Investing in Health Care: What Happens When Physicians Invest and Why the Recent Changes in the Patient Protection and Affordable Care Act Fail to Protect Patients from Their Physicians' Self-Interest

Nancy L. Zisk*

I. INTRODUCTION

Traditionally, physicians have made money by seeing patients. To-day, more than in the past, physicians also make money by investing in the diagnostic tools and services they recommend that their patients use. The Patient Protection and Affordable Care Act (PPACA or the Act), passed as a cornerstone of President Obama's presidency, is designed to protect Americans in a variety of ways, including by more stringently regulating physicians' ownership of the tools and services they recommend to their patients and by augmenting the disclosure requirements imposed on physicians when they do have a financial interest in the services they recommend.²

Under established statutory and ethical rules, physicians must disclose their ownership interests in diagnostic tools such as X-ray machines and scanning equipment, and now under the PPACA, physicians must put that disclosure in writing and provide a list of alternative providers their patients may see instead.³ This provision, which appears uncontroversial on its face, is not likely to draw a legal challenge. But re-

^{*} Professor of Law, Charleston School of Law, J.D., Duke University, B.A., Duke University. The author wishes to thank Dr. Robert Sade for his guidance and support and Stephen A. Burroughs for his research assistance.

^{1.} Patrick A. Sutton, The Stark Law in Retrospect, 20 ANNALS HEALTH L. 15, 17 (2011).

^{2.} Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010); Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010) (disclosure rules codified at 42 U.S.C. § 1395nn (2012)). On June 28, 2012, the United States Supreme Court upheld the constitutionality of much of the Act, including the mandatory minimum coverage provision (informally referred to as the "individual mandate" provision) and the more stringent disclosure rules. Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S.Ct. 2566 (2012). The only portion of the Act that the Court struck down was § 1396c, which gave the Secretary of Health and Human Services the authority to withhold Medicaid funding from states that refused to participate in the Act's Medicaid expansion. *Id.* at 2607.

^{3. 42} U.S.C. § 1395nn(b)(2)(B).

cent research suggests that, instead of protecting patients from physicians' financial self-interest, the current disclosure requirements impose a great weight on patients—forcing patients to stay with physicians and even help physicians achieve such financial goals.⁴

As shown in the American Medical Association's 1957 "Principles of Medical Ethics," there was a time when patients were protected from the financial self-interest of their physicians, who were expected to derive professional income only from patient services. But in 1975, the United States Supreme Court held that the federal antitrust laws applied to all of the "learned professions," and following that decision, restrictions on advertising, investment, and fee-setting were invalidated, making physicians free to invest in the business of medicine. Few observers disagree that physicians should earn money for what they do, but many question whether physicians should have a financial interest in the equipment they use or the facilities to which they send their patients because the prospect of financial gain has been shown to affect the decisions they make.

A physician's expectation of financial gain when a patient chooses treatment options that the physician owns creates a classic conflict of interest in the physician–patient relationship. Studies have shown repeatedly that, despite their commitment to provide the best possible care to their patients, physicians who own diagnostic and treatment tools and

.

^{4.} See Daylian M. Cain et al., The Dirt on Coming Clean: Perverse Effects of Disclosing Conflicts of Interest, 34 J. LEGAL STUD. 1 (2005); Sunita Sah et al., How Doctors' Disclosures Increase Patient Anxiety (Working Paper No. 1970961, 2011), available at http://ssrn.com/abstract=1970961 [hereinafter Sah et al., Patient Anxiety]; Sunita Sah et al., The Burden of Disclosure: Increased Compliance with Distrusted Advice (Working Paper No. 1615025, 2011), available at http://ssrn.com/abstract=1615025 [hereinafter Sah et al., The Burden of Disclosure].

^{5.} See JUDICIAL COUNCIL, AM. MED. ASS'N, PRINCIPLES OF MEDICAL ETHICS § 7 (1958), available at http://www.ama-assn.org/resources/doc/ethics/1957_principles.pdf.

^{6.} Goldfarb v. Va. State Bar, 421 U.S. 773, 786 (1975) (citing Sherman Act, 15 U.S.C. §§ 1-7).

^{7.} See, e.g., Wilk v. Am. Med. Ass'n, 895 F.2d 352 (7th Cir. 1990) (applying the Sherman Act to invalidate the AMA's prohibition against physicians associating with "unscientific practitioners" including chiropractors); In re Am. Acad. of Optometry, 108 F.T.C. 25 (1986) (applying the Federal Trade Commission Act, 15 U.S.C. §§ 41–58 (1986), to prohibit the American Academy of Optometrists from restricting advertising, solicitation, or choice of location of practice); see also Joshua E. Perry, An Obituary for Physician-Owned Specialty Hospitals, 23 HEALTH L. 24, 25 (2010); Sutton, supra note 1, at 17.

^{8.} See, e.g., Adam Candeub, Contract, Warranty, and the Patient Protection and Affordable Care Act, 46 Wake Forest L. Rev. 45, 47 (2011); Marc A. Rodwin, Physicians' Conflicts of Interest: The Limitations of Disclosure, 321 New Eng. J. Med. 1405, 1405 (1989) [hereinafter Rodwin, Physicians' Conflicts of Interest]; Rune J. Sórensen & Jostein Grytten, Competition and Supplier-Induced Demand in a Health Care System with Fixed Fees, 8 HEALTH ECON. 497, 497 (1999).

