Principles over Principals? How Innovation Affects the Agency Relationship in Medical and Legal Practice

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ABSTRACT:

This Note outlines a conceptual framework for defining and analyzing innovation in the professional practice of medicine and law. The two professions have structural and historical similarities, and both are organized around the principal-agent relationship. Some types of professional activity adhere to the traditional agency model of principal-centered practice, but innovative professionals who develop novel tools and techniques often deviate from the agency model in interesting ways. This Note explores how that distinction plays out by identifying examples from academic medicine, public interest "cause lawyering", and corporate law. The field of medicine is governed by a regulatory regime that strictly differentiates routine practice from the experimental activities of clinical research, but the legal profession is governed by a monolithic code of conduct that does not explicitly acknowledge the types of innovation described here. Certain key events in the twentieth century help to explain why the government has chosen to tightly regulate innovation in medicine but not in law, and it turns out that innovators in both fields have found ways to stretch or bend the rules. These observations shed light on each profession's unique culture and can inform current debates over regulatory reform.

* J.D. expected 2015 from the Yale Law School. The author would like to thank Professor Bill Sage for his guidance in shaping and developing the topic; Professors Jeffrey Katz, Lawrence Fox, and Susan Martyn for their helpful feedback on later drafts; and the wonderful editors at the Yale Journal of Health Policy, Law, and Ethics for their thoughtful suggestions and careful edits.

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INTRODUCTION: WORKBENCH AND LAB BENCH

Lawyering on behalf of a client is an inherently goal-oriented occupation. The Model Rules of Professional Conduct instruct each attorney to "take whatever lawful and ethical measures are required to vindicate a client's cause or endeavor" and to "act . . . with zeal in advocacy upon the client's behalf."[1] In the classical conception of litigation, the opposing lawyers deliver rousing orations and hurl pointed objections to persuade the decision makers to accept their version of the facts and interpretation of the law. This clash is the crux of our adversarial legal system, which is predicated on "the assumption that the truth of a controversy will best be arrived at by granting the competing parties, with the help of an advocate, an opportunity to fight as hard as possible."[2]

In this view, the courtroom is like a workbench. Just as a carpenter takes a block of wood and carefully cuts, shapes, and sands it down into a chair, the attorneys take turns hewing away unhelpful facts and spurious reasoning to reveal the ultimate truth at the heart of the case. Through their antagonistic advocacy, they fulfill their roles as officers of the court in a coordinated and linear journey toward securing a just resolution.[3]

As an alternative perspective, we might swap the workbench for a laboratory bench. Like scientific researchers who devise methodical experiments to determine descriptive characteristics and isolate causal relationships,[4] each attorney presents a hypothesis about the outcome of the case, and carefully combines this piece of evidence with that legal argument to see if a favorable theory will carry the day.[5] Unlike the workbench analogy, where skilled craftsmen practice routine gestures to achieve an expected end, the process of experimentation is non-linear. The results of an experiment may not turn out as expected or hoped, but each case serves to advance or reaffirm the body of legal precedent that defines what the law "is" for future litigants.[6] In this way,

1. MODEL RULES OF PROF'L CONDUCT R. 1.3 cmt. para. 1 (2013) [hereinafter MODEL RULES].

2. Robert Gilbert Johnston & Sara Lufrano, *The Adversary System as a Means of Seeking Truth and Justice*, 35 J. MARSHALL L. REV. 147, 147 (2002).

3. *See id.* at 161.

4. "[T]he structure of scientific experiments is fundamentally stable all across the basic-clinical spectrum." Steven Joffe & Franklin G. Miller, *Bench to Bedside: Mapping the Moral Terrain of Clinical Research*, 38 HASTINGS CTR. REP. 30, 34 (2008) (describing the scientific method of prospectively defined hypothesis, research methods, and outcome assessment metrics).

5. The lawyers challenging anti-contraception statutes in the 1960s, for example, proposed that the laws were unconstitutional because they "den[ied] appellants the right to liberty and property without due process of law in violation of the Fourteenth Amendment." Brief for Appellants at 11, Griswold v. Connecticut, 381 U.S. 479 (1965).

6. *See, e.g.*, 1 BRUCE ACKERMAN, WE THE PEOPLE: FOUNDATIONS 17 (1991) (explaining that the "common law tradition" is rooted in "the patterns of concrete decisions built up by courts . . . over decades, generations, centuries").

litigation creates "generalizable knowledge," the defining feature of medical research.[7]

The lab bench analogy is not appropriate for all types of legal work, however. Preparing standard documents and settling run-of-the-mill disputes seem more like the familiar everyday tasks of a craftsman. Legal activity starts to look more like experimentation when it is motivated at least in part by the desire to establish generalizable knowledge or impact beyond the desire for a favorable outcome in the particular case for the particular client. Typically, the opportunity for novel developments in law arises out of some novel element in the fact pattern or legal argument.

This division is familiar in the world of medicine, where medical practice on human patients and medical research on human subjects are strictly differentiated with separate ethical[8] and legal codes.[9] The Belmont Report, the foundational code of ethics for research on human subjects,[10] emphasizes the pursuit of "generalizable knowledge" to differentiate research from "medical or behavioral practice," which is based on diagnosis and treatment.[11] As the Report explains, "The fact that a procedure is . . . new, untested or different[] does not automatically place it in the category of research."[12] Rather, the defining feature is one of intent: research is "designed to test an hypothesis [and] permit

7. *See* 45 C.F.R. § 46.102 (2014) (defining "research" as "a systematic investigation . . . designed to develop or contribute to *generalizable knowledge*") (emphasis added).

8. *See* Nat'l Comm. for the Prot. of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, U.S. DEPT. HEALTH & HUM. SERVICES (HHS) (April 18, 1979) [hereinafter *Belmont Report*], http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html. The *Belmont Report* states that research in human subjects must be guided by the core ethical principles of respect for persons, beneficence, and justice.

9. *See* Joel Kupersmith, *Reforming the Research Regulatory System*, HEALTH AFF. BLOG (Apr. 24, 2013, 2:26 PM), http://healthaffairs.org/blog/2013/04/24/reforming-the-research-regulatory-system/ (noting that categorizing an activity as research triggers "an intensive set of requirements[,] . . . including review, approval, and continued oversight by an Institutional Review Board (IRB); reporting requirements; the necessity for informed consent (often highly complex); and other administrative components"). These requirements apply to all research in human subjects that receives federal funding, as outlined in the HHS "Common Rule." 45 C.F.R. § 46 (2014).

10. *See Federal Policy for the Protection of Human Subjects ("Common Rule")*, HHS, http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html (last visited June 6, 2013) ("The current U.S. system of protection for human research subjects is heavily influenced by the *Belmont Report*, written in 1979.").

11. *See Belmont Report*, *supra* note 8.

12. *Id.* The *Belmont Report* describes novel treatments as "experimental" whether or not they constitute research. I removed the term to avoid confusion with my chosen terminology in this Note, as explained below. *See infra* notes 21–24 and accompanying text. Briefly, I use "experimentation" as a trans-substantive concept equivalent to medical research, with a focus on generalizable knowledge. I use "uncertainty" to refer to the untested nature of novel developments.

conclusions to be drawn."[13] These conclusions go beyond the specific results of the study and express "theories, principles, and statements of relationships" in order "to develop or contribute to generalizable knowledge."[14]

This distinction between medical treatment and medical research serves as a point of departure for this Note, which explores innovation in the professional practice of medicine and law. Innovation has long been an essential feature of both occupations, but only recently have scholars begun to describe the process of innovation itself[15] and to determine how best to promote creativity as part of professional education and training.[16] Doctors and lawyers are often cited side by side in discussions of the "learned professions"[17] and obligations in principal-agent relationships.[18] These historical and structural similarities help to highlight the common processes at the heart of medical and legal innovation, and cast in sharp relief the stark differences in the way the federal government has approached the regulation of innovative practitioners in each field.[19]

This discussion matters because of the important role that doctors and lawyers play in supporting individual prosperity and promoting social wellbeing.

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13. *Belmont Report*, *supra* note 8.

14. *Id.*

15. *See* Riskin et al., *Innovation in Surgery: A Historical Perspective*, 244 ANNALS SURGERY 686, 686 (2006) ("While innovation in surgery has a rich tradition, the field and study of surgical *innovation* are new."); Kenneth C. Kettering, *Securitization and Its Discontents: The Dynamics of Financial Product Development*, 29 CARDOZO L. REV. 1553, 1554–55 (2007) ("Shelves are laden with scholarly writings on particular innovations . . . . But studies of the process of innovation, though not unknown, are comparatively few.").

16. *See* Roberta B. Ness, *Commentary: Teaching Creativity and Innovative Thinking in Medicine and the Health Sciences*, 86 ACAD. MED. 1201, 1201 (2011) ("Although academic medicine provides informal training in creativity and innovation, it has yet to incorporate formal instruction on these topics into medical education."); Karl S. Okamoto, *Learning and Learning-to-Learn by Doing: Simulating Corporate Practice in Law School*, 45 J. LEGAL EDUC. 498, 500 (1995) (noting that "*innovation* is a word we rarely hear in law school," and that "[i]nnovation requires a different kind of self-learning" than what is currently taught).

17. *See, e.g.*, Edmund D. Pellegrino, *Character, Virtue and Self-Interest in the Ethics of the Professions*, 5 J. CONTEMP. HEALTH L. & POL'Y 53, 58 (1989).

18. *See, e.g.*, E. Haavi Morreim, *The Clinical Investigator as Fiduciary: Discarding a Misguided Idea*, 33 J.L. MED. & ETHICS 586, 593 (2005) ("[I]n some cases the whole point of the activity is to promote someone's right, e.g. as when an attorney defends his client's innocence, or when a physician diagnoses and treats a patient.").

19. Clinical research is largely regulated at the federal level. *See infra* notes 185–188 and accompanying text. The legal profession is largely self-regulated. *See infra* notes 191–192, and accompanying text. Legal practice is governed at the state level, but state codes of professional conduct are based in large part on the Model Rules of Professional Conduct, which are developed by the American Bar Association (ABA). *See* Ctr. for Prof'l Responsibility, *Model Rules of Professional Conduct*, ABA, http://www.americanbar.org/groups/professional_responsibility/publications/model_rules_of_professional_conduct.html (last visited Mar. 1, 2014) ("California is the only state that does not have professional conduct rules that follow the format of the ABA Model Rules of Professional Conduct.").

The actual work of open heart surgery may bear little resemblance to cross-examining a witness, but as this Note argues, doctors and lawyers share common heuristics for improving the efficiency and efficacy of their work. Exploring the features they have in common also allows us to identify particular characteristics that make each profession unique, highlighting traits that should guide future discussions about regulatory reform.

To organize my comparison of the two occupations, I outline in Part I a generalized conceptual framework for professional activity. Routine practice and experimentation are not a stark binary; rather, they sit at opposite ends of a spectrum. Professional practice is defined by the principal-agent relationship, in which the agent aims to serve the principal's interest. Novel elements and developments move us along the spectrum toward experimentation, but the operative distinction between practice and experimentation is a reorientation of the agent's focus from the interests of the principal to the interests of the broader class of individuals to which the principal belongs.

Part II fills in the conceptual framework by examining where innovative activity actually occurs, explaining that innovation and experimentation are primarily concentrated in a few professional contexts. Academic medical centers produce most of the major advances in medical practice and research. Novel legal techniques and strategies, meanwhile, are typically generated by attorneys in two highly disparate lines of work: "cause lawyers" who use litigation as a tool for social change,[20] and attorneys in prestigious private firms who innovate on behalf of large corporate clients.

Part III notes that both professions struggle with the challenge of accurately representing reality when designing research studies or planning litigation strategy, as well as the difficulty of encouraging the adoption of novel developments beyond the small communities of innovators identified in Part II.

Despite these similarities in the processes and players of innovation, the two professions are subject to very different regulatory regimes. The federal government has imposed a dualistic regulatory model on medicine, with a bright line differentiating medical research from medical treatment. The legal profession, meanwhile, maintains a single code of professional conduct that does not explicitly acknowledge innovation. Part IV explains that difference by exploring the historical development and rationales of these regulations.

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20. "Cause lawyer" is the term used by Stuart Scheingold and Austin Sarat, who have been leaders in producing and assembling scholarship on this branch of the legal profession. *See* STUART A. SCHEINGOLD & AUSTIN SARAT, SOMETHING TO BELIEVE IN: POLITICS, PROFESSIONALISM, AND CAUSE LAWYERING 5 (2004) [hereinafter SOMETHING TO BELIEVE IN] (explaining why they prefer "cause lawyer" over other terms). Labels like public interest lawyer, movement lawyer, and social justice lawyer have also been used to signify the same class of attorneys or to differentiate within or between classes of attorneys.

Part V concludes with the observation that even with widely divergent regulatory approaches, both professions show evidence of gravitating toward the middle of the spectrum: practitioners seek to capture the benefits of novel developments, while professionals engaged in experimentation often retain elements of the principal-centered ethical framework characteristic of routine practice. This observation not only underscores the essential commonalities of innovative work in the two professions, but also brings a new perspective to current debates about the future directions of regulatory reform.

Finally, a brief note on terminology. "Experimentation" is no longer the preferred term for medical research involving human subjects, which is now called "clinical research."[21] For the purposes of this Note, however, "experimentation" will serve as a trans-substantive term for professional activities that seek generalizable knowledge or impact through planned and controlled interactions with individuals, as outlined in Section I.C.[22] Similarly, the "principal-agent relationship" will provide a generalized vocabulary for discussing patients, subjects,[23] and clients (principals) and their relationships with doctors, clinical researchers,[24] and lawyers (agents). The term "innovation" is used throughout to refer to a novel development, such as a new surgical technique or a creative corporate structure.

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21. *See* Nat'l Inst. of Child Health and Human Dev., *Clinical Trials & Clinical Research*, NAT'L INSTS. HEALTH (last updated Mar. 6, 2012), http://www.nichd.nih.gov/health/clinicalresearch/Pages/index.aspx ("Clinical research is research that directly involves a particular person or group of people."). These terms matter, as has been documented in studies polling patients about their willingness to participate in potential activities with various names. Surveyed patients have consistently reported that "medical experiments" sound riskier than terms like "medical research" or "clinical studies." *See* Ronald R. Butters et al., *Semantic and Pragmatic Variability in Medical Research Terms: Implications for Obtaining Meaningful Informed Consent*, 75 AM. SPEECH 149, 162 (2000); Jeremy Sugarman et al., *What Patients Say About Medical Research*, ETHICS & HUM. RES., Jul.–Aug. 1998, at 1, 3.

22. In medicine, this means clinical research. For the equivalent activity in law, I use the terms "impact litigation" and "test case" interchangeably.

23. In medicine, a "patient" is an individual seeking medical treatment from a physician, while an individual enrolled in a research study is called a "research subject." However, there are some in the bioethics community who now prefer the term "participants." *See Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries*, NAT'L BIOETHICS ADVISORY COMM'N, at xv n.1 (Apr. 2001), http://bioethics.georgetown.edu/nbac/clinical/Vol1.pdf (choosing the term "participant" because "subject," though "widely used . . . , impl[ies] a diminished position of those enrolled in research in relation to the researcher").

24. Individuals with training in both medical practice and academic research are sometimes referred to as "physician-researchers," highlighting "the dual role of physician-researcher in relation to the patient-subject." Robert J. Levine, *Clinical Trials and Physicians as Double Agents*, 65 YALE J. BIO. MED. 65, 66 (1992).

I. THE SPECTRUM OF PRACTICE AND EXPERIMENTATION

Practice and experimentation lie at opposite ends of the spectrum of professional activity. Part I divides the spectrum into three categories—routine practice, innovative practice, and experimentation—and explains the professional outlook and types of behavior associated with each one, drawing examples from medicine and finding comparable examples in law.

These labels are not meant to represent hard and fast classifications, since the lines that divide them are neither easy to define nor important for their precise location. Rather, the three categories serve as general signposts along a continuous spectrum. Moving along the spectrum from routine practice toward experimentation relies on a weakening emphasis on principal-centered practice and a stronger focus on generalizability with regard to a class of principals. Note that the categories I will discuss are not professional *roles*, but rather designate types of professional *activity*. A single individual may shift back and forth along the spectrum over the course of a career or even over the course of a day.[25]

A. Routine Practice

Medical and legal practice, as defined in this Note, are what most people think of when they imagine the day-to-day work of doctors and lawyers. These professionals exemplify the principal-agent relationship,[26] and each profession's code of ethics reflects a duty to further the principal's interests.[27] The American Medical Association (AMA) explains that, within the treatment relationship, the "physician is ethically required to use sound medical judgment, holding the best interests of the patient as paramount."[28] Similarly, the American Bar Association (ABA) instructs lawyers to "provide competent representation to a client,"[29] employing "whatever lawful and ethical measures are required to vindicate a client's cause or endeavor."[30]

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25. Physicians in academic medical centers, for example, often divide their time between seeing patients and conducting research. Similarly, some corporate attorneys take time away from client-centered practice to work pro bono with public interest organizations on impact litigation.

26. *See* Brenda Almond, *Reasonable Partiality in Professional Relationships*, 8 ETHICAL THEORY & MORAL PRAC. 155, 165 (2005) (noting that doctors and lawyers "have special obligations to their clients" and generally "promote their clients' interests above those of others."); Morreim, *supra* note 18, at 593.

27. The American Medical Association (AMA) exhorts physicians "to place patients' welfare above their own self-interest and above obligations to other groups, and to advocate for their patients' welfare," CODE OF MED. ETHICS Op. 10.015 (Am. Med. Ass'n 2001), echoing the ABA's command for lawyers to "act . . . with zeal in advocacy upon the client's behalf," MODEL RULES, *supra* note 1, R. 1.3 cmt. para. 1.

