAO, Continued Vigilance, *supra* note 334.

institutions and providers, and could lay out a process or flow chart for determining whether and when surgical innovation meets the definition of research. Regardless, federal regulations will not reach surgical innovation that lacks a federal nexus, e.g., novel procedures conducted in private clinics.

Required regulatory oversight for surgical innovation would in some cases lead to controlled trials of new techniques. Clinical trials are expensive, however, and there are few sources of support for surgical trials. Further, as discussed in Part I, *supra*, there is significant disagreement in the surgical community about the benefits, risks, appropriate timing and use of randomized controlled trials.

Perhaps the most significant disincentive for generally categorizing surgical innovation as research is its potential impact on reimbursement. Insurers typically deny reimbursement for experimental procedures,⁴⁷⁴ so such a classification potentially jeopardizes the financial standing of surgical institutions and providers who may face challenges recouping payments from patients who are otherwise financially unprepared to pay the large sums associated with surgery.⁴⁷⁵

Notwithstanding the potential benefits accruing to individual patients, this approach has obvious negative impacts on the aforementioned goal of encouraging innovation. These impacts emanate particularly from the additional time and costs of entering the federal research bureaucracy which may work directly or indirectly to stifle innovation. Overall this approach has significant implications for surgeons and institutions, both in time and dollars spent in monitoring, compliance and documentation, and dollars lost from reimbursement denials and collection efforts. It also may affect the financial status of sick patients who are unable to obtain reimbursement for needed surgical treatment.

C. Developing a Unique System of Oversight

The “status quo” approach and the “research” approach have commendable qualities but, as highlighted above, significant limitations as well. In the alternative, numerous commentators have suggested various strategies that considered together could be the

⁴⁷⁴ See discussion on insurance reimbursement *supra* Part I.B.

⁴⁷⁵ Margo, *supra* note 67, at 42 (“The fear that formal preliminary testing of innovative surgeries might not be reimbursed by third party payers may be a strong disincentive for academic medical centres to police seriously the area of informal research.”).

basis for development of a system of oversight tailored to surgical innovation.⁴⁷⁶

This article suggests a three-pronged approach to surgical innovation: (1) use of registries to detect and evaluate outcomes and adverse events; (2) local institutional attention and oversight to address informed consent and additional review; and (3) educational initiatives. Any innovation which clearly meets the definition of research and is subject to the federal regulations should continue to be treated as such.

Registries have proven to be valuable in documenting outcomes as surgical innovations are introduced and diffused into practice. For example, state, institutional, and surgical society registries were critical in the detection of the increased rate of bile duct injuries in laparoscopic cholecystectomy, which prompted evaluation and review of training procedures.⁴⁷⁷ In contrast, early RCTs comparing laparoscopic to the more invasive open cholecystectomy did not identify these problems, and even if they had, clinical trial results were not available until well past the stage of more widespread adoption of the procedure. The experience with laparoscopic cholecystectomy further reveals a gap in time and oversight between the first performance of the innovation and the detection, assessment and reporting of the rate of recurring injuries. Some form of mandatory state or national reporting would increase the likelihood of identifying and addressing problems in their early stages, including those related to the procedure itself or to training and credentialing of providers. This is especially the case where, as in laparoscopic cholecystectomy, the condition being treated affects numerous people throughout the country and the rate of complication is a relatively infrequent occurrence from a population perspective.⁴⁷⁸ For procedures that are more controlled or limited in diffusion, institutional data gathering may be appropriate.⁴⁷⁹

Potential models exist for registries. For example, the National Surgical Quality Improvement Program (NSQIP) was established by the U.S. government's Veteran's Administration Health System in 1992 and has a documented track record in outcomes evaluation.⁴⁸⁰

⁴⁷⁶ These include prior review. *E.g.*, Reitsma & Moreno, *supra* note 31; Casler, *supra* note 29; Jones, *supra* note 109; Ward, *supra* note 1. These also include enhanced disclosure in informed consent. *E.g.*, Jones, *supra* note 109; Strasberg & Ludbrook, *supra* note 10; McKneally, *supra* note 467; Moore, *supra* note 467. These also include monitoring. *E.g.*, McKneally, *supra* note 467; Scott, *supra* note 339, at 421, 425; Am. Coll. of Surgeons, *supra* note 78; Dossetor, *supra* note 4; Strasberg & Ludbrook, *supra* note 10.