^{9.} Marc A. Rodwin, *Medical Commerce, Physician Entrepreneurialism, and Conflicts of Interest,* 16 CAMBRIDGE Q. HEALTHCARE ETHICS 387, 387 (2007) [hereinafter Rodwin, *Medical Commerce*].

services recommend such tools and services to their patients more often than physicians who have no ownership interest. ¹⁰ Based on these studies, the law has imposed rules to minimize the effects of these conflicts of interest on medical decision-making by limiting physicians' ownership options and requiring physicians to disclose their ownership interests. ¹¹

With the PPACA's retention and strengthening of established disclosure rules, it is now time to ask whether these rules are effectively protecting patients. Unfortunately, recent research suggests that disclosure does not have the intended effect of allowing patients to choose physicians free of financial conflicts of interest and that disclosure may actually have the opposite result on patients. ¹² Indeed, one recent group of studies suggests that when patients learn of their physicians' financial interests in the recommended treatment options, patients are actually less likely to seek alternative care and more committed to doing what their physicians suggest to help their physicians reach such financial goals. ¹³ This paradoxical result is worsened when patients lose trust in their physicians' advice and begin to question whether their physicians have financial self-interests or the patients' best interests in mind when prescribing care. ¹⁴

This Article therefore considers possible ways to protect a patient's interest in receiving care and advice that reflects solely what is in the patient's best interest and not what might be in the interest of his or her physician's financial health. Part II reviews the importance of trust in the physician–patient relationship and examines how that relationship is affected by the conflict of interest that arises between patients and their physicians who own the medical facilities, devices, and treatment ser-

^{10.} See Candeub, supra note 8, at 47; Rodwin, Physicians' Conflicts of Interest, supra note 8, at 1405; Sórensen & Grytten, supra note 8, at 497; Sutton, supra note 1, at 20; see also Mireille Jacobson et al., Does Reimbursement Influence Chemotherapy Treatment for Cancer Patients?, 25 HEALTH AFF. 437, 441 (2006) (noting that providers who were "more generously" reimbursed prescribed more costly chemotherapy regimens than other less-generously reimbursed providers).

^{11.} See 42 U.S.C. § 1395nn. This statute comes from two previous iterations, known individually as "Stark I" and "Stark II," for the sponsor of the bill, Representative Fortney "Pete" Stark of California. It was recently amended by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), and the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010). For a discussion of the federal and state laws on ownership and disclosure, see *infra* Parts III, IV.

^{12.} See Cain, et al., supra note 4; Sah et al., Patient Anxiety, supra note 4; Sah et al., The Burden of Disclosure, supra note 4.

^{13.} Sah et al., Patient Anxiety, supra note 4, at 15; Sah et al., The Burden of Disclosure, supra note 4 at 34

^{14.} Sah et al., *Patient Anxiety, supra* note 4, at 15; see also Matthew J. Morris, Secrets Don't Make Friends, But They Do Make Good Business: Perception Versus Reality in Physician Financial Incentive Plans, 49 St. Louis U. L.J. 245, 255 (2004).

vices prescribed. Part III examines the ethical and statutory restrictions that have been and are currently imposed on physicians who own facilities or services to which they refer their patients. Part IV reviews the professional, state, and federal disclosure requirements imposed on physicians who diagnose and treat patients with devices and services they own, and examines the recent research suggesting that the current disclosure requirements may do little to protect patients' interests or to encourage patients to seek alternative care. 15 Part V reviews potential alternatives to protect patients in light of such research. Part VI concludes that a total ban on physician ownership would solve the problem but, given the legal constraints on imposing such a ban, recommends a change in how physicians are paid for the medical care they provide. In cases where physicians own the equipment they use in the diagnosis and treatment of their patients, physicians could be required to bill their patients a flat fee, to be disclosed prior to the start of treatment and to cover the entire course of their patients' care. 16 This will remove entirely the temptation to use diagnostic tools or treatment services for any reason other than the best interest of the patient. In light of the empirical findings that patients trust their physicians less after learning of their physicians' financial interests but nevertheless feel compelled to follow their physicians' advice and help them reach their financial goals, medical, legal, and ethics scholars and decision makers should confront these realities and adopt a model that restores the proper balance between a patient's best interest and a physician's interest in financial gain.

II. THE IMPORTANCE OF TRUST AND HOW A CONFLICT OF INTEREST AFFECTS THAT TRUST

It is by now axiomatic that before treating patients, physicians must obtain their patients' consent.¹⁷ Historically, physicians did not disclose risks to their patients, believing that such disclosure might upset the patient and scare him or her away from treatment the physician believed was necessary.¹⁸ Indeed, it was not until 1957 that a court first used the term "informed consent" when describing the duty of disclosure that is

^{15.} See Cain, et al., supra note 4; Sah et al., Patient Anxiety, supra note 4; Sah et al., The Burden of Disclosure, supra note 4.

^{16.} See Sutton, supra note 1, at 48 (suggesting payments based on "an episode of care rather than a separate fee for each performed").

^{17.} See, e.g., Moore v. Regents of Univ. of Cal., 793 P.2d 479, 483 (Cal. 1990); Quintanilla v. Dunkelman, 34 Cal. Rptr. 3d 557, 572 (Ct. App. 2005); Spencer v. Goodill, 17 A.3d 552, 554–55 (Del. 2011).