28. CODE OF MED. ETHICS Op. 10.015 (Am. Med. Ass'n 2001).

29. MODEL RULES, *supra* note 1, R. 1.1.

30. MODEL RULES, *supra* note 1, R. 1.3 cmt. para. 1.

1. Recognizing Categories of Principals

As practitioners gain experience, they develop heuristics for efficient and effective service by recognizing classes of principals and categories of problems. Doctors learn to associate patients' symptoms with a diagnosis,[31] a label that "organizes [sic] illness: identifying treatment options, predicting outcomes, and providing an explanatory framework."[32] Lawyers develop familiarity with a particular set of legal issues and deftly determine the transactional documents or legal remedies most appropriate for each client's needs.[33] This is what I term "routine practice": addressing principals' problems with the standard tools of the trade.[34]

As the name suggests, routine practice is characterized by low levels of uncertainty and no emphasis on creating generalizable knowledge. Low uncertainty doesn't mean that the work is easy or that practitioners always achieve their desired ends; it simply indicates that these types of cases present familiar situations in which the odds of success can be roughly estimated based on prior experience. Similarly, a lack of any new generalizable knowledge doesn't mean that routine practice fails to impart valuable experience to the practitioner; rather, it indicates that this type of work is not intended to produce generalizable knowledge for the benefit of *others*. Quite the reverse, in fact: practitioners may learn their craft and improve their skills by looking to generalizable knowledge developed by other professionals.

2. The Idiosyncratic Principal

If practice is defined by the furtherance of principals' best interests, then a

31. *See* Barton Childs et al., *A Science of the Individual: Implications for a Medical School Curriculum*, 6 ANN. REV. GENOMICS HUM. GENETICS 313, 316 (2005) ("In general, the doctor's orientation is toward the likenesses between cases that lead to certainty of diagnosis rather than differences that may be pointing to heterogeneity and individuality.").

32. Annemarie Jutel, *Sociology of Diagnosis: A Preliminary Review*, 31 SOC. HEALTH & ILLNESS 278, 278 (2009).

33. *See* Carl J. Hosticka, *We Don't Care About What Happened, We Only Care About What Is Going to Happen: Lawyer-Client Negotiations of Reality*, 26 SOC. PROBS. 599, 606 (1979) (explaining that lawyers in publicly funded legal services seemed to respond to a "generalized view of cases and clients developed prior to encounters with specific individuals"); Stephen Nathanson, *The Role of Problem Solving in Legal Education*, 39 J. LEGAL EDUC. 167, 179 (1989) ("For many legal transactions, prepared plans, such as precedent files, precedent documents, and procedures checklists, already exist."); Katharine Rosenberry, *Organizational Barriers to Creativity in Law School and the Legal Profession*, 41 CAL. W. L. REV. 423, 425 (2005) (noting that for "fender-bender cases[, t]he complaints were very similar, so it was not necessary to be particularly creative when drafting answers to the complaints.").

34. *See* SOMETHING TO BELIEVE IN, *supra* note 20, at 8 (defining traditional professional practice as "technical expertise put at the disposal of clients [or] patients").

necessary first step is to define what those interests are. Despite a history of paternalism,[35] both medicine and law now explicitly endorse a more active decision-making role for the principal. The agent may outline possible options and make a recommendation, but ultimately, it is the principal who determines what a favorable outcome looks like.[36] There is essentially a division of responsibility: the principal defines the goals of care, while the means of achieving those goals are primarily left to the agent.[37] Typically, principals' goals involve straightforward objectives like recovering from an illness or receiving a favorable verdict at trial, but some principals have more idiosyncratic desires.

Danielle Ofri recounts the curious dilemma faced by Mr. Ray, a man with severe Tourette's syndrome.[38] Ray's medication suppressed his expletive-laden outbursts, which allowed him to maintain a career, but he complained that the drug also dampened his improvisational skills as a jazz drummer. Dr. Ofri indicates that the standard medical response would be to "nod[] sympathetically about having to take the bad with the good."[39] Instead, Ray's doctor worked with him to devise and test a medication schedule designed to control his disease during the workdays, but which tapered off on weekends when he played music. Dr. Ofri lauds the doctor's creativity in "look[ing] beyond the standard definitions of 'treatment success' and 'medication side-effects.'"[40]

For a similar example in law, consider a defense attorney who must balance the efficient and certain resolution offered by a plea bargain with the desires of clients who value their "day in court."[41] Margareth Etienne describes clients who saw testimony as a way to "express themselves," and appreciated their lawyer

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35. *See* Edward Krupat et al., *The Practice Orientations of Physicians and Patients: The Effect of Doctor-Patient Congruence on Satisfaction*, 39 PATIENT EDUC. & COUNSELING 49, 50 (2000) (describing "the classic paternalistic doctor-patient relationship in which . . . the patient is expected to defer to the physician's judgement"); Paul R. Tremblay, *Toward a Community-Based Ethic for Legal Services Practice*, 37 UCLA L. REV. 1101, 1150 (1990) (noting concern over "the general specter of lawyer paternalism").

36. CODE OF MED. ETHICS Opinion 10.01 (Am. Med. Ass'n 1992) ("The patient has the right to make decisions regarding the health care that is recommended by his or her physician."); MODEL RULES, *supra* note 1, 1.2 cmt. para. 1 ("[T]he lawyer shall consult with the client" regarding "the means by which the client's objectives are to be pursued," but the client has "the ultimate authority to determine the purposes to be served by legal representation.").

37. *See* SOMETHING TO BELIEVE IN, *supra* note 20, at 2 ("Conventional . . . lawyering involves the deployment of a set of technical skills on behalf of ends determined by the client, not the lawyer.").

38. *See* Danielle Ofri, *How Creative Is Your Doctor?*, N.Y. TIMES: WELL, (Mar. 14, 2013, 11:20 AM), http://well.blogs.nytimes.com/2013/03/14/how-creative-is-your-doctor.

39. *Id.*

40. *Id.*

41. *See* Margareth Etienne, *The Ethics of Cause Lawyering: An Empirical Examination of Criminal Defense Lawyers as Cause Lawyers*, 95 J. CRIM. L. & CRIMINOLOGY 1195, 1213–14 (2005).

"put[ting] on a show" even if they "knew the chances of winning were very, very low."[42]

This type of creative practice introduces non-standard care processes, but is still firmly within the world of practice because the services, however unconventional they may be, are entirely devoted to furthering the interests of the principal.

B. Innovative Practice

The idiosyncratic principal represents an alternative approach within routine practice because the agent deviates from the profession's standard solution for the principal's problem. A more substantive deviation involves novel developments aimed at addressing the common needs of a *class* of principals. As agents develop expertise in sorting principals into categories, they may notice recurring problems for which there is currently no effective solution. An imaginative professional engages in "innovative practice" by conceiving a novel solution to a problem that is held in common by a group of patients or clients.[43]

Jeffrey Katz and colleagues, for example, describe the innovative use of orthopedic surgery as a palliative tool.[44] A 79-year-old woman presented to her rheumatologist with debilitating hip pain, but she was an unsuitable candidate for total joint replacement by traditional standards because she also had advanced cancer.[45] Nonetheless, Dr. Katz's team discussed hip replacement as a way to improve her quality of life, and the patient expressed "a strong preference for surgery" despite the increased risks involved and her short expected lifespan.[46] She tolerated the procedure well and enjoyed two years of pain relief and improved mobility before succumbing to cancer.

Both routine practice and innovative practice focus on the needs of individual principals. What makes this case different from the creative practice of Mr. Ray's physician in the previous section is its broad applicability. All medical care is ultimately aimed at promoting patient wellbeing, and recent decades have seen a trend toward a more subjective, patient-centered conception of what

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42. *Id.*

43. *See* Nathanson, *supra* note 33, at 176 ("The more one is familiar with standard solutions, the better one is able to draw on them" to "develop[] new solutions or options for solving problems.").

44. *See* Jeffrey N. Katz et al., *Elective Palliative Total Hip Replacement in a Patient with Lymphoma and Advanced Lung Cancer*, 59 ARTHRITIS CARE & RES. 1194 (2008). The authors note that "[t]otal hip replacement has not traditionally been regarded as a palliative treatment." *Id.* at 1195.

45. *Id.* at 1195 ("[D]isorders that threaten overall survival have long been regarded as contraindications to total joint replacement.").

46. *Id.* at 1194–95.

"wellbeing" means.[47] Even with that general principle in the background, however, Mr. Ray's highly personalized pharmacological schedule designed to accommodate his unique professional and creative pursuits represents a much more patient-specific care outcome than the hip replacement described by Dr. Katz.

Terminally ill patients who suffer from treatable chronic conditions are common in medical practice,[48] and an encounter with a single patient was enough for Katz and colleagues to conclude that "a wide range of elective procedures traditionally contraindicated in patients with terminal illness may in fact be entirely appropriate when viewed in a palliative care context."[49] This type of extrapolation fits neatly within the Belmont Report's conception of "generalizable knowledge," particularly since the authors expressed their conclusion in the language of "theories, principles, and statements of relationships" that were intended to generalize their experience for a broader audience and broader applications.[50]

This observation underscores the true distinguishing feature of innovative practice. Though some types of routine practice may introduce novel elements, innovative practice lends itself to the creation of generalizable knowledge, and the agent may well have those broader concerns in mind while working on behalf of a particular principal. The principal's welfare remains the primary goal, but the specific case helps the agent devise new approaches that will benefit like-situated principals in the future. Section II.C will explore a comparable example of innovative practice in transactional corporate law, where attorneys "develop[] new legal devices and strategies to meet the perceived general needs of their corporate clients."[51]

C. Experimentation

At the far end of the spectrum lies "experimentation," a category of professional activity dedicated to rigorously testing novel developments in

47. *See, e.g.*, PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, MAKING HEALTH CARE DECISIONS: THE ETHICAL AND LEGAL IMPLICATIONS OF INFORMED CONSENT IN THE PATIENT-PRACTITIONER RELATIONSHIP 2 (1982) (noting that the duty of informed consent for medical treatment is premised on the twin principles of patients' "personal well-being and self-determination").

48. *Cf.* Katz et al., *supra* note 44, at 1195 ("[T]he co-occurrence of advanced cancer and advanced arthritis is not unusual.").

49. *Id.* at 1194. The authors also note that their conclusion "raise[s] new questions about the risks, benefits, costs, and cost effectiveness of such interventions in the palliative care setting." *Id.* at 1195.

50. *See Belmont Report*, *supra* note 8.

51. Michael J. Powell, *Professional Innovation: Corporate Lawyers and Private Lawmaking*, 18 L. & SOC. INQUIRY 423, 447–48 (1993).

technology, process, or doctrine. Formal clinical research is the purest form of experimentation in medicine. An equivalent activity in the law is impact litigation brought with the goal of establishing a particular precedent, which I will discuss in the context of both corporate law and cause lawyering. As in innovative practice, testing the untested necessarily involves uncertainty; the defining feature of experimentation is its concrete focus on the pursuit of generalizable knowledge or impact.[52]

The two categories examined above carry the label of "practice" because they ascribe primacy to the interests of the principal. The principal is by no means irrelevant in experimentation,[53] but has become subsidiary to the interests of the broad class of individuals to which she belongs. A patient comes to represent a particular disease profile or a demographic subpopulation; a client becomes a face for the common legal struggles of a group united by race or corporate structure. In this relationship, the principals are not autonomous decision makers who define the goals of care or representation, but rather provide a vehicle for achieving the agent's goals.[54] In effect, the agent shifts the focus of

52. *See supra* text accompanying notes 11–14. Impact litigation creates knowledge in the sense of precedent that defines what the law is, as discussed in the introduction. *See also* William B. Rubenstein, *Divided We Litigate: Addressing Disputes Among Group Members and Lawyers in Civil Rights Campaigns*, 106 YALE L.J. 1623, 1632 (1997) (discussing civil rights cases that "are brought with the intention of establishing a legal precedent that will improve a group's social situation and thus they aim to have an effect on other pending cases or on future cases"). For these lawyers, establishing precedent is the ultimate goal, rather than an incidental feature of client service. *See* SOMETHING TO BELIEVE IN, *supra* note 20, at 3 (noting that "cause lawyering is associated with both intent and behavior").

53. Indeed, identifying and recruiting the appropriate principals can be a major challenge in clinical research. *See, e.g.*, Marlene H. Peters-Lawrence et al., *Clinical Trial Implementation and Recruitment: Lessons Learned from the Early Closure of a Randomized Clinical Trial*, 32 CONTEMP. CLINICAL TRIALS 291, 291 (2012) (noting "multiple barriers to patient accrual" that caused a study to be "terminated early due to low enrollment"). Cause lawyers, meanwhile, not only hope for clients who serve as a good face for the cause, *see, e.g.*, Nikole Hannah-Jones, *Race Didn't Cost Abigail Fisher Her Spot at the University of Texas*, ATLANTIC WIRE, Mar. 18, 2013, http://www.theatlanticwire.com/national/2013/03/abigail-fisher-university-texas/63247/ ("When the NAACP began challenging Jim Crow laws across the South, it . . . meticulously selected the people who would elicit both sympathy and outrage, who were pristine in form and character."), but they must also contend with the threshold of constitutional standing, *see* U.S. CONST. art. III, § 2; *see also* Lujan v. Defenders of Wildlife, 504 U.S. 555, 573–74 (1992) (noting that a plaintiff "seeking relief that no more directly and tangibly benefits him than it does the public at large does not state an Article III case or controversy").

54. *See* SOMETHING TO BELIEVE IN, *supra* note 20, at 2 (explaining that cause lawyers use "legal skills to pursue ends and ideals that transcend client service" because they have broader social goals in mind); Howard Brody & Franklin G. Miller, *The Clinician-Investigator: Unavoidable but Manageable Tension*, 13 KENNEDY INST. ETHICS J. 329, 334 (2003) ("Clinical medicine is an activity designed to produce therapeutic benefits for individual patients. Clinical research is an activity designed to produce generalizable knowledge to inform the care of future patients.").

professional duty from principal to principles.

"Success" here is a trickier concept to define than in the realm of practice, where the goals of representation are defined by the principal himself. In clinical research, the goal is to produce meaningful generalizable knowledge with the potential to improve the processes of care. Measures like methodological rigor and internally consistent results serve as a proxy for accuracy,[55] an objective assessment of whether the study actually measures what it purports to measure. Beyond that, however, researchers also strive for subjectively "good" results, those with social utility that answer unaddressed questions or that challenge conventional wisdom with provocative findings.[56]

Lawyers use impact litigation to change the law, whether on behalf of a corporate client, a social cause, or an ideological mission. Some judicial decisions have an immediate impact,[57] but many do not, whether because the verdict simply affirms the status quo or because vague language in support of abstract legal rights fails to change the situation on the ground.[58] Meanwhile, each new appellate decision adds a new layer of precedent that helps to shape the law for future litigants. Many holdings end up being clarified, reinterpreted, or reaffirmed in subsequent decisions,[59] so dedicated lawyers must be vigilant in ensuring enforcement of the laws they like and challenging the laws they don't.

In both fields, the goals of experimentation are defined by the agents rather than the principals, though the principals may well share those goals in certain instances. Though the experimentation may occur within the bounds of the principal-agent relationship, this type of work dissolves the standard "goals vs. means" division of responsibilities. Instead, the agent defines both the ends being pursued and the strategy for pursuing them.

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55. *See* Peter Jüni, *Assessing the Quality of Controlled Clinical Trials*, 323 BMJ 42 (2001).

56. The National Institutes of Health (NIH), for example, assesses research grant applications based on a measure of "overall impact" that takes into account factors like "significance" and "innovation." *See* Nat'l Insts. Health, *NIH Grants Policy Statement*, HHS at I-51 to -52 (Oct. 1, 2012), http://grants.nih.gov/grants/policy/nihgps_2012/nihgps_2012.pdf.

57. *Roe v. Wade*, for example, was "a moment of high drama . . . because in its wake not a single state abortion statute remained constitutional." Nan D. Hunter, *Lawyering for Social Justice*, 72 N.Y.U. L. REV. 1009, 1013 (1997).

58. *See* GERALD N. ROSENBERG, THE HOLLOW HOPE: CAN COURTS BRING ABOUT SOCIAL CHANGE? 421 (2008) (rejecting the courts as vehicles for social change). *But see* Hunter, *supra* note 57 (arguing that litigation complements political mobilization by providing a vocabulary of rights, a motivational focal point, and salience in the media).

59. *See* MICHAEL MELTSNER & PHILIP G. SCHRAG, PUBLIC INTEREST ADVOCACY: MATERIALS FOR CLINICAL LEGAL EDUCATION 77 (1974) (noting the extensive rounds of school desegregation litigation following *Brown v. Board of Education* aimed at clarifying and enforcing that decision).

II. THE LOCI OF INNOVATION

At a conceptual level, innovation and experimentation are defined by a degree of abstraction from the individual needs of specific principals. Beyond the necessary outlook and intent, however, successful innovations also depend on a high level of professional expertise[60] and on certain requisite resources, both financial and otherwise. As a result of these pragmatic considerations, innovative practice and experimentation tend to be concentrated in a small number of conducive professional practice settings.

The existence of a small community of innovators produces a certain degree of homogeneity, whether because like-minded individuals are simply drawn to one another or perhaps due to an acculturation of new arrivals. These relationships reflect a central tension: professionals collaborate with others in the interest of furthering shared goals, but they may also feel a competitive urge to be the first with a new idea or the best in their field. Innovation in medicine aptly reflects this tension, while the two legal tracks lean in opposite directions. Cause lawyers tend to band together to prioritize their broader mission, while experimenting corporate lawyers face heightened competition because their industry emphasizes profit incentives for both firms and individuals.

