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# The Law of Patient Innovation

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ABSTRACT

Although the movement for patient empowerment has been under way for decades, patients remain relatively marginalized by medical providers, innovators, and payers. Physicians diagnose and prescribe treatment, innovators endeavor to develop drugs and devices that they can recommend to both physicians and payers, including Medicare. Patients remain in the background, presumed to be passive recipients of breakthroughs that follow this system of discovery and finance. The law is a significant reason why this is so. This Article outlines the most significant areas of law that need to change to allow patients to innovate in collaborative partnership with their physicians, including the law of tort, human subjects research, healthcare finance, and intellectual property. By identifying these areas, changes and modifications to law may be more easily assessed by both state and federal law-makers.

## I. INTRODUCTION

Despite a decades-long movement nominally committed to patient autonomy, informed consent, and sovereignty, the actual position of the patient in the modern U.S. healthcare system remains largely that of a passive recipient of the advice of providers (generally physicians) and the drugs and devices of biomedical developers and manufacturers.[1] Although researchers have developed measures of patient engagement and patient activation, the average patient follows up on referrals to specialists, fills and manages medications, and complies with physical therapy and other regimes provided by others.[2]

To some extent, this dynamic results from the knowledge disparities between patients on the one hand and, on the other, providers and innovators. Physicians are extensively trained, and patients may be easily misled by poor information, or misunderstand valid information.

Online health information is difficult to regulate, meaning quality control is a challenge, and, further, patients vary widely in their health information literacy. Bad health information used in an improper way can be highly detrimental. Patients might trust misleading information or might make important health decisions based on sensationalized or emotionally charged stories that are not relevant to their health context.[3]

Yet patients also have a tremendous amount of knowledge about their own conditions and many of them are well-equipped to help adapt and innovate treatments. Their incentives are almost always aligned with outcomes.[4] Patients want to heal and they want to invest in what they need to do so.[5] This is particularly true for patients with complex, rare, or unknown diagnoses.[6]

Consider the case of Doug Lindsay. Doug suffered from debilitating and degenerative chronic fatigue. Related maladies ran through his family history, but there was never an effective diagnosis or treatment.[7] After consulting a 2,200-page

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1.Barbara Chubak, *Clinical Responsibility in the Age of Patient Autonomy*, 11(8) VIRTUAL MENTOR 567, Aug. 2009, at 567. ("The Principles of Biomedical Ethics by Thomas Beauchamp and James Childress, arguably the foundational text of contemporary bioethics, was first published in 1979 at the close of a decade that witnessed the rise of the international patients' rights movement. In the United States, this movement placed, and continues to place, a particular emphasis on individual choice, in keeping with the dominant political ethos of our nation, which since its conception has privileged the enlightened, rational, and productive individual actor. Out of these ideas, the principle of respect for autonomy was born, and, since then, the influence of this single principle on the provision of health care and conduct of biomedical research has eclipsed that of the other principles: beneficence, nonmaleficence, and justice.").

2. Len Schlesinger & John Fox, *Giving Patients an Active Role in Their Health Care*, HARV. BUS. REV., Nov. 21, 2016.

3. Tabitha Tonsaker, MSc, Gillian Bartlett, PhD, & Cvetan Trpkov, *Health information on the Internet: Gold mine or minefield?*, 60(5) CANADIAN FAM. PHYSICIAN 407, May 2014, at 407.

4. https://healthpayerintelligence.com/news/patient-incentives-from-payers-encourage-preventive-care-visits

5. Harold DeMonaco, Pedro Oliveira, Andrew Torrance, Christiana von Hippel, & Eric von Hippel, *When Patients Become Innovators*, MIT SLOAN MGMT. REV., Feb. 21, 2019.

6. *Id.*

7. Ryan Prior, *This College Dropout was Bedridden for 11 Years. Then he Invented a Surgery and Cured Himself*, CNN (July 27, 2019, 11:40 AM), https://www.cnn.com/2019/07/27/health/doug-lindsay-invented-surgery-trnd/index.html.

endocrinology textbook he happened upon, he reasoned that his illness may be related to adrenal glands on his kidneys.[8] After additional research, he refined his diagnosis to an autonomic nervous-system disorder.[9] Lindsay presented his findings to a conference held by the National Dysautonomic Research Foundation, a charity committed to the condition he suffered.[10] Lindsay's disorder was almost unheard of, and most researchers in attendance had determined this diagnosis was highly improbable. While at the conference, Lindsay met Dr. H. Cecil Coghlan, a medical professor at the University of Alabama-Birmingham who believed Lindsay had proposed a valid theory. Dr. Coghlan helped Lindsay repurpose a drug approved for an entirely different condition, and then helped Lindsay research and pioneer a surgery for his condition. Prior to surgery, Lindsay could sit for no more than an hour or two a day.[11] Within two months of the surgery, he was able to walk a mile to church and went on a major vacation six months after that. [12] Had Lindsay not innovated with respect to both medicine and surgery, he would not have found a cure. Doctors had been unable to figure out what was going on with his body, and his situation was rare enough that there was no market to justify pharmaceutical company investment.