^{18.} Tom L. Beauchamp, *Informed Consent: Its History, Meaning, and Present Challenges*, 20 CAMBRIDGE Q. HEALTHCARE ETHICS 515, 515 (2011).

imposed on a treating physician.¹⁹ Today, to obtain meaningful consent, physicians must disclose the risks and benefits of using the treatment they recommend, foregoing treatment, and using alternative treatment options.²⁰ Such disclosure is required because it "promotes communication and fosters trust" between physicians and the people they treat.²¹ As explained by practicing physicians sensitive to the intimacy of the physician—patient relationship and the importance of disclosure of risk, the "sine qua non of effective patient care is the patient's trust, manifested as an unwavering belief that our advice and decisions are driven by the patient's best interest."²²

When a patient visits a physician, he or she is usually sick and simply wants to get better; the patient is not a typical consumer. 23 "Someone who is ill and seeking help—unlike someone who is purchasing a pair of socks or a pound of sausages—is often vulnerable, certainly worried, sometimes uncomfortable, and frequently frightened." The patient is also almost always less educated than the physician, at least on the subject of his or her health condition, and "has an abject dependence upon and trust in his physician for the information upon which he relies during the decisional process." 25

Even if otherwise educated, an ill patient may be unable to get information or make appropriate decisions and, thus, must rely on the physician to protect him or her.²⁶ As one scholar observed, "[m]ere apprehension of serious illness transforms us: It makes us afraid and causes

^{19.} Salgo v. Leland Stanford Jr. Univ. Bd. of Trs., 317 P.2d 170, 181 (Cal. Ct. App. 1957).

^{20.} See Moore, 793 P.2d at 483 ("[A] person of adult years and in sound mind has the right, in the exercise of control over his own body, to determine whether or not to submit to lawful medical treatment." (quoting Cobbs v. Grant, 502 P.2d 1, 9 (Cal. 1972))).

^{21.} Rodwin, Physicians' Conflicts of Interest, supra note 8, at 1405.

^{22.} Michael J. Mack & Robert M. Sade, *Relations Between Cardiothoracic Surgeons and Industry*, 87 ANNALS THORACIC SURGERY 1334, 1334 (2009).

^{23.} See Mark A. Hall & Carl E. Schneider, *Patients as Consumers: Courts, Contracts, and the New Medical Marketplace*, 106 MICH. L. REV. 643, 645 (2008) (observing that patients "can rarely amass enough information about services and prices to make good decisions about hiring doctors and buying care"); see also Christopher Tarver Robertson, *Biased Advice*, 60 EMORY L.J. 653, 655 (2011) (noting that a surgical patient seeks health and "prefers to avoid the expenses, pain, inconvenience, and risks of needless surgery").

^{24.} Hall & Schneider, *supra* note 23, at 651 (quoting Raymond Tallis, *Commentary: Leave Well Alone*, 318 BRIT. MED. J. 1756, 1757 (1999)); *see also* Robertson, *supra* note 23, at 655 (observing that surgical patients are "often scared and want to go straight to surgery").

^{25.} Quintanilla v. Dunkelman, 34 Cal. Rptr. 3d 557, 571 (Ct. App. 2005) (quoting *Cobbs*, 502 P.2d at 9); *see also* Hall & Schneider, *supra* note 23, at 670 (citing Canterbury v. Spence, 464 F.2d 772, 782 (D.C. Cir. 1972) (observing that a patient's "dependence upon the physician for information affecting his well-being . . . is well-nigh abject" (ellipsis in original)).

^{26.} See Morris, supra note 14, at 253; see also Sah et al., Patient Anxiety, supra note 4, at 16 ("Patients are in a vulnerable position with a lack of expertise in medicine, limited experience with only a small number of doctors, and they enter the relationship trusting the doctor knows best and has their best interests at heart.").

us to regress to childlike states of dependence and wishful thinking. Diagnosis of serious illness furthers this transformation, as do disabling symptoms."²⁷ In essence, then, "'the patient is a captive consumer."²⁸

Unfortunately for these helpless and trusting patients, when physicians have a financial stake in the equipment they use or the facilities to which they refer patients, the physicians' "professional medical judgment may become clouded."²⁹ Just like "auto mechanics, plumbers, actors, bicycle messengers, and newspaper reporters,"30 physicians respond "rationally" to economic incentives that can interfere with their duty to place their patients' welfare above all else.³¹ As traditionally defined, a conflict of interest is "a set of conditions in which professional judgment concerning a primary interest (such as a patient's welfare . . .) tends to be unduly influenced by a secondary interest (such as financial gain)."32 Because physicians are paid a fee every time they see patients, they can "increase their income by raising fees or providing more services, either by treating more patients or by performing more services for existing patients."33 This "fee-for-service" model for paying for health care builds into the system an inherent conflict between the physician's "financial incentive to provide more care" and the patient's interest in getting better as quickly and as cheaply as possible.34 Allowing physicians to benefit financially from the medical tests and treatments they provide introduces the additional potential for financial gain and, with it, the added incentive "to act in their own interest."³⁵

^{27.} M. Gregg Bloche, *Trust and Betrayal in the Medical Marketplace*, 55 STAN. L. REV. 919, 928 (2002) (internal citations omitted).

^{28.} Hall & Schneider, *supra* note 23, at 652 (quoting Magan Med. Clinic v. Cal. State Bd. of Med. Exam'rs, 57 Cal. Rptr. 256, 263 (Ct. App. 1967)).

^{29.} See Morris, supra note 14, at 256 (citing Tracy E. Miller & William M. Sage, Disclosing Physician Financial Incentives, 281 J. Am. MED. ASS'N 1424, 1425 (1999)).

^{30.} David A. Hyman, Follow the Money: Money Matters in Health Care, Just Like in Everything Else, 36 Am. Soc'y L. Med. & Ethics 370, 371 (2010).