A. Medical Innovation in the Ivory Tower

Academic medical centers have traditionally been the main source of innovation in American medicine. The twin roles of clinical faculty member and clinical researcher developed in tandem in American medical schools around the turn of the twentieth century,[61] allowing accomplished physicians to build careers around educating students and advancing the state of knowledge in their area of specialization. Academia's major role in innovation and research has persisted because it provides a centralized location for imaginative physicians, as well as the resources necessary for medical innovation and investigation.

1. Experimentation: Administrative and Financial Support for Clinical Research

It is widely recognized that clinical trials are primarily concentrated at

60. Okamoto, *supra* note 16, at 500 ("An expert draws on prior solutions to comparable problems but ultimately must proffer a novel solution suited to the particular context of the particular situation."); *see also* Brody & Miller, *supra* note 54, at 331 (explaining that the physicians conducting research on a given disease are often those most knowledgeable about it); Rosenberry, *supra* note 33, at 427 ("[A] depth of knowledge in [the] field" is "essential for creativity.").

61. *See* A. MCGEHEE HARVEY, SCIENCE AT THE BEDSIDE: CLINICAL RESEARCH IN AMERICAN MEDICINE, 1905-1945, at 183 (1981).

academic medical centers.[62] The "supportive clinical research infrastructure" at these institutions furnishes the key resources of time and money.[63] Academic researchers are expected to conduct research as part of their job description, whereas community physicians would have to take time out from private practice.[64] The complexity of compliance with research protocols and regulations means that "repeat player" institutions benefit from institutional memory and administrative support for grant applications and protocol review. As for financial support, many academic institutions fund research activities directly.[65] More importantly, however, the availability of advanced facilities, skilled clinicians, and methodological experts makes the institutional environment conducive to securing grant funding from outside organizations.[66]

2. Innovative Practice: Broad Mindset and Meaningful Impact

Physicians in all settings must contend with a continuous influx of new medical knowledge and endless variation in patient profiles. Many respond with constant adaptations in their practice techniques.[67] These modifications fall into the category of innovative practice if they are inspired by individual patients, but pursued with broader goals in mind. Attempting to assess and track innovative practice is a more challenging endeavor than examining clinical research activity, however, because innovative practice has hazier boundaries[68] and does not

62. *See* FORUM ON DRUG DISCOVERY, DEV. & TRANSLATION, INST. MED., TRANSFORMING CLINICAL RESEARCH IN THE UNITED STATES: CHALLENGES AND OPPORTUNITIES: WORKSHOP SUMMARY 22 (2010), (noting "[t]he limited involvement of community physicians in clinical research"); Victor J. Dzau et al., *Transforming Academic Health Centers for an Uncertain Future*, 369 NEJM 991, 991 (2013) ("Academic health centers (AHCs) have long led the advancement of science and medicine by pursuing missions of clinical care, research, and education."). *But see* Lois Snyder & Paul S. Mueller, *Research in the Physician's Office: Navigating the Ethical Minefield*, 38 HASTINGS CTR. REP. 23, 23 (2008) ("[M]any *industry-funded* trials [now] take place in physicians' offices and private testing centers through contract research organizations . . . .") (emphasis added).

63. FORUM ON DRUG DISCOVERY, DEV. & TRANSLATION, *supra* note 62, at 24 (noting that academic medical centers provide "administrative and financial" support).

64. *Id.* at 23–24.

65. *Id.* at 24.

66. *See* Nat'l Insts. Health, *supra* note 56, at I-51 to -52 (noting that NIH grant reviewers look for investigators with "appropriate experience and training," as well as "institutional support, equipment and other physical resources").

67. *See* William M. Sage, *Physicians as Advocates*, COLUM. L. SCH. REP., Winter 2000, at 60 ("[P]hysicians view their daily decisions as demanding constant adaptation and compromise . . . ."); Saumita Saha, *Surgical Innovation*, 71 INDIAN J. SURGERY 6, 7 (2009) ("Most surgeons have spontaneously innovated at some point or other.").

68. *See* Martin F. McKneally & Abdallah S. Daar, *Introducing New Technologies: Protecting Subjects of Surgical Innovation and Research*, 27 WORLD J. SURGERY 930, 930 (2003) (noting that surgeons often find themselves in a "large gray zone" between "an evolutionary variation on a standard procedure" and "the first stage of what should become recognized as a formal surgical research project").

necessarily involve rigorous documentation or publication of results. Still, these clinical innovations may be more probable in academic settings, and are most likely to be widely noticed when developed or adopted there.

The academic environment emphasizes a broad and forward-thinking outlook: medical faculty members impart generalized knowledge to students, and medical researchers create generalizable knowledge in their studies. Physicians in academic institutions often take on at least one of these roles at least some of the time, and are constantly surrounded by people who perform both.[69] In this context, "expertise" consists of technical proficiency with the clinical craft, as well as the requisite imaginative capacity and broad perspective to innovate on behalf of a population of patients.

Moreover, academic physicians who innovate are best situated to disseminate new information and to formally test novel developments in clinical trials. Prior to the modern era of clinical research regulation,[70] many critically important developments in medicine arose "through an informal, unregulated innovation process,"[71] typically at the hands of an academically affiliated physician.[72] This may be due to the ways in which academic centers attract creative individuals and encourage innovative work. It could also be an issue of sampling bias, since innovations developed in private practice are less likely to be noticed and promoted than those arising out of well-connected academic centers.[73] Nonetheless, it seems plausible that both medical innovation and experimentation are anchored in academic medical centers. The two activities are inherently linked, since one may well lead to the other, and both are facilitated by the nexus of technology, funding, and interdisciplinary expertise.

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69. *See* Mehmet Toner & Ronald G. Tompkins, *Invention, Innovation, Entrepreneurship in Academic Medical Centers*, 143 SURGERY 168, 170 (2008) ("[T]he top academic medical centers have expertise in basic biological science, technology, and clinical medicine . . . , which creates a very unique and truly multidisciplinary environment for innovation.").

70. *See Federal Policy for the Protection of Human Subjects ("Common Rule"), supra* note 10 (noting that the current regulatory regime was "heavily influenced" by the *Belmont Report*, written in 1979). Subsection IV.A.1, *infra*, discusses the history of clinical research regulations in more detail.

71. McKneally & Daar, *supra* note 68, at 930. This "unregulated process" is responsible for "[m]ost of the important advances in the history of medicine, such as anesthesia, appendectomy, antibiotics, intensive care, and immunization." *Id.*

72. *See, e.g.*, Joseph Ben-David, *Roles and Innovation in Medicine*, 65 AM. J. SOC. 557, 557 (1960) (noting that medical innovations have often been developed by "practitioners who were involved in research and academic teaching"); Shuai Xu et al., *Origins of Medical Innovation: The Case of Coronary Artery Stents*, 5 J. AM. HEART ASS'N 743, 743 (2012) ("Coronary artery stent technology first arose from individual physician-inventors within academic medical centers and their associated private companies.").

73. *See* Riskin et al., *supra* note 15, at 690 (noting that community physicians may not have "the intellectual interaction and academic connections necessary to have [their] invention noticed").

3. Motivation: Of Patients, Pride, and Profits

Physicians may be motivated by a number of factors to pursue novel developments in medicine. There is the obvious goal of improving care for patients, and indeed, innovation seems to foster collaboration to that end. Physicians and researchers from different institutions may work together on new studies[74] or visit each other's practices to learn novel techniques.[75] Professional societies organized around particular methodologies and diseases can "establish standards and serve as forums for the discussion of new work."[76]

It would be naïve, however, to neglect other, less altruistic potential motivations, such as the pursuit of prestige and professional advancement.[77] Commentators have also noted the potential for heightened competition driven by increasingly important external private interests in medical innovation.[78] At a time of dwindling government support for medical research,[79] the medical device and pharmaceutical industries offer handsome compensation to physicians who assist in developing new products for commercial gain.[80] The goals of medical innovation may also shift as modern health reform continues to emphasize cost reduction and quality standards.[81]

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74. *See* FORUM ON DRUG DISCOVERY, DEV. & TRANSLATION, *supra* note 62, at 8–9 (praising long-term collaboration agreements in clinical research networks).

75. *See* McKneally & Daar, *supra* note 68, at 932.

76. *See* HARVEY, *supra* note 61, at 128.

77. *See* Norman G. Levinsky, *Nonfinancial Conflicts of Interest in Research*, 347 NEJM 759, 759 (2002) (noting "nonfinancial conflicts of interest" in clinical research including "personal benefits from publications and acquisition of grants"); *see also* HARVEY, *supra* note 61, at 59 (explaining that competition has always been present in academic medicine because "[s]uccessful scientists were rewarded with university chairs and facilities"); Riskin et al., *supra* note 15, at 688.

78. *See, e.g.*, McKneally & Daar, *supra* note 68, at 932; *see also* William J. Broad, *Billionaires with Big Ideas Are Privatizing American Science*, N.Y. TIMES, Mar. 15, 2014, http://www.nytimes.com/2014/03/16/science/billionaires-with-big-ideas-are-privatizing-american-science.html (noting that wealthy philanthropists account for a growing share of research funding, and their "personal setting of priorities . . . troubles some in the science establishment").

79. *See* Jocelyn Kaiser, *NIH Details Impact of 2013 Sequester Cuts*, SCIENCE: SCIENCEINSIDER (May 8, 2013, 3:30 PM), http://news.sciencemag.org/scienceinsider/2013/05/nih-details-impact-of-2013-seque.html.

80. *See* Levinsky, *supra* note 77, at 759 (noting "[t]he dramatic growth of relations between investigators and industry"). Financial conflicts of interest are a perennial topic of concern in both clinical trials and medical practice. *See generally* Sheila R. Shulman & Andrea Kuettel, *Drug Development and the Public Health Mission: Collaborative Challenges at the FDA, NIH, and Academic Medical Centers*, 53 BUFF. L. REV. 663 (2005) (reviewing the recent history of regulations and institutional policies on conflicts of interest at federal agencies, private companies, and universities). *See also* Shantanu Agrawal et al., *The Sunshine Act—Effects on Physicians*, 368 NEJM 2054 (2013).

81. *See* Dzau et al., *supra* note 62; Riskin et al., *supra* note 15, at 688.

B. Public Interest Law: Ideological Commitment as a Non-Financial "Resource"

Cause lawyers often pursue their ideological goals through the courts rather than (or in addition to) the legislature. Their work is thus inherently innovative, since they seek social change within the existing legal framework by reinterpreting or striking down existing laws. This activity goes beyond settling individual matters for individual clients, and targets broad visions of progress by changing what the law is or what the law means. By organizing around particular issues, cause lawyers build expertise and institutional memory. Their relationship with "resources," however, is slightly more complex.

Public interest law organizations typically operate under tight financial constraints: they are often not reimbursed directly from their work,[82] and they engage in "non-revenue-generating" activities like coalition building, media work, community outreach, and education.[83] Many are registered non-profits, and they build their budgets around private contributions and public funds.[84] The following examples illustrate how cause lawyers leverage limited financial inputs and non-monetary resources to further their missions.

1. Innovative Practice: Public Defenders and Direct Client Representation

Criminal defense and legal aid are public interest models based on direct client service rather than impact litigation. Nonetheless, client-service attorneys often have "strong ideological and political beliefs that they seek to effectuate through their work."[85] They engage in innovative practice to the extent that they "represent individuals, but over time tend to think of these individuals as a class."[86]

Margareth Etienne describes a group of public defenders who noted a trend among their Spanish-speaking and bilingual clients: those with rudimentary English proficiency were typically read their Miranda rights in English, leaving some of them bewildered and uninformed.[87] The attorneys acknowledged that

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82. They may, however, receive attorney's fees in certain types of cases. *See* Catherine R. Albiston & Laura Beth Nielsen, *Funding the Cause: How Public Interest Law Organizations Fund Their Activities and Why It Matters for Social Change*, 39 L. & SOC. INQUIRY 62, 75–76 (2014) (reporting that public interest law organizations received an average of 5% of their budgets from attorney's fees).

83. *Id.* at 62–63.

84. *See id.* at 76 (noting in Figure 2 that the budgets of public interest law organizations, on average, depended primarily on public funds and donations from foundations and individuals). Scheingold and Sarat note that public agencies and public interest organizations are the "classic sites" for cause lawyers to practice, SOMETHING TO BELIEVE IN, *supra* note 20, at 80, but that cause lawyers can also be found in corporate pro bono programs and in small law firms, *id.* at 73.

85. Etienne, *supra* note 41, at 1226.

86. *Id.*

87. *See id.* at 1240.

this practice likely fell within the bounds of the "law on the books," but together, they "devised a strategy to change the 'law on the streets.'"[88] At any trial with a Spanish-speaking or bilingual defendant, they made it a habit to inquire whether the Miranda rights had been read in Spanish.[89] It is unlikely that this simple question altered the outcome in any individual case,[90] but over time, it became standard practice for law enforcement officials to read the rights in both languages to avoid any potential complications at trial.[91]

One attorney acting alone would likely not have had much of an impact on the system, but the public defenders drew on the "resource" of a community united by a particular cause in order to affirmatively pursue a shared mission of generalizable impact. Still, the defenders never lost sight of their role as practitioners; they considered broader change to be a subsidiary goal and only pursued it to the extent that it would not negatively affect the day-to-day work of helping individual defendants.

2. Experimentation: Impact Litigation

Impact litigation can be a powerful tool in creating social change, but it can also be a protracted and expensive endeavor as lawyers shepherd a case through multiple courts over a number of years, often while also coordinating an associated media campaign. The public defenders in the last example built strength from within their own branch of the profession, coordinating laterally across offices; litigation-oriented public interest organizations, on the other hand, typically draw on ideological sympathies to marshal support from external sources.

Public interest organizations often draw their arguments from recent developments in academic legal thought, and law professors may be called upon to help with developing briefs, mooting oral arguments, or even arguing cases.[92] Similarly, private attorneys who sympathize with the goals of a test case may provide pro bono assistance.[93] These lawyers may contribute appellate experience, local knowledge, or legal advice for facets of the case that fall outside the cause lawyers' areas of expertise.[94] Corporate pro bono programs can

88. *Id.* at 1240–41.

89. *Id.*

90. *Id.* at 1242 ("The strategy was viewed as a harmless one even though the defendants in the cases in which it was used would not receive a benefit.").

91. *Id.* Not only did Spanish-speaking law enforcement officials begin routinely providing the Miranda rights in Spanish, but non-Spanish-speaking officials started carrying wallet-sized cards with a Spanish translation of the rights. *Id.*

92. *See infra* notes 96 and 97.

93. *See* Rubenstein, *supra* note 52, at 1633.

94. *See, e.g.*, Martha F. Davis, *Our Better Half: A Public Interest Lawyer Reflects on Pro Bono Lawyering and Social Change Litigation*, 9 AM. U. J. GENDER SOC. POL'Y & L. 119, 121–22

also offer traditional legal resources like research support and a physical workspace, costs that may exceed a public interest organization's budget.[95] *Lawrence v. Texas*[96] and *Griswold v. Connecticut*[97] were high-profile cases that emerged out of these types of collaboration.

The government is a popular target for test cases, which may target statutes, public benefit schemes, or individual actions by public officials. In some instances, the singular focus and intensive preparation of the cause lawyers is met with a relatively lackluster defense from the state's attorneys, for whom the case is but one of their many responsibilities.[98] In some instances, however, government officials may themselves be sympathetic with the cause lawyers' mission; they may fulfill their role out of a sense of duty, but do what they can to assist in moving the case along.[99] In cases like these, the "resource" of ideological sympathy extends across ostensibly adversarial lines, drawing assistance and support from law enforcement or judicial officials in furthering the innovative goal.

(2001) (describing a women's rights group that received pro bono assistance in navigating the bankruptcy court system).

95. SOMETHING TO BELIEVE IN, *supra* note 20, at 74.

96. 539 U.S. 558 (2003) (declaring the unconstitutionality of state prohibitions on homosexual sodomy). For an in-depth overview of the case and its social context, see DALE CARPENTER, FLAGRANT CONDUCT: THE STORY OF *LAWRENCE V. TEXAS* (2012). The national LGBT rights organization Lambda Legal was involved in the case from the beginning, but relied on private local attorneys to help them "navigate[] the lower-court minefield of Texan justice." *Id.* at 130. Lambda chose legal arguments about sex-based classifications that had "long been a favorite of legal academics," *id.* at 156, and law professors were actively involved in helping the attorneys prepare for the case, *id.* at 213. The case was argued in the Supreme Court by a pro bono attorney with extensive Supreme Court experience. *Id.* at 211.

97. 381 U.S. 479 (1965) (finding a constitutional right for married couples to access birth control). Yale Law School Professor Fowler Harper was a "principal legal strategist" for the Planned Parenthood League of Connecticut in the 1950s and 1960s as it planned a legal assault on anti-contraception laws. JOHN W. JOHNSON, *GRISWOLD V. CONNECTICUT*: BIRTH CONTROL AND THE CONSTITUTIONAL RIGHT OF PRIVACY 39 (2005). As Harper's health declined, his Yale colleague Thomas Emerson, an experienced appellate advocate, took over leadership of the case. *See id.* at 103–05.

98. *See* CARPENTER, *supra* note 96, at 214-16; JOHNSON, *supra* note 97, at 116.