⁴⁷⁷ See Strasberg & Ludbrook, *supra* note 10, at 946.

⁴⁷⁸ See *id.* at 945.

⁴⁷⁹ See *id.*

⁴⁸⁰ Jones, *supra* note 109, at 399-400.

The American College of Surgeons, with government funding, has developed and recently piloted a comparable program intended to serve the private sector.⁴⁸¹ In addition, surgical specialty societies have created effective registries.⁴⁸² Strasberg and Ludbrook advocate instituting mandatory registries, but doing so with “care and selectivity” for many reasons: high costs of data collection and analysis,⁴⁸³ need for patient confidentiality protections, reporting burdens on busy practitioners, and the continuing need for well-designed research trials to answer questions that cannot be addressed through registries.⁴⁸⁴ Thus, a mechanism needs to be created and criteria developed to prompt the creation of such registries where appropriate.

Institutional efforts at prospective data collection, while not rising to the level of formal registries, could prove valuable in the detection of adverse events.⁴⁸⁵ Such data could be collected as a part of routine quality improvement (QI) efforts. In addition, institutional QI experiences could be important resources in the development of the aforementioned criteria for registry creation.

Although registries are equipped to identify adverse events and prompt additional studies, they cannot address potential legal and ethical issues arising in the earlier stages of development, such as informed consent, the appropriate balancing of risks and benefits, and selection of patients.

Based on the preceding legal review, enhanced disclosure during informed consent and prospective review are two factors that may assist in serving the twin goals of improved patient safety and encouragement of innovation, all operating within the culture of innovation and independent decision-making that are hallmarks of surgery and its history of tremendous medical advances. These factors may assist in managing liability exposure of providers and institutions involved in surgical innovation, as well as addressing important concerns raised in the literature. Institutional controls could be introduced to manage and oversee innovation to ensure appropriate prior review and informed consent, as well as other important ethical issues. This approach

⁴⁸¹ *Id.*

⁴⁸² The Society for Cardiac Angioplasty and Interventions has created an effective registry. Strasberg & Ludbrook, *supra* note 10, at 946.

⁴⁸³ The authors make a compelling cost argument, however, in favor of registries. Using laparoscopic cholecystectomy as an example, they compare the average cost of injuries to potential savings from early detection of adverse events, and suggest that registry funding could be borne by adding a few cents to all insurance policies. Strasberg & Ludbrook, *supra* note 10, at 946.

⁴⁸⁴ *Id.*

⁴⁸⁵ *Id.*

would provide opportunities to protect patients and could also inform risk management strategies. Potential models exist for institutional control mechanisms. In 2001, Boston Children's Hospital introduced a voluntary program of institutional oversight specific to surgical innovation.⁴⁸⁶ The policy defines innovative therapy and defines the conditions under which it should be considered research that is subject to review and approval by the local IRB.⁴⁸⁷ It further provides for a distinct intermediate level of review and oversight for innovative surgery that (1) "represents a significant increase in risk, above the alternative approaches [that [sic]] could have been offered," or (2) "when the procedure is so novel that the risks and benefits are unknown."⁴⁸⁸ The system of oversight includes: independent peer review by departmental members not affiliated with the patient care team, in light of the clinical situation of the patient and available alternatives, with an emphasis on assuring patient safety; informed consent review and

⁴⁸⁶ Susan Kornetsky, Children's Hosp., Boston, Children's Hospital: Guidelines, Concepts and Procedures for Differentiating Between Research and Innovative Therapy (2001) [hereinafter Children's Hospital Guidelines] (unpublished policy) (on file with author); Telephone Interview with Susan Kornetsky, Dir. Clinical Research Compliance, Children's Hosp., Boston, in Boston, Mass. (Mar. 15, 2005) [hereinafter Telephone Interview with Susan Kornetsky, Mar. 15, 2005]. Institutional representatives prepared a manuscript for publication discussing the guidelines. SUSAN KORNETSKY, INNOVATION VERSUS RESEARCH: GUIDELINES, CONCEPTS AND PROCEDURES FOR DIFFERENTIATION (2006), http://www.childrenshospital.org/cfapps/research/data_admin/Site2206/Documents/cipp_081_015_innovation_vs_rsrch.doc (last visited Apr. 3, 2006). Telephone Interview with Susan Kornetsky, Dir. Clinical Research Compliance, Children's Hosp., Boston, in Boston, Mass. (Sept. 6, 2005) [hereinafter Telephone Interview with Susan Kornetsky, Sept. 6, 2005].