^{31.} *Id.* at 371 (quoting David Goldhill, *How American Health Care Killed My Father*, ATLANTIC, Sept. 2009, at 38, 40); *see also* Dennis F. Thompson, *Understanding Financial Conflicts of Interest*, 329 NEW ENG. J. MED. 573, 573 (1993) (noting that in their "most general form," the primary interests of physicians are "the health of patients").

^{32.} Thompson, *supra* note 31, at 573; *see also* Sah et al., *Patient Anxiety*, *supra* note 4, at 2 (defining a conflict of interest as "'a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest"') (quoting INST. OF MED. & BD. OF HEALTH SCI. POL'Y, CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE 6 (2009)).

^{33.} Rodwin, *Medical Commerce*, *supra* note 9, at 387; *see also* Sandra J. Carnahan, *Law, Medicine, and Wealth: Does Concierge Medicine Promote Health Care Choice, Or Is It A Barrier To Access?*, 17 STAN. L. & POL'Y REV. 121, 123 (2006) (noting that under a fee-for-service model, the physician's financial incentive is "to provide more care").

^{34.} Carnahan, supra note 33, at 123.

^{35.} Rodwin, Medical Commerce, supra note 9, at 387; see also Greg Radinsky, Defining a Group Practice: An Analysis of the Stark I Final Rule, 41 St. LOUIS U. L.J. 1119, 1122 (1997) (not-

A conflict of interest may not actually harm patients and, indeed, "may even be a necessary and desirable part of professional practice." Critics of limiting physician ownership argue that a physician's financial interest in the facility or diagnostic or treatment service to which he or she refers patients "creates a strong incentive to ensure that it provides high-quality care." But it is "well accepted that patients deserve medical opinions about treatment plans and referrals unsullied by conflicting motives." Even if a physician is not, in fact, motivated by the prospect of financial gain, simply "the opportunity for or mere appearance of conflict of interest reduces patient trust and causes patients to scrutinize and second-guess their physicians' decisions." Although all physicians believe that they put their patients interests above all else, empirical evidence has established that physicians who refer their patients to facilities and services they own order more tests, procedures, and exams than physicians who do not have that same financial stake.

Some of the prescribed procedures may even be unnecessary. ⁴² Indeed, there is empirical data showing that physicians recommend unnecessary tests and treatment because of the potential for financial gain—and their patients cannot evaluate whether the procedures are needed or not. ⁴³ Moreover, physicians who stand to gain financially as the cost of treatment goes up order more expensive treatment more often than physicians who lack such financial stakes. ⁴⁴ The question, therefore, becomes how best to protect patients from the overutilization of treatment

ing that a physician's "self-referral arrangements present a conflict for the physician who is trying to capitalize on an investment and maintain professional ethics").

- 36. Thompson, supra note 31, at 573.
- 37. Id. (citing Theodore N. McDowell, Jr., Physician Self Referral Arrangements: Legitimate Business or Unethical 'Entrepreneurialism', 15 Am. J.L. & MED. 61 (1989)).
- 38. Mortis, *supra* note 14, at 253 (quoting Council on Ethical & Judicial Affairs, Am. Med. Ass'n, Current Opinions of the Council on Ethical and Judicial Affairs of the American Medical Association, § 8.06, p. 31 (1986)).
 - 39. Morris, supra note 14, at 255.
 - 40. Goldhill, supra note 31, at 38, 40.
- 41. See Candeub, supra note 8, at 45, 47; see also McDowell, supra note 37, at 62 (noting the argument that physician ownership in health care facilities to which they make patient referrals encourages overutilization of medical services and creates a "damaging conflict of interest for physicians"); Rodwin, Physicians' Conflicts of Interest, supra note 8, at 1406 (citing "major" studies indicating that physicians who make referrals to facilities they own recommend more tests and procedures than physicians without ownership interests); Sutton, supra note 1, at 17 (citing empirical evidence suggesting that physicians were abusing the referral process to benefit themselves).
 - 42. See Candeub, supra note 8, at 47.
 - 43. See id.
- 44. Jacobson et al., *supra* note 10, at 442 (observing that providers who received "more generous" reimbursements prescribed more costly chemotherapy regimens than the providers who were less generously reimbursed); Rodwin, *Physicians' Conflicts of Interests*, *supra* note 8, at 1406 (noting that physicians who make referrals to facilities they own "recommend more (or more expensive) medical tests and procedures than physicians without ownership interests").

and services that has been proven to occur when physicians have a financial stake.⁴⁵

III. REGULATING SELF-REFERRALS BY LIMITING OWNERSHIP

One way to prevent a physician from referring patients to diagnostic services or treatment facilities that the physician owns is to prohibit that ownership. In 1957, the American Medical Association (AMA) did just that, directing each physician to limit his professional income only to "medical services actually rendered by him, or under his supervision, to his patients."⁴⁶ In 1975, however, the United States Supreme Court ruled that the "learned professions" were not exempt from the federal antitrust laws. 47 Relying on the Supreme Court's decision, the Federal Trade Commission sued the AMA, challenging its directive limiting physicians' income, and the AMA dropped the clause in 1979. 48 Thereafter, sources of income available to physicians changed dramatically, and physicians began buying medical facilities and treatment tools and services they expected their patients to use. 49 Faced with changes to reimbursement arrangements under Medicare, which increased limits on reimbursements and shifted focus from hospital stays to outpatient care, physicians seized the entrepreneurial opportunity presented to them and began investing in health-care facilities, laboratories, and diagnostic equipment.⁵⁰

^{45.} See McDowell, supra note 37, at 61.