While Lindsay's story is multifaceted – involving physicians, non-profit organizations committed to medical research, market failures for rare diseases, and more – this essay focuses on the law. Specifically, at which points in the patient innovation process does law facilitate or hinder treatments, medicines, devices, and/or surgeries that a patient has determined, in consultation with providers, to be in her best interest, but deviates from the standard of care? Closely related, how does law affect the decisions of payers, primarily insurance companies, to manage situations in which well-informed patients challenge standard practice, sometimes in ways that are less expensive?

## II. THE STANDARD OF CARE, HUMAN SUBJECTS RESEARCH, AND EXCEPTIONS FOR CLINICAL INNOVATION

Even when patients come to their providers with ideas and innovations as to medications, devices, and treatment regimens, providers remain constrained by the standard of care of like physicians who treat the same ailment or condition.[13] Innovation is by definition the pioneering of new treatment options.[14] The inherent conflict is clear: when a provider aids a patient or implements the patient's innovative approach, she deviates from the standard of care. The resulting conflict is one between pushing new understandings of medicine to better treat patients and risking vulnerable patients on unproven or unknown procedures. Thus, there is a need for governance of the relationship to ensure that providers do not face excess liability

8. *Id.*
9. *Id.*
10. *Id.*
11. *Id.*
12. *Id.*
13. *See* Brook v. St. John's Hickey Mem'l Hosp., 380 N.E.2d 72, 76 (1978). There are some modifications depending on local law. Some physicians are further held to the standard of physicians in that community. In most cases, the standard of care is also shaped by available resources like technology, staffing, and nearby tertiary care centers.
14. *Innovation,* DICTIONARY.COM, https://www.dictionary.com/browse/innovation?s=t (last visited Nov. 23, 2020).

and patients are adequately informed as to the standard of care and the risks that accompany the deviation and innovation.[15]

For innovations so described, they are considered "research," not medical practice, and the protections that humans enjoy when they are medical research subjects are extensive. Medical practice is defined by the Belmont Report[16] as "interventions which are designed solely to enhance the well-being of an individual."[17] "Research" is defined as activity designed to test a hypothesis and thereby contribute to general knowledge.[18] "Innovation" (other than research) is a significant departure from standard practices, but not necessarily subject to rigorous review for purposes of testing a hypothesis.[19]

These distinctions are critical when discussing surgical innovation, especially. Surgeons frequently deviate from standard practices with each patient, as each is unique and requires the surgeon to tailor each operation.[20] The law thus becomes amorphous and ill-defined at the boundary at which a surgeon is innovating or merely tailoring the surgery.

Research generally lends itself to a rigorous process of approval and verification, primarily to ensure that risks are balanced with benefits for human medical research subjects, and that the subjects are adequately informed of those risks. When attempting to add to the general knowledge of medicine, providers must be careful to take the proper steps and draw the correct conclusions.[21] The Belmont Report is clear that an evaluation of efficacy or safety falls within the realm of research.[22]

Patient innovation therefore lies between the legal protection of medical malpractice tort liability and the protections offered (importantly by federal law as well as state) for human research subjects. [23] The malpractice pathway is one in which the provider is subject to minimal scrutiny while performing the innovative treatment, but afterwards may be held liable in any malpractice suits that may be brought in tort.[24] The human subjects research pathway is a more prospective approach, requiring a greater degree of oversight and regulation, but minimizing liability for the doctor afterwards.[25]

The medical practice pathway, from a legal standpoint, is a natural extension of basic tort and medical malpractice law. The patient needs the provider to undertake the innovation, but the provider (and certainly its insurer) may be deterred by

15. *See* Anna C. Mastroianni, *Liability, Regulation, and Policy in Surgical Innovation: The Cutting edge of Research and Therapy*, 16 HEALTH MATRIX 351, 354 (2006).

16. *See generally* NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, DHEW Pub. No. (OS) 78-0012, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH 11 (1978).