99. *See, e.g.*, CARPENTER, *supra* note 96, at 145–46 (noting that the Texas prosecutor assigned to the sodomy case was a lesbian; she "did not go out of her way to create difficulties for the defense team, and assisted it in understanding the procedures of the county criminal court"); JOHNSON, *supra* note 97, at 81–83 (noting that Planned Parenthood personnel were permitted to "essentially write the script for the arrest" by cooperative police officials); *see also* Lyle Denniston, *Constitution Check: Must Government Lawyers Defend Laws They Deem to Be Invalid?*, CONSTITUTION DAILY (Feb. 25, 2014), http://blog.constitutioncenter.org/2014/02/constitution-check-must-government-lawyers-defend-laws-they-deem-to-be-invalid/ (discussing state and federal attorneys general who chose not to defend same-sex marriage laws against constitutional challenges in court).

3. Motivation: Priority on Principles

The typical cause lawyer is a person who decided to pursue social justice rather than a potentially lucrative career in private practice.[100] Given this framework of self-sacrifice and dedication, it should come as no surprise that cause lawyers tend to work together in furthering their mission. The preceding subsections discuss collaboration within organizations and with external supporters, but there is also typically a high level of coordination across public interest organizations on questions like long-term legal strategy and client selection.[101] Disputes do arise between individual attorneys or rival organizations over points of legal strategy or issues of attribution and leadership,[102] but the overall tenor may often be one of collaboration rather than competition.

C. Corporate Law: On-the-Ground Expertise

The foregoing sections outline a top-down approach to innovation that often involves academic experts, who either do the innovating themselves or take a supportive role. In this section, we trace a second track of innovation in law that is rooted in private practice. These novel developments "are not the products of law professors or researchers so much as the work of lawyers striving to further the interests of their clients," representing a "bottom-up process of lawmaking and knowledge production."[103] This client-centered model is similar to the innovative practice of the public defenders discussed in Subsection II.B.1. The main difference is the identity of the clients: public defenders innovate on behalf of indigent clients, while innovation in private practice typically benefits wealthy corporate entities.

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100. Typically, public interest lawyers have affirmatively chosen to pursue that career rather than falling into it as a back-up option. As compared to private practice, public interest positions are fewer in number, lower-paying, and less likely to be widely advertised or coordinated by a dedicated recruitment team. *See generally* Career Dev. Office, *Public Interest Careers*, YALE L. SCH. 11–14 (Sept. 2013), http://www.law.yale.edu/documents/pdf/CDO_Public/CDO_PI_Careers_Public.pdf.

101. *See, e.g.*, CARPENTER, *supra* note 96, at 128 (explaining that several national LGBT rights groups met semiannually "to share information about cases, discuss strategies, and coordinate efforts as much as possible"); Rubenstein, *supra* note 52, at 1629 (describing a "conference that the NAACP held in Chicago in 1945 to help coordinate the many restrictive covenant cases that were percolating throughout the country").

102. *See* Rubenstein, *supra* note 52, at 1626 (describing the challenges of using individual litigation to create social change on behalf of a community, including "[c]ommunity member disputes concerning the goals of litigation" and "attorney disputes about the methods of litigation"); *id.* at 1627–31 (noting Thurgood Marshall's frustration with attorney George Vaughn, who bristled at comporting with the NAACP's carefully orchestrated strategy to challenge racially restrictive covenants).

103. Powell, *supra* note 51, at 448.

1. Innovative Practice: Creative Solutions for Corporate Clients

The practice of law has become increasingly segregated along lines defined by categories of clients. Solo practitioners and small firms tend to represent individual clients and small businesses, while bigger firms more often focus on corporate clients and very wealthy individuals.[104] As clients' wealth increases, so does the complexity of their legal issues.[105] Big businesses certainly have many straightforward legal needs,[106] but they often rely on "the counsel of specialists in those areas of practice that are relatively new or are characterized by a high degree of uncertainty."[107] Disruptive innovations are concentrated among a small number of elite firms that attract graduates from top schools and clients who are willing to pay top dollar for their unique services.[108] These firms also have the necessary resources for the intensive background research that may be required for developing new legal devices that need to withstand judicial challenge.

Academia is conspicuously absent from this description of corporate innovative practice. The ivory tower played an important role in medical innovation and cause lawyering, and there are certainly instances where legal academics perform a similar function in the world of corporate law and financial regulation.[109] In general, though, academia plays a more peripheral role in this sphere.[110] During the wave of hostile corporate takeovers in the 1980s, for

104. *See* Randolph N. Jonakait, *The Two Hemispheres of Legal Education and the Rise and Fall of Local Law Schools*, 51 N.Y.L. SCH. L. REV. 863, 869 (2006/07).

105. *Compare id.* at 887 ("[T]he work of attorneys representing individuals is almost all legally routine."), *with* Milton C. Regan, *Professional Responsibility and the Corporate Lawyer*, 13 GEO. J. LEGAL ETHICS 197, 207 (2000) ("The rapid pace of change in the corporate world demands that lawyers create new legal forms and arrangements."), *and* Eric Mankin, *Innovation in Practice: Why It's So Hard*, 32 L. PRAC. 42, 42 (2006) ("Law firms introduce new legal services and products on an ongoing basis as part of their work with sophisticated clients in industries such as entertainment and financial services.").

106. *See* George W. Dent, Jr., *Business Lawyers as Enterprise Architects*, 64 BUS. LAW 279, 318 (2009).

107. Powell, *supra* note 51, at 450.

108. *See id.*

109. *See, e.g.*, Kevin E. Davis, *Contracts as Technology*, 88 N.Y.U. L. REV. 83, 121–22 (2013) (noting that "academics have generated at least a few examples of contractual innovations"); Ward Farnsworth, *The Legal Academy and the Profession*, *in* THE OXFORD HANDBOOK OF LEGAL STUDIES 6 (Peter Cane & Mark Tushnet eds., 2003) ("A number of important ideas in antitrust law were pressed by scholars in the 1960s and 1970s and then adopted fairly quickly by courts," which the author describes as "an exceptional case where the impact [of legal scholarship] has been large."); Lee Fang, *The Scholars Who Shill for Wall Street*, THE NATION, Nov. 11, 2013, http://www.thenation.com/article/176809/scholars-who-shill-wall-street (explaining that legal academics' studies and opinions that critique financial regulations are increasingly being relied on, solicited, and even paid for by large corporations).

110. *See, e.g.*, Clair A. Hill, *Introduction: Theory Informs Business Practice*, 77 CHI.-KENT L. REV. 3, 3 (2001) ("In my years as a corporate law academic, I've been surprised at the paucity of interactions between those who study corporate law and those who 'do' it."). Indeed, the corpus of

example, a variety of documents were produced detailing the increasingly complex range of options for takeover strategies and defenses.[111] These guides were typically authored by "expert practitioners, not academics."[112]

The "most significant and controversial of the several new defensive antitakeover devices" was the shareholder rights plan, known as the "poison pill."[113] The device was conceived by Wachtell Lipton Rosen Katz, one of "the dominant legal players in the hostile takeover game,"[114] in the midst of a "desperate takeover struggle" for one of its clients.[115] Soon, however, the firm began recommending the pill as a protective measure for its other clients, and continued to add or modify features of the basic plan. This development proceeded "independent of the particular needs of . . . any . . . particular client. The firm was developing and refining the new legal device much as a manufacturing company might modify a new product after an initial market test."[116] In this way, the firm's representation of an individual client served the dual purpose of supporting the client's specific business objectives, as well as building generalizable knowledge in the field of antitakeover defenses.

2. Experimentation: Litigation Arising Out of Practice

The process of introducing and tweaking the poison pill falls under the category of innovative practice because it constituted "private lawmaking on behalf of clients and in the course of [the] practice of law."[117] However, any novel development in practice has the potential to be carried through into experimentation if challenged in court. Corporate attorneys who successfully

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legal academia as a whole is often critiqued for being too disconnected from the real world of legal practice. *See* Farnsworth, *supra* note 109, at 1 (noting that legal academics "usually see little sign that anything they write is valued by the legal system or makes an impact on it"); *id.* at 7 ("[C]ommonly, hot academic fads are driven by or accompany a politics unpalatable to the legal system."); Adam Liptak, *The Lackluster Reviews that Lawyers Love to Hate*, N.Y. TIMES, Oct. 21, 2013, http://www.nytimes.com/2013/10/22/us/law-scholarships-lackluster-reviews.html ("Law reviews are not really meant to be read. They mostly exist as a way for law schools to evaluate law professors for promotion and tenure.").

111. *See* Powell, *supra* note 51, at 448. The ensuing discussion focuses on Michael Powell's description of the firms involved in corporate takeover work in the 1980s, one of the "comparatively few" studies on the "process of innovation" in private law. Kettering, *supra* note 15, at 1554–55, 1555 n.2.

112. Powell, *supra* note 51, at 448.

113. *See id.* at 429. The poison pill established certain new shareholder rights that were contingent upon outside companies acquiring a certain percentage of stock. The rights were intended both to protect minority shareholders and to encourage the acquiring company to enter into negotiations early in the process. *See id.* at 435.

114. *Id.* at 433.

115. *Id.* at 434.

116. *Id.* at 436–37.

117. *Id.* at 427.

defend an innovation in court while assisting a particular client can thereby establish the innovation's legitimacy more broadly for use with other clients.[118]

This is ultimately what occurred with the poison pill, with the Delaware Supreme Court defying expectations by officially sanctioning the device in 1985.[119] Though the case concerned a single company's use of a shareholder rights plan to avert a hostile takeover, "the wider debate was couched in terms of [the] central social and economic values that were seen to be involved,"[120] just as cause lawyers often abstract away from their clients and focus on broader themes of social justice.[121] Throughout this process, it was the "expert practitioners who [were] actively engaged in developing and reworking the law," with legal academics relegated to the position of "commentators and critics."[122]

3. Motivation: Priority on Profit

Private law firms' motivation to innovate likely has less to do with an idealized notion of what corporate law should look like and more to do with pragmatic concerns about acquiring and retaining clients.[123] Rather than responding to the needs of clients as they arrive, entrepreneurial firms proactively "develop[] new legal devices and strategies to meet the perceived general needs of their corporate clients" and market those innovations to drum up business.[124] This process plays out at a micro level within firms as well, since individual attorneys must compete with each other to bring in new clients and establish rank in the firm.[125]

Competition between and within firms has intensified in recent years in response to an increasingly globalized market with sophisticated and cost-conscious clients.[126] The disaggregation and specialization of legal services and

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118. *Id.* at 429 ("If challenged and upheld by the courts [new practices or devices] become institutionalized in the common law.").

119. *See id.* at 438–39 (discussing *Moran v. Household International Inc.*, 490 A.2d 1059 (Del. Ch. 1985), *aff'd*, 500 A.2d 1346 (Del. 1985)).

120. *Id.* at 438.

121. *See, e.g.*, CARPENTER, *supra* note 96, at 194 (noting that oral arguments in *Lawrence v. Texas* focused on the language of liberty and due process, and never explicitly mentioned sex or referred to the defendants by name); Rubenstein, *supra* note 52, at 1630–31 (describing how an unsophisticated lawyer cut through the technical legal arguments concerning restrictive covenants in a rousing peroration about racial equality).

122. Powell, *supra* note 51, at 448–49.

123. *See id.* at 447 (explaining that large firms in the 1980s "competed with each other over what exactly constituted the best legal product" for deterring hostile takeovers).

124. *Id.*; *see also id.* at 442 ("Skadden Arps did not sit back and wait for clients to call but rather took the initiative to develop and promote its own plan, which it was careful to differentiate from other competing plans.").

125. *See id.* at 427; Regan, *supra* note 105, at 198.

126. *See* William D. Henderson & Rachel M. Zahorsky, *Law Job Stagnation May Have*

the rise of in-house legal counsel put additional pressure on firms to innovate on behalf of their corporate clients.[127] To justify their high rates, they must add value beyond handling routine legal paperwork.

III. THE NATURE OF "TRUTH" IN MEDICINE AND LAW

Scientific experimentation does not proceed in a haphazard or lackadaisical fashion. While innovative practice may occur spontaneously as practitioners attempt to grapple with the problems presented to them, true experimentation is a more deliberate and deliberative endeavor. "[T]he structure of scientific experiments is fundamentally stable all across the basic-clinical spectrum," and involves a number of well-established steps for defining a hypothesis and research methods.[128] Lawyers who bring test cases employ similarly rigorous methods in their attempts to experiment with the law through litigation.[129] However, important differences arise out of the structure of the American legal system, highlighting a major divergence in what is otherwise a remarkably similar set of processes for innovation shared by the two professions.

Notably, though both professions use a carefully defined representation of reality as a starting point for their experiments, they diverge in the extent to which they strive for accuracy. Clinical research aims to uncover objective scientific facts. A new treatment will likely be ineffective if its creators have inaccurately assessed the nature of the disease or the biological mechanism targeted for intervention. In the law, however, academics and judges alike have moved away from a strict conception of fixed, objective "natural" law, and toward a more nuanced view of judicial decision making as influenced by

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127. *See* Gillian K. Hadfield, *Legal Infrastructure and the New Economy*, 8 I/S: J.L. & POL'Y 1, 19 (2012) ("What the new economy enterprise needs from law is not just more of what the old economy enterprise needed; it needs things that are different."). The importance of innovation as a business strategy has led some to wonder about the possibility or desirability of patents on novel legal methods and strategies. *See generally* Stephanie L. Varela, *Damned if You Do, Doomed if You Don't: Patenting Legal Methods and Its Effect on Lawyers' Professional Responsibilities*, 60 FLA. L. REV. 1145 (2008).

128. Joffe & Miller, *supra* note 4, at 34. These authors note that the scientific method has been fairly stable for over 100 years. *Id.* They outline the defining features of a scientific experiment as "(1) articulation of the research question or hypothesis; (2) specification of the experimental materials; (3) identification of the intervention under study; (4) stipulation of the experimental conditions . . . ; and (5) description of the methods for measuring study outcomes and other study data." *Id.*

129. *Cf.* MELTSNER & SCHRAG, *supra* note 59, at 78 ("[M]any successful test cases are planned with great care."). Like scientists, the lawyers craft a hypothesis and devise a legal methodology in the abstract to address a particular legal question.

ideology, temperament, and non-legal "policy" considerations.[130] Lawyers recognize the malleability and variability of legal "truths" across judges and over time, and incorporate that same malleability into their arguments to present the version of the case they think is most likely to sway the decision maker.

Undoubtedly, the two professions take opposite perspectives on the importance of fidelity to reality in their experimental set-ups. Both professions converge, however, on the challenges of translating innovations and experimental outcomes into the anticipated broader social benefit.

A. Negotiating Fact and Fiction

1. Practice: Emphasis on the Principal Means Adherence to Reality

In both medicine and law, agents learn to sort principals into categories as they attempt to determine the cause of this patient's distress and the cause of action best suited to that client's problem.[131] This distillation leaves some commentators concerned about the extent to which we reduce the rich and varied experience of health and illness into lists of diagnoses and quantified biomarkers, or compress complex social structures and human narratives of struggle into bare-bones fact patterns and enumerated causes of action.[132] Ultimately, though, practitioners are ethically beholden to each principal's needs *as defined by the principal*,[133] meaning that any narrowing that occurs is in the service—and under the supervision—of the person whose identity is being narrowed. Professionals engaged in innovative practice may be mindful of the broader effects of novel developments, but they never lose sight of ensuring the successful resolution of each principal's individual case.

In experimentation, on the other hand, the principal is meant to be subsumed into the class of individuals that she represents. Professionals must smooth over individual distinctions and variations to discover generalizable medical truths and secure generalizable legal impacts. Here we see a divergence between medicine and law in the methods and motivations of experimentation.

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130. *See, e.g.*, Note, *Natural Law for Today's Lawyer*, 9 STAN. L. REV. 455, 455 (1957).

131. *See supra* notes 31–34 and accompanying text.

132. *See, e.g.*, Herbert A. Eastman, *Speaking Truth to Power: The Language of Civil Rights Litigators*, 104 YALE L.J. 763, 766 (1995) (decrying "the chasm separating what those clients told me about their lives and what I wrote to the court as factual allegations in the complaint—sterile recitations of dates and events that lost so much in the translation"). *See generally* Note, *The Plaintiff as Person: Cause Lawyering, Human Subject Research, and the Secret Agent Problem*, 119 HARV. L. REV. 1510, 1516–17 (2006) (discussing the concept of "narrative surrender" in law and medicine) [hereinafter *The Plaintiff as Person*].

133. *See supra* notes 36 and 37 and accompanying text.

2. Clinical Research: Distortion Avoidance

Clinical researchers strive for accuracy in their results, since success is defined in part by how closely the study captures the real-life etiology of disease or mechanisms of recovery. The research community has long recognized the existence of bias[134] and the limits of imperfect measurements.[135] Researchers make every effort to minimize these distortions through rigorous study design,[136] account for them in statistical methodology,[137] and acknowledge them in their publications.[138] In striving for accuracy, researchers engage in distortion *avoidance*, seeking to minimize any differences between their reported results and the reality those results purportedly describe.

3. Impact Litigation: Purposive Distortion

Litigators, by contrast, engage in *purposive* distortion. They selectively suppress and emphasize different aspects of the record, presenting the case as they'd like it to be perceived by judge, jury, and general public. Certain legal fictions are simply a fact of life, familiar common law heuristics roughly superimposed on reality for the sake of consistent and workable judicial decisions.[139] Other distortions, however, may be introduced intentionally to present a compelling narrative or elicit certain questions of law.