^{46.} PRINCIPLES OF MEDICAL ETHICS, *supra* note 5, § 7. In the preamble to its *Principles of Medical Ethics*, the AMA explained the purpose of the principles:

These principles are intended to aid physicians individually and collectively in maintaining a high level of ethical conduct. They are not laws but standards by which a physician may determine the propriety of his conduct in his relationship with patients, with colleagues, with members of allied professions, and with the public.

Id. pmbl. Section 7 states as follows:

In the practice of medicine a physician should limit the source of his professional income to medical services actually rendered by him, or under his supervision, to his patients. His fee should be commensurate with the services rendered and the patient's ability to pay. He should neither pay nor receive a commission for referral of patients. Drugs, remedies or appliances may be dispensed or supplied by the physician provided it is in the best interests of the patient.

Id. The current version of the AMA's Code of Medical Ethics is available at http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics.shtml. *See also* Am. Med. Ass'n v. F.T.C., 638 F.2d 443, 446 n.1 (2d Cir. 1980), *aff'd*, 455 U.S. 676 (1982).

^{47.} Goldfarb v. Va. State Bar, 421 U.S. 773, 787 (1975).

^{48.} See In re Am. Med. Ass'n, 94 F.T.C. 701 (1979) (holding that the Federal Trade Commission Act, 15 U.S.C. § 45, prohibits the AMA from restricting its physician members to advertise for and solicit patients and participants in other competitive practices). The AMA unsuccessfully challenged the FTC's ruling in federal district court. See Am. Med. Ass'n v. F.T.C., 638 F.2d 443 (2d Cir. 1980), aff'd, 455 U.S. 676 (1982).

^{49.} Sutton, supra note 1, at 17.

^{50.} *Id*.

Prompted by concern over escalating costs of the Medicare program that followed this regulatory change, in 1989 Congress ordered the Office of Inspector General for the Department of Health and Human Services to conduct a study of the financial relationships physicians had with health-care facilities, laboratories, medical supply companies, and diagnostic equipment and examine whether these relationships affected the delivery of care. The study analyzed whether a physician's financial interests influenced the recommendations made to his or her patients and whether those recommendations increased costs. The results of the study indicated that physicians with a financial interest in laboratory testing facilities ordered more laboratory tests—up to forty-five percent more—than physicians without that financial interest, adding, at that time, more than \$28 million in laboratory costs to the Medicare system.

In response to these findings, Congress enacted legislation in 1989 prohibiting a physician from referring a Medicare patient for clinical laboratory services to an entity in which the physician, or the immediate family member of the physician, had a financial relationship and prohibited the entity from submitting a claim for payment for such a referral.⁵⁴ Now known as "Stark I" for the bill's sponsor, California Congressman Fortney "Pete" Stark and for the legislation that followed, this prohibition of self-referrals was intended to augment a 1972 law prohibiting giving or taking kickbacks for referring Medicare or Medicaid patients to diagnostic or medical testing facilities or labs.⁵⁵ Similar to the intent of the Stark I legislation, the federal "Anti-Kickback" statute was intended to remove a physician's incentive to order "superfluous tests and procedures" and thereby control the increasing costs imposed on the Medicare and Medicaid programs. 56 Under the current Anti-Kickback law, violators face civil as well as criminal penalties of up to five years in prison and \$25,000 in fines.⁵⁷

Understanding that violations of the Anti-Kickback statute were difficult to prove because of the law's requirement of proof of

^{51.} *Id.* at 18 (citing Office of Inspector Gen., U.S. Dep't of Health & Hum. Servs, Financial Arrangements Between Physicians & Health Care Businesses (1989) [hereinafter *DHHS Study*]).

^{52.} Sutton, supra note 1, at 18 (citing DHHS Study, supra note 51, at iii).

^{53.} Id.

^{54.} Ethics in Patient Referrals Act of 1989, Pub. L. No. 101-239, § 1877, 103 Stat. 2106; see United States v. Rogan, 459 F. Supp. 2d 692, 711 (N.D. III. 2006), aff'd, 517 F.3d 449 (7th Cir. 2008).

^{55. 42} U.S.C. § 1320a-7b (2011) (originally enacted as Social Security Amendments of 1972, Pub. L. No. 92-603, § 242(b), (c), 86 Stat. 1329, 1419).

^{56.} Perry, supra note 7, at 26 (citing § 242(b), (c), 86 Stat. at 1419).

^{57. 42} U.S.C. § 1320a-7b (2012).

knowledge and intent, ⁵⁸ and in light of physicians' increasing self-referrals given their freedom to invest in medical equipment, facilities, and services, Representative Stark originally proposed legislation that went beyond kickbacks and would have criminalized self-referrals. ⁵⁹ Stark's proposal would also have prohibited the laboratory or facility from seeking payment from any source, including Medicare, the patient, or the private insurer. ⁶⁰ This proposal met with "stiff opposition" from the AMA, ⁶¹ and the final legislation was much less limiting—prohibiting only self-referrals of Medicare patients to clinical laboratories and containing a number of exceptions that allowed physicians to avoid the limitations of the law. ⁶²

Following the enactment of Stark I, several studies confirmed the Inspector General's findings that physicians with a financial stake in diagnostic and treatment services recommended those services more often than physicians without a financial stake. Accordingly, in 1993, Representative Stark proposed a comprehensive ban on self-referral. Fark's proposal would have extended Stark I's ban on referrals for clinical laboratory services to include a list of other services such as physical therapy, occupational therapy, radiology, and the furnishing of outpatient prescription drugs, ambulance services, home infusion therapy, and inpatient and outpatient hospital services. The proposal would also have extended the ban to all payers, including Medicare, Medicaid, Blue Cross/Blue Shield, all other commercial carriers, and Health Maintenance Organizations.