17. Nancy M.P. King, *The Line Between Clinical Innovation and Human Experimentation*, 32 SETON HALL L. REV. 573, 573 (2002) (citing NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, DHEW Pub. No. (OS) 78-0012, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH 11 (1978).

18. *Id.*

19. Mastroianni, *supra* note 13, at 361.

20. *Id.* at 364.

21. *See Id.* at 358-59.

22. *Id.* at 361.

23. *Id.* at 370-71.

24. *Id.*

25. *Id.*

tort liability.[26] A patient whose innovation has failed and results in real or perceived injuries will not only have the basic elements of a tort claim satisfied, but will inevitably have experts who will testify that the innovated procedure or treatment did not meet the standard of care.[27] In some cases, an innovative surgery may fall outside what is considered the customary practice; however, in other cases, courts appear to give great deference to defendant-physicians in exercising their best judgement.[28] Indeed, some courts recognize therapeutic innovation as a defense, carving out protections for physicians who make themselves knowledgeable about treatment alternatives and work with patients to innovate in ways that promote patient welfare but do not arise to experimentation.[29]

Alternatively, patient innovation may be advanced as research. Within the research framework, the innovation process is necessarily researcher led, with specific rules that weigh risks to patients and ensure that they are effectively and comprehensively informed.[30] The patient is made aware of all risks and benefits of the treatment, and sometimes even the physician is forced to re-examine their thinking and justifications for a procedure.[31] Informed consent adds an ethical layer of patient protection to the legal one. [32] The process is overseen by an Institutional Review Board ("IRB") or ethics committee, which is charged with approving the research protocol and monitoring patient benefits and risks over the course of the study.[33]

Yet by its nature, the federally guided research process marginalizes patients. Patients are not generally interested in research design that contributes to knowledge, including requirements for double-blind clinical trials. They are interested in innovations that will promote their own health and lives.[34]

Even the ethical criteria of patient research are tilted against patient-led innovation.[35] While an operation or procedure may pose risks desperate patients are willing to ignore at their peril, these same risks are weighed by Institutional Review Boards and ethics committees, who may give decisive weight to the benefits of not treating the patient, or not innovating.[36]

Physicians are constrained legally by a potential for severe liability in the face of malpractice suits.[37] Federal regulations guiding informed consent cabin the patient into a passive role.[38] The informed consent process allows the patient to take an active role in the process only by permitting or prohibiting the innovative

26. *Id.* at 376.
27. *Id.* at 377
28. *See* Brook v. St. John's Hickey Mem'l Hosp., 380 N.E.2d 72, 76 (1978) (holding that a physician injecting a contrast medium into the calves of a child instead of the standard gluteal muscle site was not a breach, as the physician adjudged it the prudent course after reading journal articles about injuries from injecting contrast medium in the wrong places).
29. Mastroianni, *supra*, note 13, at 380-81.
30. *Id.*
31. *Id.* at 416-18
32. *See* King, *supra* note 15, at 578.
33. 45 C.F.R. § 45.111 (2020); 21. C.F.R. § 56.111 (2020).
34. Mary E. Tinetti & Ethan Basch, *Patients' Responsibility to Participate in Decision Making and Research*, 309(22) JAMA 2331, 2331 (2013).
35. King, *supra* note 15, at 573.
36. *Id.*at 581.
37. Alberto Galasso & Hong Luo, *Physicians liability and medical innovation*, VOX EU CEPR,(July 24 2016), https://voxeu.org/article/physician-liability-and-medical-innovation.
38. *See* Benjamin Littenberg & Charles D. MacLean, *Passive Consent for Clinical Research in the Age of HIPPA*, 21(3) J. OF GEN. INTERNAL MED. 207, 211 (2016).

treatment solution offered by the physician.[39] In short, patients have the final say in whether a treatment happens, and when a physician circumvents the patient's approval, some courts have held the physician liable for battery.[40]

## III. THE LAW OF HEALTHCARE PAYMENT

Even if a patient succeeds in convincing his or her physician that the risk of malpractice liability is negligible and decides to proceed outside the federally-regulated research process, who is to pay for potentially expensive innovations developed by patients?[41] Insurance companies, the Centers for Medicare and Medicaid Services, and even charitable organizations typically make decisions as to whether to cover treatment based on proven safety, efficacy, and standard practice.[42]