In the book *Flagrant Conduct*,[140] Dale Carpenter recounts the events leading

134. *See generally* STEPHEN B. HULLEY ET AL., DESIGNING CLINICAL RESEARCH (2011). The authors note that "chance, bias and confounding can all be reasons why a real association might be missed or underestimated." *Id.* at 141. They discuss sources of bias and error including confounding factors, *id.* at 132, the placebo effect, *id.* at 149, and self-reported questionnaires, *id.* at 9.

135. *See* Donald L. Patrick & Richard A. Deyo, *Generic and Disease-Specific Measures in Assessing Health Status and Quality of Life*, 27 MED. CARE at S217, S225 (1989) (describing the requisite properties of a high-quality measurement tool, including "validity, reliability, responsiveness, effect size analysis, and generalizability").

136. *See, e.g.*, HULLEY ET AL., *supra* note 134, at 45 (discussing double-blind trials as a solution to differential bias).

137. *See, e.g.*, *id.* at 139 (discussing statistical adjustment to account for confounding factors).

138. Peer-reviewed studies typically include a "limitations" section that explicitly enumerates potential sources of error, which serves as a note of caution about putting too much faith in any one study's results. *See, e.g.*, *JAMA Instructions for Authors*, JAMA (last updated Mar. 11, 2014), https://jama.jamanetwork.com/public/instructionsForAuthors.aspx (requiring original research submissions to include "a comment section placing the results in context with the published literature and addressing study limitations").

139. For several examples of legal fictions and an overview of recent theoretical perspectives on the subject, see Nancy J. Knauer, *Legal Fictions and Juristic Truth*, 23 ST. THOMAS L. REV. 1, 1–5 (2010).

140. CARPENTER, *supra* note 96.

up to the Supreme Court's decision in *Lawrence v. Texas*,[141] which declared the unconstitutionality of state anti-sodomy laws. The Texas statute regulated sexual conduct, but the Lambda Legal attorneys and their pro bono and academic allies crafted legal arguments that emphasized intimate personal relationships and the importance of family.[142] These themes were echoed and codified in Justice Kennedy's majority opinion.[143] According to Carpenter's research, however, the two men arrested for violating the Texas law were neither in a romantic relationship, nor had they even engaged in the alleged sexual activity.[144] For the purposes of challenging the law, all that mattered was that John Lawrence and Tyron Garner were arrested in the right place at the right time for the right reasons. Their attorneys entered a plea of "no contest" to preserve a clean factual record,[145] then "abstracted away" from specific acts and specific defendants into lofty rhetoric about liberty and due process.[146]

Important decisions on emotionally fraught subjects like civil liberties often depend on lawyers' ability to successfully transcend the facts of the dispute at issue and redefine the case in terms of core social values that will resonate with the court and the general public.[147] Similarly, litigators in momentous corporate cases are likely to speak about economic principles and impact beyond the specific decision.[148] Here again we see innovative lawyers ascribing primacy to principles over principals, and judges are often willing to play along with the kabuki theater of an individual case when all parties are aware that broader social reform is at stake.[149]

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141. 539 U.S. 558 (2003).

142. CARPENTER, *supra* note 96, at 193 (explaining how "the advocates distanced themselves from the actual circumstances" of the arrest and focused on the concepts of intimacy, relationships, privacy, and family).

143. *Id.* at 259–60; *see also Lawrence*, 539 U.S. at 567 ("When sexuality finds overt expression in intimate conduct with another person, the conduct can be but one element in a personal bond that is more enduring.").

144. *See* CARPENTER, *supra* note 96, at 104 (summarizing the many reasons supporting the author's contention that "there is no reason . . . to believe that there was any actual sex in the U.S. Supreme Court's heralded sexual freedom decision"). The two men arrested for homosexual conduct later denied it, and there were stark inconsistencies in the reports of the two sheriff's deputies who claimed to have observed the act. *See id.* at 61–74.

145. *See id.* at 131 (describing the no contest plea as a "clean option").

146. *Id.* at 247. During the hour of oral arguments at the Supreme Court, no one mentioned the words "anal sex" or "oral sex," nor did anyone refer to either of the defendants by name. *Id.* The lawyers opted for a "strategy . . . to shine a harsh light on the Texas law rather than focus on the defendants." *Id.*

147. *See supra* note 121.

148. *See, e.g.*, Powell, *supra* note 51, at 429 (describing the Delaware case that judicially sanctioned the poison pill).

149. *See* CARPENTER, *supra* note 96, at 140 (explaining how the defendants in *Lawrence* persuaded a Texas judge to increase the size of the fine levied against them in order to satisfy the monetary threshold for appeal). *But see* JOHNSON, *supra* note 97, at 47 (noting that some Justices on

B. Outcomes, Implementation, and Adoption

Innovative professionals are motivated at least in part by the hope of an impact beyond the particular patient or client. However, the outcome of an individual instance of innovation or experimentation may not have a direct link with that broader social purpose. Practicing physicians and lawyers are notorious for their resistance to change,[150] an admirable trait to the extent that adherence to old habits protects principals from risk and uncertainty, but one that may also delay the adoption of potentially beneficial new technologies and techniques. This section examines various mechanisms by which novel developments expand outward from the small communities of innovation outlined in Part II to become part of professional practice more generally. The previous section explained that the fields of medicine and law engender different approaches to factual accuracy in experimentation. These divergent notions of veracity continue to play a role in explaining how novel ideas and techniques are disseminated through each profession.

1. Medicine: Evidence and Guidelines

New ideas and implements developed in medical practice are often adopted and adapted early on by other innovators.[151] Innovations that survive this stage generally follow one of two paths toward broader use. Some new developments are "perceived to have such profound benefits that they [are] introduced and widely disseminated without proper evaluation" in clinical trials.[152] These innovations may ultimately live up to the high expectations,[153] but some later turn out to be "ineffective or even harmful."[154] Meanwhile, novel techniques and tools that do not enjoy widespread adoption early on may undergo formal clinical trials, but even highly favorable results at this stage may fail to overcome the

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the Supreme Court found offensive the idea of "contrived litigation" dedicated to vindicating abstract principles).

150. *See* Riskin et al., *supra* note 15, at 691 ("Health care has been described as the most entrenched, change-averse industry in the United States."); Rosenberry, *supra* note 33, at 456 (discussing "organizational barriers to creativity in law schools and the legal profession").

151. *See, e.g.*, Riskin et al., *supra* note 15, at 689 ("Since some surgeons are technologically savvy and relish new technology, they are often early adopters.").

152. Saha, *supra* note 67, at 7.

153. *Id.* (citing the examples of laparoscopic cholecystectomy, organ transplantation and joint replacements).

154. *Id.* (citing prefrontal lobotomy for schizophrenia and radical mastectomy for breast cancer); *accord* McKneally & Daar, *supra* note 68, at 930 (citing radical mastectomy and routine tonsillectomy); Christina Reith et al., *Randomized Clinical Trials—Removing Unnecessary Obstacles*, 369 NEJM 1061, 1061 (2013) (citing "treatment with anti-arrhythmic drugs after heart attacks" and "routine glucocorticoid use for head injury").

inertia of traditional practice[155] or the fear of malpractice liability.[156]

It seems that both paths toward acceptance proceed apace irrespective of the formal evidence base, with the existence or non-existence of new clinical trials having little immediate impact. Leaders in medicine and public health have become increasingly vocal in their support for evidence-based medicine, imploring physicians to adhere to best practices and restructuring processes of care to establish evidence-based default clinical pathways.[157] Despite these exhortations, the data continue to show wide variation in utilization rates for various procedures[158] and frequent disregard for evidence-based best practices.[159] Blue ribbon panels may articulate clinical guidelines based on hard data from

155. *See* Chris Degeling, *Fractured Hips: Surgical Authority, Futility, and Innovation in Nineteenth Century Medicine*, 33 ENDEAVOUR 128, 132 (2009) ("[S]ometimes the introduction and validation of new forms of evidence is not sufficient to alter the inertia of long-accepted surgical practices."); Jacky Swan et al., *The Object of Knowledge: The Role of Objects in Biomedical Innovation*, 60 HUM. REL. 1809, 1810 (2007) ("[E]ven where the application of scientific knowledge to new treatments has been 'proven' through clinical trials, uptake rates are sometimes poor, as it can be difficult to convince medical and health practitioners to change their existing practices.").

156. *See* Michael D. Greenberg, *Medical Malpractice and New Devices: Defining an Elusive Standard of Care*, 19 HEALTH MATRIX 423, 426 (2009) ("American case law does not appear directly to have addressed the problem of malpractice risk associated with innovative new technology use."). States vary in their methods for defining the standard of care, but "all versions of the malpractice standard are ultimately based on an evaluation of the appropriateness of a physician's conduct, by comparison to what reasonable physicians either do, or should do, in similar circumstances." *Id.* at 430. Innovation is, by definition, a deviation from the standard of care. A successful innovation is cause for celebration, but a deviation that harms a patient is a potential cause of action. In that sense, clinical research regulations serve a protective function: IRB review and informed consent can shield physician-researchers from liability when they test out carefully planned deviations from the standard of care. *See infra* notes 186–190 and accompanying text.

157. *See* Jerry Avorn, *Healing the Overwhelmed Physician*, N.Y. TIMES, June 11, 2013, http://www.nytimes.com/2013/06/12/opinion/healing-the-overwhelmed-physician.html (explaining how medical organizations can play a "'curation' role" by distilling clinical evidence into practice guidelines); *see also* Martin Roland, *Linking Physicians' Pay to the Quality of Care—A Major Experiment in the United Kingdom*, 351 NEJM 1448, 1449 (2004) ("The 1990s were the years of evidence-based medicine, when health professionals gradually came to accept that there were better and worse ways of doing things.").

158. *See* Joseph P. Newhouse & Alan M. Garber, *Geographic Variation in Medicare Services*, 368 NEJM 1465, 1468 (2013).

159. *See* J.B. McKinlay et al., *Sources of Variation in Physician Adherence with Clinical Guidelines: Results from a Factorial Experiment*, 22 J. GEN. INTERNAL MED. 289, 292 (2007) (noting that compliance with various evidence-based guidelines among primary care physicians varied from 6% to 88%); Justin Kung et al., *Failure of Clinical Practice Guidelines to Meet Institute of Medicine Standards: Two More Decades of Little, If Any, Progress*, 26 ARCHIVES INTERNAL MED. 1628, 1628 (2012) (noting that in general, "clinical practice guidelines have played an increasingly prominent role in dictating the practice of medicine," but that these guidelines "demonstrate[] poor compliance with [Institute of Medicine] standards, with little if any improvement over the past two decades").

clinical trials, but it seems that practitioners are nonetheless willing to adopt untested innovations and ignore rigorously proven improvements. This may be due to ignorance of the most recent data[160] or simply the belief that they know what's best for their own patients.[161]

Whatever happens in practice, though, the research community takes note of new updates in the field, and the results from one clinical study often serve as the jumping-off point for another. Research is an inherently iterative process, with each experiment building on and refining the results of those that came before.[162]

2. Law: Subjective Legal "Truths"

The process of implementation plays out differently in law, in part because of the nature of legal "truths." Medical research purports to describe immutable biological facts, and practicing physicians may choose to disagree with the reported results based on other public studies or their own personal experience. Legal truths, however, are ultimately determined and articulated by judges.[163] Practicing attorneys are not free to disregard judicial precedent the way doctors can shrug off non-binding clinical guidelines.[164]

For this reason, lawyers are typically cautious about adopting novel products that were developed in innovative practice. They may be reluctant to pursue legal strategies that have yet to receive official sanction in the legislature or the courts, since their clients would face the risk of an unfavorable judicial decision that could expose them to liability. Even if a novel legal product or theory is approved in one state or circuit, it may not receive similarly favorable treatment in other jurisdictions, and thus lawyers may choose to proceed with caution.

A curious caveat to this argument rests on the principle of strength in numbers: the very fact of widespread adoption could have an effect on a judge's ruling, since the overall consequences of rejecting a particular practice depend in

160. Avorn, *supra* note 157 (describing the constant influx of new information and wryly commenting that "even the most superbly assembled evidence doesn't disseminate itself").

161. *See* Christel Mottur-Pilson, *Physician Explanations for Failing to Comply with "Best Practices"*, 4 EFFECTIVE CLINICAL PRAC. 207, 207 (2001) (noting that "physicians may disagree about what constitutes 'best practices'").

162. The first step in this iterative process is simply to confirm the results. *See* Joffe & Miller, *supra* note 4, at 34 (noting that reproducibility of results is an essential component of creating truly generalizable knowledge).

163. Every law student is familiar with Justice Marshall's famous maxim that judges have the duty to "say what the law is." Marbury v. Madison, 5 U.S. 137, 177 (1803). *See also* ACKERMAN, *supra* note 6, at 18 (explaining the Burkean view that the common law consists of the "gradual accretion of concrete decisions" by judges over time).

164. *Cf.* Sage, *supra* note 67, at 59 ("[L]awyers perceive authority as derived from man-made law . . . , while doctors regard authority as based on science and therefore subject to individual control.").

large part on how prevalent the practice already is.[165] In general, however, it seems the burden of testing novel legal products in court falls on the innovators themselves, with a favorable decision paving the way for broader implementation and use.[166]

The type of experimentation most commonly associated with cause lawyers is less tightly linked to the everyday practice of law, and may not involve so straightforward a question as the validity of a particular corporate structure or contractual feature. Some cases really do produce an immediate and obvious effect, particularly when a pervasive law is declared unconstitutional and can no longer be legally enforced.[167] In some instances, though, society can be as unresponsive to a purported change in the law as free-spirited physicians often are to the latest set of clinical guidelines from an expert panel in faraway Washington, D.C. This raises interesting questions about the difference between "the law as it is written [and] as it is applied."[168]

In some cases, a statute alleged to be unconstitutional may not even be routinely enforced, but activist groups seek to have it declared unconstitutional on principle as a statement about justice, or because its very existence has insidious side effects.[169] In other cases, a decision may seem like a decisive legal victory, but then falls short on actually producing the change articulated in its aspirational vision. *Brown v. Board of Education* is one of the most well-known and publicly praised decisions in recent Supreme Court history, but it is also often cited as a prime example of an ostensibly forceful judicial decree whose implementation depended on intense and chaotic action in legislatures, government offices, and courts across the country.[170] Cases like *Brown* have led

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165. *See* Kettering, *supra* note 15, at 1562. Kettering describes the weak doctrinal underpinnings for the now-common financial practice of securitization, but opines that courts are unlikely to declare it unlawful because of the "drastic adverse consequences for holders of the vast quantity of outstanding securitized debt." *Id.* Thus, he concludes that "the doctrinal shakiness of securitization is now irrelevant, because the product has grown too big to fail." *Id.*

166. *See, e.g.*, Powell, *supra* note 51, at 440. Wachtell Lipton invented the "poison pill" anti-takeover device, and was the only firm to use it until it was upheld by the Delaware Supreme Court in a 1985 decision. *Id.* at 439. "Once the Delaware Supreme Court had put its seal of approval on the poison pill, however, its diffusion occurred very rapidly," and "within nine months of the court's decision 263 companies had poison pills in place." *Id.* The history of the poison pill is discussed at greater length in Subsection II.C.1, *supra*.

167. *See* Hunter, *supra* note 57, at 1013 (noting that after *Roe v. Wade*, "not a single state abortion statute remained constitutional").

168. Etienne, *supra* note 41, at 1212.

169. *See* CARPENTER, *supra* note 96, at 107–08 (discussing the pernicious effects of a law that "packs a strong cultural message about the group it affects," even when enforcement is rare); JOHNSON, *supra* note 97, at 15 (noting that the Connecticut anti-contraception law had "never been enforced," but "likely had a chilling effect on the provision of birth control information," particularly to low-income women).

170. *See* MELTSNER & SCHRAG, *supra* note 59, at 77 (noting that "hundreds of lawyers have

some commentators to claim that litigation is an imperfect tool for social change, or even that litigation alone can never succeed if it's not part of a broader movement of political mobilization.[171]

Of course, the Supreme Court rulings discussed in this Note are notorious for reasons far beyond their impact on the particular legal question at issue in the case. The *Griswold* decision, for instance, achieved a victory by allowing clinicians to provide contraception to married couples without fear of legal sanction, but the case has deeper import in the history of American jurisprudence as the genesis of the modern doctrine of privacy.[172] The law is an ever-flowing river that may change course at any moment. *Griswold*'s privacy rights and *Brown*'s equal protection rights have been subject to constant and often inconsistent reinterpretation.[173] Just as each new clinical study furthers the quest to refine our understanding of disease and wellbeing, experimentation in the law feeds an ongoing process of iterative jurisprudential exploration quite apart from considerations about the concrete day-to-day impacts of each decision.

IV. REGULATING THE PROFESSIONS: EXPERIMENTATION ACKNOWLEDGED AND IGNORED

Thus far, this Note has largely focused on outlining broad similarities—qualified by a few distinctions—in the way the medical and legal professions approach practice, innovation, and experimentation. Enormous differences exist, however, when it comes to the way these distinctions are treated under the law. In Part IV, I briefly trace each profession's history through the twentieth century to better understand how key events and public pressures produced a formal split

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spent twenty years in school desegregation litigation—some of the suits new test cases to interpret [*Brown v. Board of Education*] . . . , some of them mere enforcement actions" against "recalcitrant school boards" or "unreconstructed federal district judges"); Hunter, *supra* note 57, at 1013 (noting the importance of "legislative enactment and litigation enforcement" in *Brown*'s wake).

171. *See* ROSENBERG, *supra* note 58, at 421 ("[T]here is no substitute for political action . . . . [N]ot as a fallback position, not as a complement to a legal strategy, but as the strategy itself."); Kevin R. Johnson, *Lawyering for Social Change: What's a Lawyer to Do?*, 5 MICH. J. RACE & L. 201, 215 (1999) (arguing that "[o]f all the tools for change, political action holds the most transformative potential," while litigation has only "a marginal impact"). *But see* Hunter, *supra* note 57 (arguing that litigation complements political mobilization by providing a vocabulary of rights, a motivational focal point, and salience in the media).