^{58.} Perry, supra note 7, at 26 (citing Omnibus Reconciliation Act of 1980, Pub. L. No. 96-499, § 917, 94 Stat. 2599 (codified as amended at 42 U.S.C. § 1320a-7(b) (2006))); see also Sutton, supra note 1. at 18.

^{59.} Sutton, supra note 1, at 19; Perry, supra note 7, at 27.

^{60.} Perry, supra note 7, at 27 (citing John K. Iglehart, The Debate Over Physician Ownership of Health Care Facilities, 321 NEW ENG. J. MED. 198, 201 (1998)); see also Sutton, supra note 1, at 17.

^{61.} Perry, *supra* note 7, at 27. Perry notes that not all physicians were opposed and cites certain physician organizations, including the American College of Radiology, the American College of Surgeons, the American College of Nuclear Medicine, and the American Clinical Laboratory Association, who supported Stark's proposal. *Id.* at 27 n.78 (citing MARC A. RODWIN, MEDICINE, MONEY, AND MORALS: PHYSICIANS' CONFLICTS OF INTERESTS 127 (1993)).

^{62.} Perry, *supra* note 7, at 27 (citing Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6204(a), 103 Stat. 2236 (1990) (codified at 42 U.S.C. § 1395nn (2006))); *see also* Sutton, *supra* note 1, at 19–20.

^{63.} See Sutton, supra note 1, at 20–23 (examining nine studies, all confirming overutilization by physicians with financial ties).

^{64.} *Id.* at 23 (citing Comprehensive Physician Ownership and Referral Act of 1993, H.R. 345, 103d Cong. (1993)).

^{65.} Sutton, *supra* note 1, at 23–24.

^{66.} Id. at 23 (citing 139 CONG. REC. E84 (daily ed. Jan. 6, 1993) (statement of Rep. Stark)).

Although Stark's bill did not pass, much of its content was enacted and became known as "Stark II." The new law extended the ban on self-referrals to payments for Medicaid patients in addition to Medicare patients, and it included Stark's recommendation to ban self-referrals for not only laboratory services but also ten "designated health services," including services for physical therapy, occupational therapy, radiology, and inpatient and outpatient hospital treatment. It did not go as far as Stark had proposed, however, and allowed private commercial payers to continue to pay for self-referred services.

Stark II also contained a number of exceptions, including the "whole hospital" exception ⁷⁰ and the "ancillary in-office services" exception. ⁷¹ The whole hospital exception allowed physicians to maintain ownership interests in hospitals to which they referred their patients as long as the financial interest was "in the entire hospital and not merely in a distinct part or department of the hospital." ⁷² This provision was intended to protect physician-owned hospitals in traditionally underserved rural areas, and the consensus in Congress at the time was that any potential for economic gain was diluted when the referring physicians owned the whole hospital and not just the portion to which they referred their patients. ⁷³

The PPACA changed the rules on referrals to physician-owned hospitals, prohibiting the expansion of those hospitals after March 23, 2010, and banning any new ones not certified as Medicare providers after December 31, 2010.⁷⁴ With the exception of certain rural providers, physician-owned hospitals are now prohibited from increasing the number of operating rooms, procedure rooms, or beds included in their licenses af-

72. 42 C.F.R. § 411.356(c)(3)(iii) (2011).

^{67.} Omnibus Reconciliation Act of 1993, Pub. L. No. 103-66, § 13562, 107 Stat. 312 (codified at 42 U.S.C. § 1395nn (2012)).

^{68.} *Id.*; see Sutton, supra note 1, at 23–24 (citing 139 CONG. REC. E84 (daily ed. Jan. 6, 1993) (statement of Rep. Stark)); Perry supra note 7, at 33 n.80.

^{69.} Sutton supra note 1, at 24 (citation omitted).

^{70. 42} U.S.C. § 1395nn(d)(3) (2010).

^{71.} Id. § 1395nn(b)(2).

^{73.} See Perry, supra note 7, at 27 (citing H.R. REP. No. 111-443, at 4 (2010)).

^{74.} Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6001(a)(3), 124 Stat. 119, 685–87 (2010) (codified at 42 U.S.C. § 1395nn(d)(3) (2012)). Responding to concerns over the inconsistent dates in this provision, the Center for Medicare Services has proposed a rule to resolve this inconsistency and to clarify that hospitals that are not physician-owned hospitals as of March 23, 2010, could not become physician-owned hospitals between then and December 31, 2010. See Medicare Program, 75 Fed. Reg. 46432 (proposed Aug. 3, 2010) (to be codified at 42 C.F.R. pts. 410–413, 416, 419, 482, 489) ("[I]f a hospital has no physician ownership or investment as of March 23, 2010, and later adds physician owners or investors, the hospital will not satisfy the whole hospital ... exceptions."); see also The Patient Protection and Affordable Care Act, CTRS. FOR MEDICARE SERVS. (Dec. 10, 2010), https://www.cms.gov/LegislativeUpdate/downloads/PPACA.pdf.

ter December 31, 2010, effectively dooming the future of the physicianowned hospital.⁷⁵

The ancillary in-office services exception allowed physicians to diagnose and treat their patients using equipment and services they own. The contrast to the limitations it imposed on physician-owned hospitals, the PPACA did little to change the ancillary in-office services exception contained in Stark II. The Pursuant to the Stark II exception, physician group practices were allowed to own and operate—and receive compensation for—imaging services and other designated health services provided within their group practices without running afoul of the prohibition against self-referral. This exception allowed physicians to avoid the Stark law as long as certain supervision, location, and billing requirements were met and, as many observers argue, essentially swallowed the rule. The PPACA amendments do not change the substance of the exception but, as described below, impose additional disclosure requirements on physicians who self-refer.