While patient innovation is driven by the unique resources of personal experience and dedication to life improvement, payers are able to utilize massive amounts of data regarding their customers (those same patients).[43] Payers have significantly more information about the long-term effects of drugs and are able to push for innovation in light of that information. One such example was the removal of Vioxx from the market after Kaiser Permanente, a large integrated provider and payer, was able to demonstrate the drug caused fatal heart attacks.[44] Vioxx was a new generation of pain medication developed by Merck. The drug obtained FDA approval.[45] However, years later, Kaiser Permanente undertook a study to compare patients who took the drug with those who had not and found that those who took it were significantly more likely to experience a heart attack.[46] Kaiser Permanente could do this because of its considerable access to patient information. The information available to Kaiser was much larger in scope than that of Merck's lab studies. After the results of the data were published, Vioxx was pulled from the market, and its risks were eliminated.[47]

This story demonstrates that innovation for payers does not come in the form of any sort of physical good (i.e., the artificial pancreas or a new pain medication), but rather in the form of information.[48] Payers are able to learn more about healthcare, as opposed to providing a physical, tangible innovation.[49]

As a result, the current incentives for medical innovation (patents and exclusivity) are generally not conducive to payer data innovation.[50] In the absence of a new good to sell, payers keep secret the information they learn regarding health care

39. Mastroianni, *supra* note 13, at 416-18.
40. *Id.* at 417.
41. Sonali R. Mishra et al., *"Not Just a Receiver": Understanding Patient Behavior in the Hospital Environment*, PROCEEDINGS OF THE SIGCHI CONFERENCE ON HUMAN FACTORS IN COMPUTING SYSTEMS. CHI CONFERENCE, 3103–3114 (May 2016), https://doi.org/10.1145/2858036.2858167 ("During these stays, patients are often viewed as passive recipients of care, rather than as active stakeholders who can make decisions and even prevent errors.").
42. *See* Demonaco et al., *supra* note 4.
43. Rebecca S. Eisenberg & W. Nicholson Price, *Promoting Healthcare Innovation on the Demand Side*, 4(1) J.L.&BIOSCI. 3, 3 (2017).
44. *Id.* at 8.
45. *Id.*
46. *Id.*
47. *Id.*
48. *See* Demonaco et al., *supra* note 4.
49. Eisenberg & Price, *supra* note 41, at 30.
50. *Id.* at 12.

and use what they learn for themselves to cut costs and increase profit where possible.[51] Therefore, a patient who innovates as to treatment must not only prove its effectiveness, but also its cost efficiency, for purposes of most payer interests. The motivations payers have to innovate can be similar to, but may differ from, patients. While patients are seeking relief from disorders or symptoms, often payers are seeking to minimize costs in healthcare.[52] Payers usually target innovation that can reduce cost either by remaking a drug from prescription-only to over-the-counter, or by demonstrating that a newer and more expensive drug is not necessary compared to a cheaper, older drug.[53] This sort of cost minimizing is only available to payers, as the other major actors in the healthcare system either are missing the resources or incentives to do so.[54] The drug manufacturers and providers both seek a profit, and the patient has minimal access to the larger data necessary to drive the innovation payers are able to create.[55]

However, some advocates for patient innovation claim a comparative analysis of risk is possible. Demonaco argues the risks taken on by patients using homemade devices and treatments should be compared to the risks a patient faces if not using any device at all. [56] When this paradigm is used, the benefits offered by a device may outweigh the risks it involves. Often, payers are willing to share their information with physicians, who may use it in some circumstances to aid patient innovations.[57]

Payer innovation in aid of patient innovation may also advantage physicians. One such example is off-label prescription, or when a drug is used for something other than what it was produced and tested for by the manufacturer.[58] Drug manufacturers have little to no incentive to undertake expensive trials for the efficacy of drugs in off-label uses.[59] Payers can fill a vital role here by supporting the doctor's off-label uses as a means for treatment and verifying its effectiveness with large-scale data. Because a payer is the only one with access to broad spectrum data regarding treatment practices of patients, they are able to confirm an off-label use as effective or not and have an incentive to do so.[60]

Doctors, then, are exercising a healthy and justified skepticism regarding patient innovation. A homemade remedy or device can be incredibly risky for the patient. Additionally, a patient offering an opinion on their treatment in the face of a doctor's expertise is, at the least, unhelpful. In the rare instance that a patient can research sufficiently as to discuss with confidence their own ailments and potential treatments, doctors still act with trepidation upon a patient's recommendations.[61] Payers present a slightly different story in that they are equipped with patient data