⁴⁸⁷ Children's Hospital Guidelines, *supra* note 486.

Innovative therapy occurs when a practitioner proposes to use a treatment, procedure or intervention in a way that deviates from commonly accepted practice in a clinical encounter. Innovative therapy can be characterized by one or more of the following principles: a) A non-standard treatment or approach that is used solely to attempt to enhance the well being of an individual patient. b) A change from a currently accepted practice by the medical community that is based on scientific observations and explicit rationale. c) The modification of commonly accepted procedures in small incremental steps. d) Whenever innovative therapy differs significantly from routine practice it should be viewed as experimental. In all such cases the need to evaluate the therapy/procedure by a scientifically sound methodology under a formal research protocol should at least be considered although the fact that the procedure is novel does not automatically place it in a category of research. However, when new procedures are used repeatedly, they should be made the object of formal research at an early stage, in order to determine whether the innovation is both safe and effective.

Id.

⁴⁸⁸ *Id.*

approval at the administrative level of the IRB (not full committee review); and documentation of peer review and informed consent processes.⁴⁸⁹ The policy further provides guidance on distinguishing between innovative therapy and research and provides illustrative examples of each of the three resulting categories: (1) research, (2) “[i]nnovative [t]herapy with [o]versight,” and (3) “[i]nnovative [t]herapy without [s]pecial [p]rotections.”⁴⁹⁰ Ambiguous cases are decided by the department chair, and a mechanism has been instituted to assist surgeons in identifying procedures that should be characterized as research, prompting consideration under formal procedures for IRB approval. The success of this 2001 program has not yet been fully evaluated, but it serves as a model for locally-based attempts to reign in the uncertainties and ambiguities surrounding surgical innovation, in an attempt to enhance patient safety while encouraging innovation.

Educational initiatives⁴⁹¹ by institutions and professional associations will be important in assisting surgeons in identifying the circumstances under which surgical innovation constitutes research or otherwise requires additional disclosure to patients. This is especially important in light of the empirical data showing confusion and misunderstanding among surgeons about when surgical innovation should be treated as research. Educational initiatives could also point out the benefits of independent review. If combined with training, credentialing, and monitoring related to the introduction of new procedures into the clinic setting, more patients may be protected from the “risks of the ‘learning curve.’”⁴⁹² Such initiatives could go far in broadly influencing surgeons’ understandings of the appropriate standard of care for surgical innovation.

At core, a failure to recognize the need for increased attention to surgical innovation is a failure to acknowledge the vulnerability of the patient and the risk to the physician-patient relationship.⁴⁹³ In his assessment of surgical innovation, Margo states it as follows: “The most likely threat to patients may not be that an untested treatment is unsafe, but that the trust of patients in their physicians may be compro-

⁴⁸⁹ *See id.*

⁴⁹⁰ *Id.*

⁴⁹¹ Commentators include educational initiatives in their recommendations. *See, e.g.,* Sussman, *supra* note 467, at 21; Rutan et al., *supra* note 47; Jones, *supra* note 109.

⁴⁹² Jones, *supra* note 109, at 401. Note also that the American College of Surgeons has stressed the importance of credentialing as well. Am. Coll. of Surgeons, *Statement on Emerging Surgical Technologies and the Evaluation of Credentials*, 79 AM. C. SURGEONS BULL. 40 (1994).

⁴⁹³ Margo, *supra* note 67, at 41.

mised⁴⁹⁴ Once such trust is undermined, the public's willingness to allow professional self-regulation and deference to physician judgment can be replaced by aggressive regulation and oversight. Such a response risks chilling innovation at the expense of present and future health benefits to patients, creating an imbalance in the goals of patient safety and encouragement of innovation.

⁴⁹⁴ *Id.*