IV. DISCLOSURE RULES AND THEIR IMPACT ON PATIENTS

The Stark law has controlled overutilization by limiting referrals by physicians who own facilities, tools, and services they recommend to their patients and by requiring disclosure of the interests that are allowed so that patients may decide for themselves whether to follow this self-interested advice or to seek care from another physician. While the PPACA continues to require physicians who self-refer to disclose ownership interests, it further requires physicians to inform patients that such

.

^{75.} See 42 U.S.C. § 1395nn(d)(2)–(3) (2012); see also Sutton, supra note 1, at 32; Perry supra note 7, at 28. As Sutton noted, "the clear intent of the provision is to maroon physician owned hospitals in a sort of regulatory purgatory until they eventually wither away entirely or they are purchased by non-physician owners." Sutton, supra note 1, at 32 (quoting Victor Moldovan, Will Healthcare Reform Kill Surgeon Ownership?, ORTHOPRENEUR, Mar./Apr. 2010, at 33, available at https://www.orthoworld.com/site/docs/op/online/2010/marapr/editorial_moldovan.pdf). The amendment has increased the burden on even nonphysician owners, requiring hospitals relying on the whole hospital exception to submit annual reports to the Secretary of Health and Human Services describing all owners or investors in the hospital and the nature and extent of their ownership or investment interests. 42 U.S.C. § 1395nn(d)(3) (2012). An association of physician-owned hospitals challenged this provision in federal district court in Texas on grounds that it is unconstitutionally vague and violates the Due Process, Equal Protection, and Takings Clauses of the United States Constitution, but the court granted summary judgment in favor of the government. Physician Hosps. of Am. v. Sebelius, 781 F. Supp. 2d 431 (E.D. Tex. 2011).

^{76. 42} U.S.C. § 1395nn(b)(2) (2010).

^{77.} See id.

^{78.} See id.; Sutton supra note 1, at 30–31.

^{79.} See Sutton, supra note 1, at 31; see also Radinsky, supra note 35, at 1149 (noting that the economic advantages to the ancillary in-office services exception "cannot be denied").

^{80. 42} U.S.C. § 1395nn(b)(2)(B).

^{81.} See id.

services could be obtained from alternative suppliers and to provide a written list of alternative suppliers located in the area in which the patients reside. Now that the Supreme Court has ruled that the balance of the PPACA is constitutional, including the more stringent disclosure rules, it is appropriate to consider the impact of these disclosure rules on patient care. 83

Specialty physician associations' rules and states' laws on disclosure impose requirements similar to those in the PPACA, but few have gone as far as requiring physicians to furnish written lists of alternatives. 84 The AMA cites the current disclosure law and directs its physicians to "provide full disclosure" of their financial interest to their patients. 85 According to the AMA, "full disclosure" requires that the disclosure be in writing and accompanied by a list of "effective alternative resources."86 The AMA further requires that physicians inform their patients that they "have the option to use one of the alternative resources" and that "they will not be treated differently by the physician if they choose an alternative provider or entity."87 The AMA also reminds physicians that they "should make referrals to providers based only on the needs of the patient and the medical standard of care in order to provide quality health care to their patients."88 According to the AMA, following these rules will allow patients "to make informed decisions." Notably, however, the AMA acknowledges that these alternative resources may not exist.90

^{82.} Id

^{83.} See generally Cain et al., supra note 4; Sah et al., Patient Anxiety, supra note 4; Sah et al., The Burden of Disclosure, supra note 4.

^{84.} See Mack & Sade, supra note 22, at 1334; Morris, supra note 14, at 253 (citing Miller & Sage, supra note 29, at 1424); see also AM. ACAD. OF ORTHOPAEDIC SURGEONS, CODE OF ETHICS AND PROFESSIONALISM FOR ORTHOPAEDIC SURGEONS § III.B. (2011), http://www6.aaos.org/news/PDFopen/PDFopen.cfm?page_url=http://www.aaos.org/about/papers/ethics/code.asp; Ethical Standards for Cardiothoracic Surgeons Relating to Industry, SOC'Y OF THORACIC SURGEONS, http://www.sts.org/about-sts/policies/ethical-standards-cardiothoracic-surgeons-relating-industry (last visited Feb. 23, 2012). These rules are consistent with well-established rules that medical societies have imposed on their members who have conflicts of interest with their societies or industry interests. See Standards for Commercial Support: Standards to Ensure Independence in CME Activities, ACCREDITATION COUNCIL CONTINUING MED. EDUC., http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c uploaddocument.pdf (last visited Feb. 23, 2012).

^{85.} AM. MED. ASS'N, CODE OF MEDICAL ETHICS, CURRENT OPINIONS & ANNOTATIONS OF COUNCIL ON ETHICAL & JUD. AFF., Policy 32, *Physician Self-Referral*, (adopted by Am. Med. Ass'n Bd. of Tr., Feb. 17, 2010), *available at* http://www.acmq.org/policies/policies32and33.pdf.

^{86.} Id.

^{87.} Id.

^{88.} Id.

^{89.} *Id*.

^{90.} *Id.* (stating that patients should be given a list of effective alternative resources, "if any, that are reasonably available").