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51. *Id.*
52. *Id.*
53. *Id.*
54. *Id.*
55. *Id.*
56. *See* Demonaco et al., *supra* note 4.
57. Eisenberg & Price, *supra* note 41, at 30.
58. Sam F. Halabi, *Off-Label Marketing's Audiences*: *The 21st Century Cures Act and the Relaxation of Standards for Evidence-Based Therapeutic and Cost-Comparative Claims*, 44 AMERICAN JOURNAL OF LAW & MEDICINE 181 (2018).
59. *Id.*at 18.
60. *Id.* at 19.
61. Rebecca E. Say &Richard Thomson, *The Importance of Patient Preferences in Treatment Decisions–Challenges for Doctor*s, 327 BMJ 542, 544 (2003).

exceeding that of providers or even drug testing by manufacturers.[62] While often the interests of providers and payers collide, much can be accomplished when the two are able to cooperate.[63]

Relatively little writing or literature is available regarding the attitude an insurance company may have towards, say, Doug Lindsay's situation. After all, it would be a hard pitch to an insurance company to get them to greenlight a surgery created by their customer. However, Eisenberg talks at length about the primary motivation of payer innovation: profit.[64] It is perfectly reasonable to assume, then, that an insurance company may be at least interested in covering the cost of cheaper and more effective treatments, despite them being created by the patient. For example, in Lindsay's situation, the two choices are to continue a lifetime of high-cost care, in and out of hospitals and paying for expensive treatments that doctors are uncertain about; or paying for one surgery that Doug has prepared a lengthy treatise to demonstrate the possibility of a cure. With the success of Lindsay's surgery came an elimination of costly treatments, so it appears logical the payer would support these innovations where it can. Another example is the artificial pancreas, as discussed by Demonaco.[65] A combination of a basic insulin pump and a cheap ($30) computer can create a more effective treatment than the constant use of disposable test kits and costly doctor's appointments.[66] So, considering the profit incentive, it makes sense for a payer in many situations to financially support patient innovation in some measure.

The patient innovator has several complicated motivations, ranging from solving their own ailments, to helping others do the same, to potentially making a marketable product. The payer is interested in profit.[67] Payers innovate where profit intersects with new knowledge. For example, Blue Cross worked to get a non-sedative antihistamine approved as an over-the-counter (OTC) medication instead of one requiring a prescription.[68] The manufacturers of the non-sedative antihistamine were resistant to change the drug to OTC, so as to maximize the amount of time they had the exclusive right to sell the drug. However, Blue Cross California demonstrated that the non-sedative was just as safe if not safer than standard (sedating) antihistamines, and thus should be approved as an over-the-counter alternative.[69]

The other side of this coin is the efficiency check payers offer on the system.[70] Often, manufacturers and providers are creating newer and more elaborate forms of treatment (new drugs, devices, procedures, and methods) that cost more, and may or may not be more effective than the previous treatments. The payer offers a check on this by working to determine what is the most efficient method of treatment. One example is payer research into precision medicine.[71] This is a form of treatment

62. Jeff Lagasse, *Better Data Sharing Between Payers, Providers Can Move the Needle on Social Determinants of Health*, (Mar. 24, 2020), https://www.healthcarefinancenews.com/news/better-data-sharing-between-patients-providers-can-move-needle-social-determinants-health.
63. *See Id.*
64. Eisenberg & Price, *supra* note 41, at 5.
65. *See* Demonaco et al., *supra* note 4.
66. *Id.*
67. Eisenberg & Price, *supra* note 41.
68. *Id.* at 8.
69. *Id.*
70. *Id.* at 18.
71. *Id.* at 21.

where a genetic test is taken of a patient to identify what drugs would be the most effective in the patient due to their genetic makeup.[72] The resulting treatment is able to specifically target those who would benefit from a preventative drug (such as Herceptin, used to prevent breast cancer).[73] This interests large drug manufacturers less because they are interested in ensuring as many people purchase and consume their drug as possible. But it aligns neatly with what payers want, to ensure only those who need treatment are getting it. This forced efficiency acts as a check on the drug makers in a way that benefits patients as well as payers.

The primary resource payers are utilizing for innovation is their data.[74] Many payers do not have their own drug researchers or clinical lab studies, but they have access to all the healthcare information of their clients. From doctor visits to prescriptions to diagnoses, payers know a great deal about those for whom they issue payments This offers them an opportunity that drug manufacturers and even providers do not have. With a large-scale and long-term view of all of their patients, payers are much more able to recognize trends that others may not. A manufacturer may not understand the long-term effects of its drug, especially when those effects materialize outside the time of a clinical study. A provider may not realize their patient is seeing another doctor for something that seems unrelated but can tie into their work (such as patients prescribed Vioxx seeking a cardiologist). And a patient has no way of knowing their experience is part of a larger trend. The only one who can really step into this place is the payer who is seeking to reduce their costs by implementing new standards based on the large-scale data they have.