172. JOHNSON, *supra* note 97, at 223 ("The constitutional right of privacy established in *Griswold* . . . was extended . . . to cover such important dimensions of human existence as marriage, procreation, family relationships, child rearing, and education."); *see, e.g.*, *In re* Quinlan, 70 N.J. 10, 40 (1976) (relying on the privacy analysis outlined in *Griswold* to establish the right for patients to refuse life-sustaining treatment).

173. *See, e.g.*, GARY ORFIELD & SUSAN E. EATON, DISMANTLING DESEGREGATION: THE QUIET REVERSAL OF *BROWN V. BOARD OF EDUCATION* 3–4 (1996) (analyzing the history of school desegregation and affirmative action policies and noting a "profound shift of judicial philosophy" in the Court's interpretation of *Brown*'s fundamental principles).

between medical practice and clinical research, and why no such division exists within the legal profession.

A. History of Professional Regulation

1. Medical Dualism: A Response to Past Abuses

The relationship between science and medicine changed dramatically around the turn of the twentieth century. Rapid advances in the natural sciences prompted increasing scientific rigor in medical training and clinical practice,[174] which in turn generated the hybrid role of the "clinical scientist, versed in the bedside practice of medicine and capable of applying the knowledge and techniques of the basic sciences to the study of human disease."[175] At this time, it was common for physicians to experiment on their patients, often without their knowledge.[176]

Revelations of the cruel experiments performed on prisoners in the Nazi concentration camps during World War II shocked the global conscience and inspired the Nuremberg Code, the first international agreement on the ethics of research on human subjects.[177] The Code did not have the force of law,[178] but rather urged physicians to adhere to the ethical research principles as a matter of self-enforced professional responsibility.[179] The Code called for informed consent and voluntary participation from subjects,[180] but in the ensuing years, some American researchers quietly resumed the practice of carrying out potentially harmful experiments on their patients without their knowledge.[181]

In 1966, Harvard researcher Henry Beecher published an article in the *New England Journal of Medicine* describing twenty-two recent studies that put

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174. *See* HARVEY, *supra* note 61, at 404–05.

175. *Id.* at 183. By the end of the nineteenth century, there was a generally recognized distinction between the fields of basic scientific research and medical practice. *Id.* at 128. Clinical researchers existed as a blended role, which "served to bridge the gap" between these professional identities. *Id.* at 183.

176. *See generally* SUSAN E. LEDERER, SUBJECTED TO SCIENCE: HUMAN EXPERIMENTATION IN AMERICA BEFORE THE SECOND WORLD WAR (1997) (describing several experiments conducted clandestinely by medical professionals and by the government in the years 1890 to 1940); *see also* Krupat et al., *supra* note 35, at 50 (describing medical paternalism more generally).

177. *See* Jonathan R. Markman & Maurie Markman, *Running an Ethical Trial 60 Years After the Nuremberg Code*, 8 LANCET ONCOLOGY 1139–40; *see generally* Office Human Research Prots. *The Nuremberg Code*, HHS, http://www.hhs.gov/ohrp/archive/nurcode.html (last updated Nov. 7, 2005).

178. Markman & Markman, *supra* note 177, at 1140.

179. *See* Office Human Research Prots., *supra* note 177 (phrasing the ethical rules as normative professional guidelines rather than hard rules).

180. *Id.* ("The voluntary consent of the human subject is absolutely essential.").

181. *See* Henry K. Beecher, *Ethics and Clinical Research*, 274 NEJM 1354, 1354 (1966); Markman & Markman, *supra* note 177, at 1141–43.

human lives at risk.[182] These studies were carried out at prestigious institutions and were well known in the medical community, but the patients involved were often not aware that they had been subjects in a medical experiment.[183] A few years later, news broke of the Tuskegee syphilis study, a thirty-year, government-funded initiative in which clinicians falsely promised treatment to African American men suffering from venereal disease and instead simply recorded the progression of their illness.[184]

In response to these well-publicized abuses, the federal government conducted hearings, passed legislation, and ultimately established firm ethical and legal requirements for research on human subjects.[185] The ethical underpinnings of this regulatory framework were laid out in the Belmont Report, which explained the imperative to seek voluntary informed consent from research subjects, to refrain from studies in which the risk to human subjects outweighs the potential benefits of the research, and to avoid recruiting subjects from populations that are vulnerable to coercion or abuse.[186] These requirements are codified in the Department of Health and Human Services' "Common Rule,"[187] along with a requirement that all proposed research on human subjects be reviewed by an Internal Review Board (IRB) to ensure adequate protections.[188] Regular medical practice is not affected by these regulations; they only apply to clinical research, defined as any "systematic investigation" designed to "contribute to generalizable knowledge."[189] Whereas the Nuremberg Code

182. Beecher, *supra* note 181. For example, Beecher describes two studies where patients were injected with live cancer cells to test the human immune response. *Id.* at 1358–59.

183. *Id.* at 1354.

184. *See About the USPHS Syphilis Study*, TUSKEGEE UNIV., http://www.tuskegee.edu/about_us/centers_of_excellence/bioethics_center/about_the_usphs_syphilis_study.aspx (last visited June 16, 2013); *see also* Robert M. White, *Unraveling the Tuskegee Study of Untreated Syphilis*, 160 ARCHIVES INTERNAL MED. 585, 595 (2000) (noting that scientific publications describing the Tuskegee study "did not disturb the editors, peer reviewers, and readership," but that the study generated national controversy after "a newspaper article exposed it").

185. *See* Tom L. Beauchamp & Yashar Sangai, *The Historical Foundations of the Research-Practice Distinction in Bioethics*, 33 THEORETICAL MED. & BIOETHICS 45, 47–48 (2012).

186. *Belmont Report*, *supra* note 8. These ethical "applications" are derived from the three fundamental principles of respect for persons, beneficence, and justice.

187. 45 C.F.R. § 46 (2014). *See generally Federal Policy for the Protection of Human Subjects ("Common Rule")*, *supra* note 10.

188. 45 C.F.R. § 46.109. The Common Rule only applies to federally funded research, but the FDA has imposed largely identical requirements on research submitted as part of applications for approval of FDA-regulated products. *See* 21 C.F.R. § 50 (2014). Large academic medical institutions typically require IRB approval for all studies involving human subjects. *See, e.g.*, Office of the Vice President for Research, *Institutional Review Board: Does My Research Need IRB Review?*, U. MINN. (last updated Jan. 6, 2014), http://www.research.umn.edu/irb/research.html ("The university's IRB has assured federal regulatory agencies that the institution will review and approve all research that meet the federal definition of human subjects research.").

189. 45 C.F.R. § 46.102. "Activities which meet this definition constitute research for

envisioned research ethics as a component of individual professional responsibility, the Common Rule represents an external intrusion into the prevailing model of self-regulation.[190]

2. Legal Monism: One Code of Ethics for Many Categories of Conduct

Lawyers have been fiercely committed to the idea of self-regulation since state bar associations were first formed around the turn of the twentieth century.[191] The profession's self-defined role has been the pursuit of justice through adversarial client-centered advocacy.[192] The main professional codes of conduct underwent significant changes in 1969 and 1983,[193] transitioning from a set of aspirational guidelines for ethical behavior and civic virtue to a set of baseline requirements for minimally acceptable conduct.[194] Despite the increased specificity of the modern rules, however, they failed to acknowledge the innovation and experimentation that were already occurring among certain established branches of the profession.[195]

The "corporate revolution" that followed World War I institutionalized the primacy of the publicly traded corporation, prompting increased regulation from

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purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes." *Id.* The definition of "generalizable knowledge" is largely stated in terms of the intentions of the researchers, *see supra* notes 11–14 and accompanying text, which can create uncertainty where an activity designed for quality improvement is construed by HHS enforcers as research, *see infra* notes 236–237 and accompanying text.

190. Self-regulated professions generally seek to preserve their autonomy, but "self-governance is understood to be rooted in a delegation of the legislature's power to regulate . . . . The state grants the authority to self-regulate—and can take it away." Gillian K. Hadfield, *Legal Barriers to Innovation: The Growing Economic Cost of Professional Control over Corporate Legal Markets*, 60 STAN. L. REV. 1689, 1696 (2008).

191. Marvelle C. Webber, *Origin and Uses of Bar Associations*, 7 A.B.A. J. 297, 300 (1921) (arguing that state bar associations should be created because "the bar itself should have broad powers of discipline and control over [admissions]"); *see also* Robert J. Kutak, *Model Rules of Professional Conduct: Why Do We Need Them?*, 36 OKLA. L. REV. 311, 315 (1983) ("There can be no question but that our profession—perhaps more so than any other—is seriously committed to self-regulation."). "Congress has largely remained out of the field of lawyer regulation," Hadfield, *supra* note 190, at 1699, with state courts and bar associations playing a critical role in devising and enforcing the rules, *see id.* at 1698.

192. *See* Johnston & Lufrano, *supra* note 2, at 147.

193. *See generally* Carl Horn, III, *Evolution of Lawyer Self-Regulation: 1908 to 2008 in a Nutshell*, 1 CHARLOTTE L. REV. 3 (2008); John M. Tyson, *Short History of the American Bar Association's Canons of Professional Ethics, Code of Professional Responsibility, and Model Rules of Professional Responsibility: 1908–2008*, 1 CHARLOTTE L. REV. 9 (2008).

194. *See* Tyson, *supra* note 193, at 10.

195. However, the profession's sense of civic duty arguably does encompass serving the public interest as lawyer-statesmen. *See* SOMETHING TO BELIEVE IN, *supra* note 20, at 49; Karen L. Loewy, *Lawyering for Social Change*, 27 FORDHAM URB. L.J. 1896, 1872–74 (2000).

the government.[196] The ensuing specialization among practicing attorneys produced the modern stratified model in which large, elite firms cater to large, corporate clients.[197] Cause lawyering, meanwhile, is commonly thought to have originated with the civil rights movement in the 1960s.[198] There was a backlash against this new form of advocacy from within the legal profession and the public at large,[199] but the organized profession eventually made a kind of uneasy peace with cause lawyering.[200] Indeed, the same politicized identity and strategic litigation tactics have been taken up by liberal and conservative attorneys on a variety of issues, meaning that cause lawyering is now firmly entrenched within the profession and widely represented across the political spectrum.[201]

B. Public Perception and Public Regulation

1. Public Trust

A comparison with the physician-researcher split in bioethics suggests some possibilities that may underlie the legal profession's continued failure to acknowledge its own experimental arm in the codes of professional conduct. Doctors have long been highly trusted as a profession.[202] Trust in medical researchers has not been as carefully studied, but it seems that researchers today benefit from general public trust in universities and health care institutions.[203] Goodwill toward medical researchers is distinct from the public's positive feelings about doctors,[204] however, and is more easily lost in the event of suspicious conduct.[205]

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196. *See* Hadfield, *supra* note 190, at 1703–04.

197. *See supra* text accompanying notes 104–108.

198. *See* SOMETHING TO BELIEVE IN, *supra* note 20, at 4.

199. *See* Thomas M. Hilbink, *"The Kids Are Alright:" Cause Lawyering on Television in 1960s America*, *in* THE CULTURAL LIVES OF CAUSE LAWYERS 203, 204 (Austin Sarat & Stuart Scheingold eds., 2008) ("Many Americans were deeply anxious about this emerging subculture within the generally tradition-bound and well-established legal profession.").

200. *See* SOMETHING TO BELIEVE IN, *supra* note 20, at 40.

201. *See id.* at 3.

202. *See* Mark A. Hall et al., *Trust in Physicians and Medical Institutions: What Is It, Can It Be Measured, and Does It Matter?*, 79 MILBANK Q. 613, 624 (2001); Leo J. Shapiro & Assocs., *Public Perceptions of Lawyers: Consumer Research Findings*, ABA 6 (Apr. 2002) [hereinafter *Public Perceptions of Lawyers*], http://www.cliffordlaw.com/abaillinoisstatedelegate/publicperceptions1.pdf (noting that doctors ranked highest out of ten professions on measures of public confidence).

203. *See* Michael McDonald et al., *Trust in Health Research Relationships: Accounts of Human Subjects*, 3 J. EMPIRICAL RES. HUM. RES. ETHICS 35, 40 (2008); Sugarman et al., *supra* note 21, at 5.

204. *See* Mark A. Hall et al., *Measuring Trust in Medical Researchers*, 44 MED. CARE 1048, 1048 (2006).

205. *See* McDonald et al., *supra* note 203, at 39 ("[T]rust in research relationships . . . could

Even today, the specter of past abuses hangs over experimentation on human subjects. Any article on research ethics typically makes at least a passing reference to this tragic history, and any publicized incident of research subjects coming to harm generates renewed calls for stricter regulations.[206] The memory of past transgressions on the part of clinical researchers also lingers in the public consciousness. For example, individuals who know about the Tuskegee study tend to have less trust in clinical researchers overall and are less likely to consent to participation in research studies.[207]

The history of experimentation in law[208] is, in some ways, the inverse of this cautionary tale. Unlike doctors, lawyers have traditionally been viewed with suspicion and distrust, tolerated as a necessary evil rather than admired as a noble calling.[209] Indeed, the three main seismic shifts in professional self-regulation were motivated in part by a desire among lawyers to improve the public perception of their profession.[210] Cause lawyers, on the other hand, are often held in higher regard than the general profession for the very reason that makes them an anomaly under the Model Rules: rather than acting as a "hired gun" and selling their skills to the highest bidder, they dedicate themselves to serving their conception of the public interest.[211]

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be easily broken.").

206. *See, e.g.*, Rebecca Dresser, *First-in-Human Trial Participants: Not a Vulnerable Population, but Vulnerable Nonetheless*, 37 J.L. MED. & ETHICS 38, 41 (2009) (noting that after a trial in which several subjects experienced severe adverse drug reactions, "some experts called for systemic changes to increase . . . trial safety").

207. Vickie L. Shavers et al., *Knowledge of the Tuskegee Study and Its Impact on the Willingness to Participate in Medical Research Studies*, 92 J. NAT'L MED. ASS'N 563 (2000). It has also been consistently documented that African Americans are more likely than other groups to view medical research as risky and to decline participation. *See, e.g.*, Sugarman et al., *supra* note 21, at 5 (finding this distrust "not surprising[]," given that the African American community "was the subject of perhaps the most egregious episode of abuse of human subjects in American history").

208. This section focuses on cause lawyers, since they represent the most radical departure from traditional legal ethics by shifting the focus from the individual client to the broader social mission.

209. *See Public Perceptions of Lawyers*, *supra* note 202, at 6 ("[T]he legal profession is among the least reputed institutions in American society.").

210. *See* Tyson, *supra* note 193, at 18 ("[A]mendments to the Canons, Model Code, and Model Rules have addressed the changes in the practice of law and expectations of society."); Lewis F. Powell, *The President's Annual Address: The State of the Legal Profession*, 51 A.B.A. J. 821, 822 (1965) (explaining the motivations for updating the professional rules of conduct, including poor public opinion of the profession); *see also* Webber, *supra* note 191, at 300 (noting that state bar associations were created because the legal profession did not hold the "confidence and esteem of the public" and "no greater improvement in this situation can be had without bringing the entire bar into an organization" that "shall be responsible for their professional conduct").

211. *See* Austin Sarat & Stewart Scheingold, *Bringing Cultural Analysis to the Study of Cause Lawyers: An Introduction*, *in* THE CULTURAL LIVES OF CAUSE LAWYERS, *supra* note 199, at 1, 2;

As it turns out, some members of the public reject the traditional premise of lawyers as neutral advocates who preserve the innate justice of the adversarial system. According to a study commissioned by the ABA, the legal profession has "a reputation for winning at all costs, and for being driven by profit and self-interest, rather than client interest."[212] It seems that the public suspects all lawyers of harboring motivations extraneous to their clients' needs, and many would prefer that those motivations stem from a desire to serve the public interest rather than from self-interest.

2. Public Awareness

Often, however, the media and the public simply fail to distinguish between traditional and cause lawyers.[213] Major test cases on important issues typically receive prospective media attention leading up to the oral arguments or the decision, but the coverage tends to focus on the clients rather than the attorneys. The lawyers are often referenced only as "a form of citation to the law";[214] they are portrayed as legal experts helping a brave client seek justice rather than as movers and shakers in a coordinated ideological movement that may well have planned the case from the ground up.[215]

The fact that there are media representations of these cases at all raises another salient point of difference with the medical context, since clinical research is typically conducted out of the public eye in hospitals and laboratories. The public may learn of major discoveries in news coverage of recent findings, but the focus only shifts to the individual researchers when the media profiles a star of the field,[216] or when something goes wrong and a research subject is

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Public Perceptions of Lawyers, *supra* note 202, at 11 (noting that civil rights lawyers enjoy a more positive public perception than the profession at large because they are "said to be working in the public interest").

212. *Public Perceptions of Lawyers*, *supra* note 202, at 7. This attitude likely applies to the corporate lawyers we have been discussing, whose work on behalf of large corporations fails to generate the feel-good response of civil rights attorneys.

213. *See* Sarat & Scheingold, *supra* note 211, at 7 (noting that "representations of cause lawyers in popular culture are often hard to distinguish from representations of mainstream lawyers").

214. Laura J. Hatcher, *Of Windmills and Wetlands: The Press and the Romance of Property Rights*, *in* THE CULTURAL LIVES OF CAUSE LAWYERS, *supra* note 199, at 188, 188.