Another hurdle is the data itself. The reality is that perfect data about imperfect humans is very difficult, if not impossible, to collect. There are a myriad of problems encountered in the data.[75] First, patients change payers over their lives. A payer does not always have life-long data on one patient, as they move around between providers.[76] Additionally, secrecy (as discussed above)[77] and HIPAA dis-incentivizes payers from sharing patient data with patients who might benefit from it.[78] There is no standardized format for data of health records, so it can be difficult or impossible to merge data across payers.[79]

## IV. THE LAW OF DRUG AND DEVICE REGULATION

The U.S. Food and Drug Administration is the most important regulator of drugs and devices relevant to patient innovation.[80] As the authority on guidelines and safe practices, compliance with their standards is necessary to offer innovations in a commercial setting. This review, approval, and subsequent compliance with FDA regulations is expensive and often cost-prohibitive for treatments with small markets.[81]

72. *Id*. at 20-21.
73. *Id.* at 20.
74. *Id*. at 12.
75. *Id.* at 23.
76. *Id.* at 22.
77. *See* discussion *supra* Part III.
78. *See* discussion *supra* Part III.
79. Eisenberg & Price, *supra* note 41, at 5.
80. FOOD AND DRUG ADMINISTRATION, FDA AT A GLANCE (October 2019), *available at* https://www.fda.gov/media/131874/download.
81. *See* Demonaco et al., *supra* note 4.

Patient innovators circumvent this by avoiding commercialization. 90% of patient innovators offer their designs and inventions for free to the public.[82] Because these patients are not selling their developments, they do not need to conduct large-scale tests of their product, and instead can simply make it and share what they found works with others in similar situations.[83] Under the commerce clause, the FDA cannot regulate noncommercial activity.[84] Patient innovators are seeking some form of treatment for their own needs, thus their reward and motivation is not profit, but rather relief from symptoms or a cure.[85]

Payers encounter the FDA in more complicated ways. The FDA works closely with manufacturers to ensure sufficient testing is being performed. Because payers want to learn more about drugs on the market, the FDA prefers not to be involved.[86] The FDA states their "institutional mission is approving new drugs, not re-evaluating already approved drugs."[87] The FDA prefers to rely on clinical studies over observational studies.[88]

The FDA encourages drug manufacturers to research off-label uses for their drugs to assist in off-label innovation.[89] The FDA prohibits the active marketing of off-label uses, but even that assertion has receded in the face of some First Amendment challenges, which have argued that all parties should be able to make truthful, non-misleading statements about drugs, even off-label uses.[90]

The FDA has adapted the payer's model of developing patient records for its own research purposes, which carries an indirect approval of payer methods. In what is called the Sentinel Program, the FDA has established a network of patient records so as to monitor the long-term effects of drugs.[91]

In sum, the FDA appears to be apathetic at best and resistant at worst toward patient innovation. Patients who develop their own cures or devices must circumnavigate the FDA by sidestepping the bases of federal jurisdiction. The FDA has not taken an overtly hostile position towards these patient innovators who stay within the non-commercial space.[92] Payers face both hurdles and assistance from the FDA: sometimes they are resistant towards re-examining a drug in light of new evidence, other times they work closely with payers to research the efficacy and safety of drugs with long-term data, and recently they have begun adapting payer methods to do research for themselves.

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82. *Id.*
83. *Id.*
84. *Id.*
85. *Id.*
86. Eisenberg & Price, *supra* note 41, at 9.
87. *Id.* at 11.
88. https://endpts.com/fda-will-allow-observational-studies-as-part-of-a-push-for-real-world-evidence-new-framework-says/
89. *Id.* at 18-19.
90. *Id.* at 19.
91. *Id.* at 39.
92. Scott Gottlieb, *FDA's Comprehensive Effort to Advance New Innovations: Initiatives to Modernize for Innovation*, U.S.FOOD AND DRUG ADMINISTRATION (Aug. 29, 2018), https://www.fda.gov/news-events/fda-voices/fdas-comprehensive-effort-advance-new-innovations-initiatives-modernize-innovation.