215. For discussions of how this plays out in a variety of films and news media reports, see *id.* (discussing media coverage of conservative property rights lawyers); Michael McCann & William Haltom, *Nothing to Believe In: Contemporary Films About Public Interest Litigation*, *in* THE CULTURAL LIVES OF CAUSE LAWYERS, *supra* note 199, at 230 (discussing the films *Erin Brokovich* and *North Country*); Stuart A. Scheingold, *Now You See It, Now You Don't: Cause Lawyering, Popular Culture, and* A Civil Action, *in* THE CULTURAL LIVES OF CAUSE LAWYERS, *supra* note 199, at 331 (discussing the book and film versions of *A Civil Action*).

216. *See, e.g.*, *Profiles in Science*, N.Y. TIMES, http://www.nytimes.com/interactive/science

harmed.[217] These latter instances of opprobrious retroactive awareness may feed public feelings of blame or betrayal for studies that are perceived as unethical by design.[218]

Most clinical research and most litigation proceed without major mishap or public awareness. When harm does occur, however, the public perceives the injury differently in the medical and legal contexts. Everyone can agree that a healthy research subject who suffered severe consequences during an experiment suffered a direct harm.[219] The stakes may be just as high for clients in appellate cases, since criminal defendants may be appealing sentences of life imprisonment or execution. Even in civil cases, clients with strong beliefs about racial equality or religious liberty may accord these values equal weight with physical health. Nonetheless, any ruling on equal protection or abortion inevitably leaves some members of the public feeling validated and others feeling oppressed.[220] Moreover, the public may blame the "activist judges" who made the decision rather than the cause lawyers who argued in favor of it.[221]

The emerging picture of cause lawyers is that of a generally favored subset within a generally disfavored profession. In this light, it seems hardly surprising that they have not been the target of regulatory constraints. The legal profession may tacitly avoid drawing distinctions because practitioners benefit from being associated with a publicly admired form of lawyering.[222] The potential harms to clients or society are on par with those of abusive clinical research, but the government has had no need to step in because there has been no public outcry for tighter restrictions on a class of lawyers that generally receives praise, when

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/profiles-in-science-series.html (last updated Apr. 8, 2013) ("A series of articles and videos about leaders in science.").

217. *See, e.g.*, Sabrina Tavernise, *Study of Babies Did Not Disclose Risks, U.S. Finds*, N.Y. TIMES, Apr. 10, 2013 (listing the individual researchers associated with a study under review by the federal Office of Human Research Protections).

218. *See, e.g.*, Dresser, *supra* note 206, at 42 (discussing such a response following the death of Jesse Gelsinger in a gene transfer study).

219. However, confusion over research methods can even produce public opprobrium for studies that likely didn't increase the risk of harm at all. *See, e.g.*, Jeffrey M. Drazen et al., *Informed Consent and SUPPORT*, 368 NEJM 1929 (2013) (arguing that a recent study in which several preterm infants suffered death or blindness was consistent with known research at the time it was initiated, and was thus wrongly targeted for enforcement action by the Office for Human Research Protection (OHRP)); *see also* Tavernise, *supra* note 217 (describing the OHRP enforcement action in the *New York Times*).

220. *See* BARRY FRIEDMAN, THE WILL OF THE PEOPLE: HOW PUBLIC OPINION HAS INFLUENCED THE SUPREME COURT AND SHAPED THE MEANING OF THE CONSTITUTION 9 (2009) (noting that after a controversial Supreme Court decision, "those who disagree with the justices lash out at the Court and the power of judicial review. Those who agree with the justices jump to their defense, waving the Constitution.")

221. *See id.* at 9 (noting that often in the court of public opinion, "a fight over the Constitution becomes one about the judges").

222. SOMETHING TO BELIEVE IN, *supra* note 20, at 127.

the public notices it at all.[223]

C. Protecting Cause Lawyers from Regulation

An intriguing wrinkle to this story is that the Supreme Court has, in fact, singled out cause lawyers as a distinct group, but only in order to *protect* them from regulation. Most notably, the Court held in 1978 that cause lawyers are exempted from state prohibitions on soliciting clients.[224] Justice Powell's opinion in *In re Primus* sums up the ethos of cause lawyering by explaining that organizations like the ACLU and the NAACP pursue litigation not as "a technique of resolving private differences," but as "a form of political expression and political association."[225] The activities of lawyers like ACLU attorney Edna Primus were thus held to be protected under the First Amendment, including their practice of identifying and contacting potential clients.[226] By way of contrast, Justice Powell referenced another decision handed down the same day affirming each state's right to proscribe "solicitation by lawyers who seek to communicate purely commercial offers of legal assistance to lay persons."[227]

Though Justice Rehnquist dissented in the outcome, nowhere in his opinion does he reject the majority's "tale of two lawyers,"[228] which portrayed cause lawyers as distinct from private firms that solicit clients for pecuniary gain. Indeed, no member of the Court disputed the existence of cause lawyers as a subclass of attorneys qualitatively distinct from traditional lawyers; the sole point of disagreement was on the question of whether legislatures and courts can reliably distinguish between the two, or even have the constitutional authority to do so.[229]

In re Primus concerned a private organization, but the courts have also stepped in to prevent the government from unduly interfering in legal programs funded by public dollars. Peter Joy describes a number of statutory restrictions on legal services programs and legal aid clinics at public universities that were struck down under the First Amendment or the Equal Protection Clause.[230] Aside

223. There have been cries for public reform of the bar in general following events like Watergate or the Enron collapse, but "the history of the ABA's professional regulation is to resist these calls for reform . . . and to maintain the regime of self-regulation." Gerard J. Clark, *Monopoly Power in Defense of the Status Quo: A Critique of the ABA's Role in the Regulation of the American Legal Profession*, 45 SUFFOLK U. L. REV. 1009, 1027 (2012).

224. *In re* Primus, 436 U.S. 412 (1978).

225. *Id.* at 428.

226. This is a critical part of cause lawyers' work, since they often work very hard to find just the right client for each case. *See supra* note 53.

227. *Id.* at 422 (citing Ohralik v. Ohio State Bar Assn., 436 U.S. 447 (1978)).

228. *Id.* at 440–41 (Rehnquist, J., dissenting).

229. *Id.*

230. Peter A. Joy, *Government Interference with Law School Clinics and Access to Justice:*

from certain situations where the courts have found a right to appointed counsel,[231] the government has discretion in choosing whether to fund a legal aid program at all. Once funded, however, the judicial consensus seems to be that the government may not place restrictions on the types of clients those lawyers can represent or the types of arguments they are allowed to make.[232] The ABA has also come out in support of independence for legal services programs and legal aid clinics in law schools,[233] evincing the high-level professional approval of public interest lawyers working to represent the underrepresented with both direct services and broader, cause-based initiatives.

The courts are much better than the general public at recognizing and describing cause lawyers, and seem willing to defend their work against certain kinds of regulatory encroachment. This judicial protection is one facet of the generally favorable attitude toward cause lawyers explored in the foregoing sections, a halo of goodwill that may help to explain why cause lawyers are not subject to the kind of strict legal oversight that governs clinical research. Cause lawyers are not the only ones innovating within the law, as discussed in Part II, but attorneys in white shoe firms who represent corporate clients fit with the public's conception of what lawyering normally looks like. Because their innovation and experimentation is likely to be perceived as general legal practice, corporate lawyers are unlikely to be singled out for specific regulation, even if their experimentation is actually quite different from the work of other lawyers. While the innovative cause lawyers discussed in this section were protected from regulation because they *stood out* from the profession for their mission-driven work, innovative corporate lawyers may be similarly protected due to their invisibility *within* the profession.

When Is There a Legal Remedy?, 61 CASE W. RES. L. REV. 1087 (2011). A law prohibiting legal aid lawyers from bringing constitutional challenges on behalf of indigent clients was struck down in *Legal Services Corp. v. Velazquez*, 31 U.S. 533 (2001). *See* Joy, *supra*, at 1098–1100. When the University of Mississippi disciplined clinical professors for helping law students to participate in a desegregation case, the Fifth Circuit found it to be unlawful discrimination under the Equal Protection Clause and a violation of due process. *See* Trister v. Univ. of Miss., 420 F.2d 499 (5th Cir. 1969); Joy, *supra*, at 1100–01.

231. *See* Gideon v. Wainwright, 372 U.S. 335 (1963) (holding that indigent criminal defendants have a right to appointed counsel under the Sixth Amendment); Franco-Gonzalez v. Holder, CV 10-02211 DMG (DTBx), 2013 WL 3674492 (C.D. Cal. Apr. 23, 2013) (holding that individuals in immigration detention who have serious mental disorders "are entitled to the reasonable accommodation of appointment of a Qualified Representative to assist them in their removal and detention proceedings under Section 504 of the Rehabilitation Act").

232. Notably, these decisions only pertain to the faculty, who are licensed practitioners; courts are more permissive with regard to restrictions on the students themselves. *See* Joy, *supra* note 230, at 1105.

233. *See* Joy, *supra* note 230, at 1107 (describing various ABA statements and policies).

V. GRAVITATING TOWARD THE CENTER: IMPLICATIONS FOR REFORM

Though medicine and law now exist under very different regulatory frameworks, both professions show tendencies of gravitating toward the center of the spectrum between practice and experimentation. Practitioners hope to give their patients and clients the benefits of innovation, while professionals engaged in experimentation are often reluctant to relinquish a principal-centered outlook. Part V describes these shared inclinations and explores the implications for each profession's rules of conduct, paying special attention to the specific reforms that are currently being considered in each field.

A. Medicine and Clinical Research

1. A Bright Line with Gray Areas

Because of the stark regulatory bifurcation between medical practice and clinical research, any federally funded activity deemed to "contribute to generalizable knowledge" under the Common Rule triggers a swathe of substantive and procedural requirements.[234] The determination is thus an important one, but is not always easy to make because of the hazy line between research and innovative practice.[235]

"Innovative therapies need not be classified as research . . . so long as they are designed solely to benefit the patient" and are not intended to create generalizable knowledge.[236] This criterion is nominally dispositive, but the distinction is highly subjective, and may change over time as a given treatment is modified and refined. Such delicate parsing can also seem quibbling and misguided in the context of clinical care that generates knowledge without compromising patient interests. A gray area that has attracted attention lately is quality improvement initiatives that involve routine data collection on patient outcomes.[237] These activities may well aim to produce generalizable knowledge useful for improving processes of care, but they have no impact on individual

234. *See supra* text accompanying notes 187–190.

235. *See* PLoS Med. Editors, *How Can We Draw the Line Between Clinical Care and Medical Research?*, 4 PLOS MED. 1707, 1707 (2007).

236. David B. Resnik, *The Clinical Investigator-Subject Relationship: A Contextual Approach*, 4 PHIL. ETHICS & HUMAN. MED. 16 (2009). The AMA's Code of Medical Ethics does not explicitly address innovation, but innovative practice seems consistent with the imperative to "use sound medical judgment, holding the best interests of the patient as paramount." CODE OF MED. ETHICS Op. 10.015 (Am. Med. Ass'n 2001).

237. *See* Brody & Miller, *supra* note 54, at 341 (noting that it may be "difficult to distinguish between some of the more innovative forms of quality monitoring and improvement and formal research trials"); Kupersmith, *supra* note 9 ("[T]he more rigorous the approach to quality assessment (and therefore greater likelihood of data validity), the more burdens that apply, with the result that good research is discouraged.").

patients' care, and would be extremely burdensome if subjected to requirements like informed consent due to the large number of patients involved.[238]

Meanwhile, there is an ongoing debate in the research community about whether the ethics of clinical research are meant to replace traditional medical ethics or simply to supplement them. The "difference thesis" holds that medical practice is about treating patients while clinical research is about seeking generalized knowledge, which may involve compromising the care of individual patients to ensure accurate results.[239] As long as the protocol has been reviewed for an appropriate balance of risks and benefits and patients have provided informed consent, such a study would be deemed ethical. Some researchers instead support a "therapeutic orientation" for clinical research.[240] They maintain that each participant in a research study should be seen as both a subject and a patient, and adherence to a study protocol should not take precedence over providing the best treatment for each individual's medical needs.[241] The main guiding documents in research ethics do not resolve this ambiguity: the text of the Belmont Report suggests that research is distinct from care,[242] but the Institute of Medicine identifies both research integrity and patient safety as "primary interests" that should not be compromised, with no indication of what to do if the two conflict.[243]

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238. For a notorious recent example, see Mary Ann Baily, *Quality Improvement Methods in Health Care*, *in* FROM BIRTH TO DEATH AND BENCH TO CLINIC 147, 148 (Mary Crowley ed., 2008). Researchers at Johns Hopkins University Hospital reduced the incidence of catheter-related bloodstream infections by 66% after analyzing routinely collected patient data following the implementation of a safety checklist. When the researchers published their findings in 2006, however, the federal Office for Human Research Protection (OHRP) determined that the activity constituted research and should have been subjected to the usual Common Rule protections. After an outcry from the medical community, OHRP backed down and allowed the Hopkins project to proceed.

239. *See* Brody & Miller, *supra* note 54, at 332; Joffe & Miller, *supra* note 4, at 39; Rosamond Rhodes, *Rethinking Research Ethics*, 5 AM. J. BIOETHICS 7, 20 (2005).

240. *See* James A. Anderson, *Contextualizing Clinical Research: The Epistemological Role of Clinical Equipoise*, 30 THEORETICAL MED. & BIOETHICS 269, 284 (2009); Robert J. Wells, *Letter to the Editor*, 38 HASTINGS CTR. REP. 6, 7 (2008).

241. This view relies in part on the critique that the difference thesis does a poor job of explaining where ethical research ends and exploitation begins. Given the history of the field, some argue that it is better to risk undermining the research protocol than to risk harming human lives. *See* Resnik, *supra* note 236 (critiquing the view that the difference thesis is permissible so long as researchers do not exploit their subjects); Wells, *supra* note 240, at 6.

242. *See supra* text accompanying notes 11–14. *See generally* Beauchamp & Sangai, *supra* note 185 (explaining the history of the *Belmont Report*'s ethical differentiation of research and practice).

243. *See* COMM. ON CONFLICT OF INTEREST IN MED. RESEARCH, EDUC. & PRACTICE, CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE 6 (Bernard Lo & Marilyn J. Field eds., 2009). For an overview of this report, see Robert Steinbrook, *Controlling Conflict of Interest—Proposals from the Institute of Medicine*, 360 NEJM 2160 (2009).

This debate bleeds over into other areas of research ethics, including discussions about the therapeutic misconception[244] and the value of clinical equipoise.[245] The continuing dialogue on these and other issues demonstrates that ambiguity exists both in differentiating practice from experimentation and also in defining the precise ethical requirements on the latter side. Many clinical researchers are loath to abjure the clinician's mantra to look out for the needs of patients, which keeps the ethics of research tethered to the ethics of practice, despite the existence of an alternate ethical and regulatory framework.

2. Implications for Reform: Amending the Common Rule

In 2011, the U.S. Department of Health and Human Services (HHS) issued an Advanced Notice of Proposed Rulemaking (ANPRM) with several proposed modifications to the Common Rule.[246] Among other changes, the ANPRM aims to replace the all-or-nothing model of human subjects protection with a system in which the level of protection is scaled to match the level of risk. For example, certain types of low-risk studies would be eligible for an "expedited review" process with no annual follow-ups, and others would be exempt from many regulations entirely. As of the time of writing, the public comment period has closed and HHS has yet to announce further action.

Clinical research commentators have proposed or endorsed similar changes over the years,[247] and the foregoing discussion of physician and researcher attitudes lends further support to this proposal. In a way, the ANPRM shifts the regulatory model to approximate what many physicians were already doing. On one hand, any deviation from standard clinical practice could theoretically be considered "experimentation" in that the physician is testing a hypothesis about an uncertain outcome, thereby exposing the patient to risk in the pursuit of

244. Some research subjects fail to understand that a study's primary purpose is to produce knowledge, not to provide personal benefit to them. *See* Gail E. Henderson et al., *Clinical Trials and Medical Care: Defining the Therapeutic Misconception*, 4 PLOS MED. 1735 (2007). Academics concerned about valid informed consent worry that the therapeutic orientation contributes to the therapeutic misconception. *See* Brody & Miller, *supra* note 54, at 330; Henderson et al., *supra*, at 1736.

245. "According to clinical equipoise, it would be wrong to randomize subjects to two arms of a clinical trial, unless the medical community genuinely was uncertain as to which of the two treatments was superior." Brody & Miller, *supra* note 54, at 330 (noting that equipoise is one corollary of the therapeutic orientation); *see also* Joffe & Miller, *supra* note 4, at 39–40 (arguing that "[t]he therapeutic orientation in the guise of the principle of clinical equipoise categorically rules out the use of placebo controls when proven effective treatments exist," which "promotes use of methodologically inferior study designs") (internal footnote omitted).

246. *See ANPRM for Revision to Common Rule*, HHS, http://www.hhs.gov/ohrp/humansubjects/anprm2011page.html (last visited Mar. 10, 2014).

247. *See, e.g.*, Kupersmith, *supra* note 9; McKneally & Daar, *supra* note 68; Reith et al., *supra* note 154.

generalizable knowledge about whether the care deviation will work.[248] Physicians do not design and register a formal clinical trial for each instance of such behavior, however, since this clinical variation is essential for tailoring interventions to each patient's needs and developing novel techniques through innovative practice.[249] Conversely, the debate over the difference thesis illustrates that clinical researchers are wary of research that poses a high risk to patients, even when such risk would likely be permissible under the risk-benefit balance of the Common Rule. A sliding scale of risk-adjusted protections attempts to capture and address the tension between the innovative and therapeutic goals of medicine and research.