## V. THE LAW OF INTELLECTUAL PROPERTY

Innovations may also be valuable in ways that are sufficient to be protected by patents, copyrights, or trademarks.[93] Given the potential financial interests, a conflict of interest may develop between the patient and the provider as to who "owns" all or most aspects of the innovation. While surgical processes are notoriously difficult to protect with intellectual property mechanisms, devices may in fact be very valuable, especially some that patients have developed like those relevant to physical therapy.[94]

In the well-known case of *Moore v. The Regents of the University of California*, a patient sued the doctor who treated him for hairy-cell leukemia, challenging the physician's orders to remove his spleen as well as "blood, bone marrow aspirate, and other bodily substances," The patient alleged that the physician's intent to use those substances in potentially lucrative clinical research conflicted with the patient's interest in the best health outcome.[95] The Supreme Court of California determined that the physician had breached his fiduciary duty, not of loyalty, but of disclosure, since the economic interest of a physician may be material to a patient's decision. [96]

[A] physician who is seeking a patient's consent for a medical procedure must, in order to satisfy his fiduciary duty and to obtain the patient's informed consent, disclose personal interests unrelated to the patient's health, whether research or economic, that may affect his medical judgment.[97]

In that decision, the court adopted the "reasonable patient" standard when determining materiality. [98] Most courts have adopted a "reasonable physician" inquiry that operates much like a standard of care analysis privileging physicians' opinions of one another, not the trust relationship they share with the patient. [99]

Several courts have held that physicians have an affirmative duty to disclose information that will affect a patient's care.[100] For instance, physicians have an affirmative duty to disclose to patients any financial interest in clinical research.[101] What happens when a patient comes to the physician with a potentially lucrative

93. Joshua A. Vecht, ET AL.,*Surgeons produce innovative ideas which are frequently in the labyrinth of patents*, 35 EUR J.CARDIOTHORAC SURG. 400, 400(2009).

94. Jonas Anderson, *Nonexcludable Surgical Method Patents*, 61, WM. & MARY L. REV.637, 676 (2020).

95. Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 481 (Cal. 1990).

96. *Id.* at 485.

97. *Id*.

98. Nadia Sawicki, *The Abortion Informed Consent Debate: More Light, Less Heat*, 21 CORNELL J.L. PUB. POL'Y 1, 19 (2011); Nixdorf v. Hicken, 612 P.2d 348, 354 (Utah 1980) ("The relationship between a doctor and his patient creates a duty in the physician to disclose to his patient any material information concerning the patient's physical condition. This duty to inform stems from the fiduciary nature of the relationship . . . .").

99. 5 Med. Malpractice (Matthew Bender) § 22.05 (2013) (reporting that the reasonable patient standard "remains the minority position"). In states using the reasonable physician standard, a physician would only be required to disclose "an interest extraneous to the patient's health" if other physicians customarily did so. Moore, 793 P.2d at 484.

100. Emmett v. Eastern Dispensary and Casualty Hosp., 396 F.2d 931, 935 (D.C. Cir. 1967) ("We find in the fiducial qualities of that relationship (between physician and patient) the physician's duty to reveal to the patient that which in his best interests it is important that he should know.").

101. Marc. A Rodwin, *Strains in the Fiduciary Metaphor: Divided Physician Loyalties and Obligations in a Changing Health Care System*, 21 AM. J. L. & MED. 241, 248 (2005).

idea? How might patient interest in healing and physician interest in a patent compromise the patient innovation possibilities?

Indeed, by choosing to seek out and desire medicine labeled "cutting edge" and innovative, patients drive demand for those who innovate and may be interested in such incentives.[102] Surgeons in particular are driven by prestige and economic demand to innovate. It is not just patients who drive this demand. The best hospitals want pioneering surgeons, media attention is given to those who can make a breakthrough, and academic communities give prestige to innovative surgeons.[103] All of this acts as a drive for surgeons to be the next pioneer, and at the forefront of that is the patient who demands a new treatment for their ailment. Should patients decide they no longer desire innovative surgeries, there would be little financial incentive for surgeons and providers to continue pushing new bounds. While the raw demand for an innovative procedure results in providers willing to do so, the flip side is the risk the patient offers as a potential liability for the provider.[104] When a new procedure becomes available, there is a lifecycle of malpractice suits that arise, driving physicians to perfect and stabilize the procedures and make patients safer.[105]

## VI. SOLUTIONS

Ultimately, there is a balance that must be sought among the competing legal interests outlined above: innovating and advancing human understanding of medicine, while maintaining the safety and agency of patients. This balance is what the federal Belmont Report sought, as well as subsequent federal regulations on innovation.[106] The current attitude by legal scholars appears to be a desire to increase oversight and place more restrictions on innovation.[107] Recommendations center around increasing oversight through registries and standardizing decision-making for physicians. The benefits are obvious, fewer rogue physicians means fewer injuries. But the downsides to restricting innovation to established standards of care or expensive formalized research are important to consider as well.