B. Innovation and Experimentation in Law

1. Defining the Client's Goals

Unlike medicine, the law affords a single set of professional ethics for activity all along the practice-experimentation spectrum. The ABA Model Rules direct attorneys to "take whatever lawful and ethical measures are required to vindicate a client's cause or endeavor,"[250] which roots any creative developments within a client-centric practice orientation.

The word "lawful" raises interesting questions for innovation, since novel developments introduced in practice may not definitively be seen as legal by the profession at large until they are sanctioned by a judge or codified in a statute.[251] It may well be sufficient for the innovating lawyer to *believe* that the new development is lawful based on a competent legal assessment,[252] similar to the Code of Medical Ethics' insistence on a good-faith effort at "sound medical judgment."[253] Creativity and innovation can help advance the needs of individual clients, but the Model Rules' focus on "vindicat[ing] a client's cause or

248. *See* Brody & Miller, *supra* note 54, at 342–43.

249. *See supra* note 67.

250. MODEL RULES, *supra* note 1, R. 1.3 cmt. para. 1.

251. *See* Subsection III.B.2, *supra* (discussing the processes by which novel legal products and theories disseminate within the profession).

252. A lawyer's competence to handle an issue depends on factors like the "relative complexity and specialized nature of the matter, the lawyer's general experience, the lawyer's training and experience in the field in question, the preparation and study the lawyer is able to give the matter." MODEL RULES, *supra* note 1, R. 1.1 cmt. para. 1. This may explain why innovative practice is typically limited to a small group of high-powered private firms, since they may be uniquely positioned to satisfy these criteria for highly complex transactions and corporate structures. *See supra* text accompanying notes 104–112.

253. *See supra* note 236; *see also* MODEL RULES R. 1.2(d) (noting that a lawyer may "counsel or assist a client to make a good faith effort to determine the validity, scope, meaning or application of the law").

endeavor" [254] can produce ethical quandaries in the legal contexts we have been discussing. As it turns out, corporate attorneys and cause lawyers nevertheless find ways to innovate and experiment within the bounds of ill-fitting professional ethics by carefully selecting their clients and carefully defining their clients' goals.

Corporate attorneys face a conceptual challenge. As Milton C. Regan explains, "[t]he lawyer who represents a corporation represents an abstraction: her client is the corporate entity rather than any of the individuals who act on its behalf."[255] The challenge of serving a legal construct may explain why corporate lawyers often act in an advisory capacity, helping to guide the direction of the corporation in addition to meeting its basic legal needs.[256] To a certain extent, corporate lawyers collapse the distinction between the ends and means of representation:[257] they serve the interests of their client, but may also play an active role in determining what those interests are. Innovative lawyers who develop new legal products and approaches may suggest goals for the corporation that are only possible by virtue of the attorneys' expertise and creativity. If all goes well, the corporation gains a competitive edge and the law firm bolsters its reputation for cutting-edge work.

Cause lawyers face a similar conceptual challenge, since they advocate on behalf of a social movement that may have divisive constituent factions.[258] In order to get to the courtroom, however, they must attach the cause to a particular client capable of meeting the requirements of standing.[259] Using individual cases as vehicles for broader legal reform seems to defy the Model Rules' edict for zealous "advocacy upon the client's behalf,"[260] which is why cause lawyers are perceived by some as "a deviant strain within the legal profession."[261]

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254. MODEL RULES, *supra* note 1, R. 1.3 cmt. para. 1.

255. Regan, *supra* note 105, at 199.

256. *See* Donald K. Langevoort & Robert K. Rasmussen, *Skewing the Results: The Role of Lawyers in Transmitting Legal Rules*, 5 S. CAL. INTERDISC. L. J. 375, 377 (1997) (noting that business law "is probably the setting in which elite lawyers are most widely employed in an advisory capacity"); Powell, *supra* note 51, at 432.

257. *See supra* notes 36 and 37 and accompanying text (describing the traditional division of authority as one where the client determines the goals of representation and the lawyer decides the means).

258. *See supra* note 102 and accompanying text; *see also* Eastman, *supra* note 132, at 801 ("Sometimes I wondered who my client was—the person with the name, the class she represented, or the issue behind her . . . .").

259. *See supra* note 53. Unlike social movements, corporations are legal entities that are capable of suing and being sued as if they were people. *See, e.g.*, Louisville, Cincinnati, and Charleston R.R. Co. v. Letson, 43 U.S. (2 How.) 497, 555 (1844) (superseded on other grounds by statute as noted in Hertz Corp. v. Friend, 559 U.S. 77 (2010)).

260. MODEL RULES, *supra* note 1, R. 1.3 cmt. para. 1.

261. Sarat & Scheingold, *supra* note 211, at 2. These authors cite cause lawyers' unabashed partisanship as an additional component of their deviancy. The Model Rules note that a "lawyer's

What happens, for example, when the lawyer has the opportunity to settle a case, or to win in court on a technicality? Both these options could provide swift and definitive resolution for the client, but would fail to establish the precedent the lawyer was hoping for.[262] Some clients may be reluctant to risk victory on their personal dispute, or to endure the publicity associated with being the face of the case. Under the Model Rules, the lawyer could discuss the goals of litigation and attempt to persuade the client to stay the course,[263] but would ultimately have to accede to the client's demands.[264]

To avoid this problem, experienced cause lawyers typically screen potential clients to make sure they are willing to prioritize the movement's goals over any personal concerns.[265] There would seem to be no conflict under the Model Rules if the client is as enthusiastic about social reform as the lawyers themselves. Clients are tasked with determining the goals of representation, which could reasonably involve decisions like declining settlement offers and pushing for a trial. In such a scenario, the whole business of cause lawyering can be recast as client-centered advocacy on behalf of a social-minded client.[266] These cause

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representation of a client . . . does not constitute an endorsement of the client's political, economic, social or moral views or activities," MODEL RULES, *supra* note 1, R. 1.2(b), but cause lawyers are "eager to take sides in social conflict and to identify themselves with the sides they take," SOMETHING TO BELIEVE IN, *supra* note 20, at 9. Thus, they "destabiliz[e] the dominant understanding of lawyering as properly wedded to moral neutrality." Sarat & Scheingold, *supra* note 211, at 2.

262. MELTSNER & SCHRAG, *supra* note 59, at 2; *see also In re* Primus, 436 U.S. 412 (1978) (noting that the NAACP represents individual clients in segregation cases but rejects "any relief short of full integration"). *But see* MODEL RULES, *supra* note 1, R. 1.2(a) ("A lawyer shall abide by a client's decision whether to settle a matter."). For an example where settling a dispute concerning a specific agency decision vitiated standing for the purposes of challenging the underlying rule, see Summers v. Earth Island Institute, 555 U.S. 488 (2009).

263. *See* MODEL RULES, *supra* note 1, R. 1.2 cmt. para. 2 (noting that in the event of a disagreement, "the lawyer should . . . consult with the client and seek a mutually acceptable resolution.").

264. MODEL RULES, *supra* note 1, R. 1.2 cmt. para. 1 (noting that the client has "the ultimate authority to determine the purposes to be served by legal representation"). Negotiations over the goals of representation also create the potential for sophisticated cause lawyers to manipulate less educated clients. *See* DAVID LUBAN, LAWYERS AND JUSTICE: AN ETHICAL STUDY 317 (1988); Loewy, *supra* note 195, at 1884–85.

265. *See* MELTSNER & SCHRAG, *supra* note 59, at 82 (noting that many cause lawyers will "accept only clients who are willing to be test case litigants" and all that that entails); *see also* CARPENTER, *supra* note 96, at 131–34 (explaining how two men arrested for sodomy were hesitant about a protracted public legal campaign, but were ultimately persuaded to act as test case litigants after hearing about the history of the LGBT rights movement).

266. Some have argued that cause lawyering is only truly ethical when it incorporates the principles of informed consent, as in clinical research. *See* Loewy, *supra* note 195, at 1892; *The Plaintiff as Person*, *supra* note 132, at 1512. Warning potential clients about the implications of participating in cause-oriented litigation is both commendable and prudent, but a rigorous informed consent requirement may fail to assist vulnerable clients any more than cause lawyers' consciences already do. This has to do with the specific nature of legal practice, *see* Etienne, *supra* note 41, at

lawyers have broad goals of generalized impact, which means they are well out of the zone of routine practice. Nonetheless, they manage to adhere to the letter of the Model Rules and the spirit of client-centered zealous advocacy, despite the fact that the true nature of their motivations falls outside the scope of practice envisioned in those rules.

2. Implications for Reform: Proceed with Caution

The initial inquiry of this Note focused on similarities in the actual processes of innovation in experimentation in medicine and law. Despite the many shared features, the foregoing discussion suggests that imposing medicine's dualistic regulatory model in the legal context would be inappropriate or at least unnecessary. The Model Rules do not explicitly acknowledge experimentation, but the two innovative strains of lawyers discussed here have nonetheless settled into a comfortable quasi-compliance. The safeguards of conscience and client satisfaction prevent attorneys from trampling clients' desires in a quest for legal change.

Thus, an awareness of legal experimentation may not in and of itself suggest new directions for regulatory reform, but it can certainly play a role in informing the existing debate over proposed changes to the Model Rules. The intensifying global competition for legal services[267] has generated growing interest in novel approaches to payment, employee compensation, and practice management.[268] Some argue that these structural adjustments are inhibited by regulatory restrictions, such as prohibitions on multi-jurisdictional or multi-disciplinary practice[269] or the rules on conflicts of interest.[270] A full discussion of specific proposals is beyond the scope of this Note, but those considering the merits of proposed changes would do well to reflect on the potential repercussions for legal activity all along the practice-experimentation spectrum.

As one example, consider a prominent set of recent proposals from a group

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1256–58 (rejecting the notion of informed consent as a waiver of conflicts of interest in cause lawyering), as well as with general problems with informed consent that have manifested in the research context, *see* Sugarman et al., *supra* note 21, at 6 (noting that despite informed consent, up to 40% of research subjects are unaware that they are enrolled in a research study); Tavernise, *supra* note 217 (explaining that fear of legal liability has resulted in "voluminous [informed consent] forms that do more to protect the institution than to empower the potential subject").

267. *See supra* notes 126 and 127 and accompanying text.

268. *See, e.g.*, Erik Mazzone, *The Innovation Imperative: Adapt or Die?*, 39 L. PRAC. 4 (2013) (suggesting institutional innovations in response to recession and discussing barriers to innovation).

269. *See* Clark, *supra* note 223, at 1028–34 (2012); Hadfield, *supra* note 127, at 9.

270. *See* Lawrence Fox, *The Gang of Thirty-Three: Taking the Wrecking Ball to Client Loyalty*, 121 YALE L.J. ONLINE 567 (2012), http://www.yalelawjournal.org/forum/the-gang-of-thirty-three-taking-the-wrecking-ball-to-client-loyalty (critiquing proposed changes to the rules on conflicts of interest).

of thirty-three large corporate firms,[271] who argued that the current rules limit the firms' ability to effectively represent or sue certain entities.[272] The proposed changes would likely allow firms to boost their profits by increasing the number and diversity of permitted clients and causes of action. These revisions would alter the landscape of attorney and firm incentives in routine practice, and some critics have expressed concern about the repercussions of weakening existing rules designed to safeguard attorneys' loyalty to their clients.[273]

What about the effects on innovation? A firm that develops a novel legal product for Client A may have success replicating that product for other clients, as explained in Section II.C. The current rules on conflicts of interest and imputation prevent anyone in the firm from working on any matters on behalf of entities that are adverse to Client A,[274] so loosened rules on loyalty would allow the firm to work with a much broader array of new clients. The proposal would thus seem to offer a means of accelerating innovation in the corporate world, since the experts who develop novel products and theories would be able to spread them more quickly to more potential clients.

On the other hand, relaxing the rules on conflicts of interest might also harm Client A's interests. Imagine Entity B who is adverse to Client A. After the innovative transaction is completed on behalf of Client A, Entity B might expressly seek out the same firm in order to take advantage of their unique expertise on the workings of that novel product. The proposal would permit such representation even while the firm continued to represent Client A, as long as the adverse representation of Entity B did not pertain to a "substantially related" matter.[275] Thus, the potential for the adverse Entity B to gain an unfair advantage would depend on how far courts were willing to stretch that language. Courts that recognize the large role that some corporate attorneys play in guiding corporate strategy and direction[276] may well take a broad view of matters "substantially related" to the representation, which would significantly attenuate the proposal's impact.

Given the lack of specific rules for innovation in the law, the only

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271. *See, e.g.*, *id.* (describing changes proposed by 33 AmLaw 100 firms).

272. *See* Robert C. Bernius et al., *Proposals of Law Firm General Counsel for Future Regulation of Relationships Between Law Firms and Sophisticated Clients*, ABA COMM'N ON ETHICS 20/20 (Mar. 2011), http://www.abajournal.com/files/ABA_Ethics_Commission_Proposals_--_3-8-11.pdf (proposing a new set of rules on conflicts of interest and limitations on liability for "sophisticated clients").

273. *See* Fox, *supra* note 270; Diane Lourdes Dick, *Legal Ethics, Commercial Practice, and the Certainty Imperative: A Cautionary Note*, 40 N. KY. L. REV. 279, 286–88 (2013).

274. *See* MODEL RULES, *supra* note 1, R. 1.7, 1.8, 1.10; *see also* Fox, *supra* note 270, at 572–74 (discussing rules on conflicts of interest).

275. Bernius et al., *supra* note 272, at 4.

276. *See supra* notes 255–257 and accompanying text.

protections for clients and for society are those built into the general professional code of conduct. A change like loosened restrictions on conflicts of interest may well alter firms' decision making on when and how to pursue legal outcomes with broad impacts beyond the specific case. These questions of incentives for firms and individual attorneys merit further discussion.

C. Attitudes Toward Rules

I conclude with a final contrast between the medical and legal professions that relates to their attitudes toward rules and authority. Doctors are trained to be "autonomous decision-makers" who make tough choices on the fly in the face of overwhelming uncertainty.[277] Swapping one set of written rules for another when physician-researchers switch from medical practice to clinical research may create new legal obligations, but will not necessarily undermine the medical professional's deep-seated faith that she can trust her gut and follow her instincts.

Legal education is precisely the opposite, inculcating students with the habit of referring back to sources of authority and verifying compliance.[278] Clever attorneys can always find a loophole, and it seems corporate and cause lawyers may have done just that with regard to the Model Rules: they've accommodated the requirements of client-centered advocacy by playing a role in defining their clients' goals, as well as by seeking out the right kind of clients. This latter behavior may once have been difficult to reconcile with state prohibitions on solicitation,[279] but the *In re Primus* decision took care of that problem.[280] ACLU attorney Edna Primus did what cause lawyers do best when they encounter an objectionable law: she climbed up to the Supreme Court and used litigation to change it.

These prevailing professional attitudes about authority work in precisely opposite directions, which explains how they managed to produce the same ultimate effect of gravitating toward the center of the practice-experimentation spectrum. The medical profession is regulated by strict legal requirements on clinical research, but physician-researchers have learned to be comfortable making decisions in defiance of specific rules whenever doing so seems to be in

277. Sage, *supra* note 67, at 59; *accord* Riskin et al., *supra* note 15, at 690 (noting that "[s]urgeons are fundamentally decision makers," which is why they "have historically been idea generators and creative practitioners within their craft").

278. *See* SOMETHING TO BELIEVE IN, *supra* note 20, at 51; Kutak, *supra* note 191, at 315; Sage, *supra* note 67, at 59 ("[R]ule-based governance is natural to lawyers, whose business is writing, interpreting, and enforcing rules.").

279. *See, e.g.*, MELTSNER & SCHRAG, *supra* note 59, at 86. This book was published four years before the *In re Primus* decision, and the authors sigh that "[w]ere it not for the ethical restrictions on advertising and solicitation, the public interest lawyer might simply identify the characteristics of the ideal plaintiff, locate him, and ask him if he would mind lending his name to a suit."

280. *See supra* text accompanying notes 224–229.

the best interest of their patients. Innovating lawyers, on the other hand, face no additional regulatory strictures on their work, but their rule-abiding tendencies result in processes of innovation and experimentation that often fully comply with the demands of the practice-centric Model Rules of Professional Conduct.

VI. CONCLUSION

"Trial and error" is a familiar heuristic for problem solving that involves repeated attempts with varied methods until an approach finally works or generates clues for further refining the strategy. Clinical trials and judicial trials both demand a far more systematic approach, but they do involve the risk of "error" to the extent that patients and clients may be subjected to the risk of the unknown, albeit often with their consent. In routine practice, such risk would only be imposed when it furthered the principal's own goals, but experimentation is precisely designed to discover the unknown, using individual cases to map out new territory with "generalizable knowledge."

Moving along the spectrum from routine practice to experimentation involves a growing focus on generalizable knowledge as agents abstract away from the needs of individual principals. Successful innovative practice and experimentation also require deep professional expertise and resources, whether in the form of financial or human capital. As a result, these activities tend to be concentrated in practice settings like academic medical centers, public interest law organizations, and prestigious private firms.

Though the processes of innovation are similar across medicine and law, there are notable differences arising out of the unique structure of the American legal system. The two professions also face starkly divergent regulatory models: medicine has a bright line dividing clinical practice from clinical research, while lawyers of all stripes are governed by the same code of professional ethics. Nevertheless, professionals all along the spectrum in both occupations seem to lean toward the center, combining the novelty of innovation with the principal-centered orientation of traditional practice. In this way, medicine and law achieve a rough balance in according equal weight to principles and principals.