One solution may be expanding what is considered the standard of care. If we simply consider the standard of care to be what other doctors in the same situation do, then we will see only incremental improvements, as the common law contemplates.[108] However, if we expand the standard of care to both allow for innovation and require adherence to certain guidelines, it is a promising middle ground.

Some jurisdictions are already doing this. In *Henrich v. Sweet*, the 1st Circuit indicated having a procedure reviewed by an Institutional Review Board before implementing it upon a patient may serve as a partial defense to malpractice claims.[109] This allows for a patient and her doctor to practice somewhat outside standards of practice, but only at the approval of neutral observers who may adjudge the risks

102. Mastroianni, *supra* note 13, at 363-364.
103. *Id.*
104. *See generally Id.* at 374 (speaking on medical practice pathway to legal oversight).
105. *Id.* at 374-75 (quoting Kenneth A. De Ville, *Medical Malpractice in Twentieth Century United States: The Interaction of Technology, Law and Culture,* 14 INT'L J. TECH. ASSESSMENT HEALTH CARE 197, 204 (1998)).
106. *See generally* King, *supra* note 15, at 573-582.
107. Mastroianni, *supra* note 13, at 433; King, *supra* note 15, at 581.
108. Charles P. Sabatino, *The Evolution of Health Care Advance Planning Law and Policy*, 88 THE MILBANK Q. 211, 218 (2010).
109. Heinrich v. Sweet, 308 F.3d 48, 69 (1st Cir. 2002).

and benefits better than the doctor or the patient. By expanding the standard of care to not simply cover the actions of the doctor immediately surrounding the treatment of the patient, but rather including how they go about seeking professional review, it may be possible to limit the risks of rogue treatment while also allowing doctors to innovate in a streamlined manner.

Establishing a standard of care that requires doctors to submit to oversight from Institutional Review Boards or federal guidelines, and patients to give informed consent can result in patients being treated safely and doctors being able to innovate and pioneer new treatment. Doug Lindsay's story has what appears to be a typical demonstration of a doctor's attitude to patient innovation. Many of the doctors Doug met with were skeptical of his theories and proposed treatment plans.[110] This comes with good reason, too. Often, patients know little beyond what their body tells them. "I'm chronically exhausted" can be the symptom of a wide array of symptoms, and it seems unreasonable that a patient should have much say in diagnosis theorizing as the individual with years of training and experience in this subject. It took Doug attending the conference of Dysautonomic Researchers with years of his own research into this narrow topic before even one person at the conference listened to him.[111] Later, when he designed a surgery, he prepared over 300 pages of research, plans, and evidence of the efficacy of this surgery, and he still had to pitch it to many, many surgeons before one of them agreed to perform it.[112] The risks faced by surgeons who agree to perform unproven surgeries can include financial loss in the form of malpractice suits and loss of their license.[113]

Payers could open up more channels to receive innovative and cost-effective ideas from patients. Many have some limited forums for patient feedback; most have some sort of technological review for recently approved or contemplated drugs and devices. These arms of insurance companies could be expanded and some of their own research resources dedicated to mining their own data to confirm experimental hypotheses. The information could be published for patients to consult with their physicians.

With respect to intellectual property, the problems are more difficult to solve, but they may be rarer. Use of medications off-label is likely to mean that they are no longer protected by patents in any case.[114] Surgical methods are already difficult or impossible to patent.[115]

## VII. CONCLUSION

Patient innovation is an important step in the decades-long movement toward patient autonomy, agency, and sovereignty. This essay has endeavored to outline some of the main legal barriers and questions that surround patient innovations, the physicians, payers, and regulators that surround them. As these innovations

110. Prior, *supra* note 6.
111. *Id.*
112. *Id.*
113. Ronald M. Stewart et al., *Trauma Surgery Malpractice Risk: Perception Versus Reality* 241(6) ANN. SURG. 969 (2005).
114. *See* Sam F. Halabi, *The Drug Repurposing Ecosystem: Intellectual Property Incentives, Market Exclusivity, and the Future of "New" Medicines*, 20 YALE J.L.AND TECH.1, 24 (2018).
115. *See* Anderson, *supra* note 90, at 637.

advance with more access by patients to more information, hopefully, it will provide a useful guide to addressing the many complicated questions that will arise.