State laws allowing self-referral or use of physician-owned services mirror the federal and AMA rules by requiring disclosure of financial interest that, in many cases, must be in writing at or prior to the time that the referral is made. 91 Like the AMA's rule, some state laws require that the written disclosure also include a statement that the patient may obtain services from another provider, even though the laws do not require the physician to provide a list of alternatives. 92 Tennessee, for example, directs physicians with financial interests in health facilities, equipment, or pharmaceuticals to disclose the ownership interest "at the time of referral and prior to utilization," and also warns that the "physician shall not exploit the patient in any way, as by inappropriate or unnecessary utilization."93 The Tennessee statute further states that the "patient shall have free choice either to use the physician's proprietary facility or therapy or to seek the needed medical services elsewhere," although the statute does not explicitly require the physician to explain this to his or her patients.⁹⁴ The Virginia statute is similar to Tennessee's, requiring written notice "in bold print" that discloses the financial ties and explicitly requiring the physician to "advise the patient of his freedom of choice in the selection of such facility or entity." 95 North Carolina limits self-referrals to only those entities located in a county with a "demonstrated need" where alternative financing is not available, and then only if the physician discloses the investment interest and gives the patients a list of "effective alternative facilities."96 The North Carolina statute also requires physicians to inform their patients of the "option to use one of the alternative

^{91.} See, e.g., N.J. STAT. ANN. § 45:9-22.5b(a)(2) (West 2012); S.C. CODE ANN. § 44-113-40 (2012); see also MASS. GEN. LAWS ANN. ch. 112, § 12AA (West 2012) (requiring physicians to disclose their financial ownership interests in physical therapy services if they refer their patients to those services); cf. CONN. GEN. STAT. § 20-7A(c) (2012) (ownership interests excluding in-office ancillary services must "be verbally disclosed to each patient or shall be posted in a conspicuous place visible to patients in the practitioner's office").

^{92.} See, e.g., KAN. STAT. ANN. § 65-2837(b)(29) (2012) (defining "[u]nprofessional conduct" as including "[r]eferring a patient to a health care entity for services if the licensee has a significant investment interest in the health care entity, unless the licensee informs the patient in writing of such significant investment interest and that the patient may obtain such services elsewhere"); MD. CODE ANN., HEALTH OCC. § 1-303(b) (West 2012) (requiring a written statement that discloses the ownership interest and states that the patient may choose to obtain the health-care service from another health care entity and also requiring that the patient acknowledge receipt of the disclosure in writing); MINN. STAT. § 147.091(p)(4) (2012) (requiring written disclosure in advance that includes "a statement that the patient is free to choose a different health care provider").

^{93.} TENN. CODE ANN. § 63-6-502(b)(1)–(2) (West 2012). Similarly, Massachusetts requires physicians to disclose their financial ownership interests in physical therapy services, among others, if they refer their patients to those services. MASS. GEN. LAWS ANN. ch. 112, § 12AA (West 2012).

^{94.} TENN. CODE ANN. § 63-6-502(b)(4) (West 2012).

^{95.} VA. CODE ANN. § 54.1-2964A (West 2012).

^{96.} N.C. GEN. STAT. § 90-408(c) (West 2012).

facilities" and to assure them that "they will not be treated differently" by the physician if they choose one of the alternatives. 97

The question, however, is whether the disclosure rules actually do allow patients to make "informed decisions" about their care. Significantly, recent studies suggest that disclosure of physicians' financial ties and invitations to go elsewhere do not encourage patients to either question their physicians' ability to provide quality care or seek alternative care. Studies that have focused on patient behavior after being told of a physician's financial interest in the prescription of certain care suggest that disclosure does not protect patients or change the decisions they make about their care. In fact, "[p]atients rarely abandon doctors, reject doctors' recommendations, or demand second opinions. Quite to the contrary, the physician—patient relationship "often facilitates an atmosphere where the patient is reluctant to initiate conflict or question the physician's judgment because the patient must rely on the physician's professional medical judgment.

Consistent with the notion that a sick patient relies "with an abject dependence" on the physician to decide on and direct his or her care, ¹⁰³ it should come as no surprise that this sick patient does not sever the physician—patient relationship upon learning that the physician would enjoy financial gain from the prescribed course of treatment. ¹⁰⁴ The fact of the matter is, "[t]he patient's bond with the doctor is neither easily created nor lightly sacrificed. Doctor and patient develop information about and confidence in each other—information and confidence that must laboriously be re-created when the patient changes doctors." ¹⁰⁵

More significantly, studies that have examined the effect of disclosure on patient behavior suggest that disclosure does not always increase a patient's understanding of the treatment options or lead to trust. ¹⁰⁶ Instead of protecting patients' interests, disclosure actually produces ad-

98. See id.; see also Cain et al., supra note 4; Sah et al., Patient Anxiety, supra note 4; Sah et al., The Burden of Disclosure, supra note 4.

^{97.} Id.

^{99.} Cain et al., supra note 4; Sah et al., Patient Anxiety, supra note 4; Sah et al., The Burden of Disclosure, supra note 4.

^{100.} See Hall & Schneider, supra note 23, at 653.

^{101.} *Id.* at 652 (citing CARL E. SCHNEIDER, THE PRACTICE OF AUTONOMY: PATIENTS, DOCTORS, AND MEDICAL DECISIONS (1998)).

^{102.} Morris, supra note 14, at 256.

^{103.} Cobbs v. Grant, 502 P.2d 1, 9 (Cal. 1972), cited in Quintanilla v. Dunkelman, 34 Cal. Rptr. 3d 557, 571 (Ct. App. 2005).

^{104.} Hall & Schneider, *supra* note 23, at 653 ("[I]llness inspires especially 'thick' and vital personal relationships that patients hate to disturb.").

^{105.} Id. at 652-53.

^{106.} Cain et al., supra note 4, at 7; Sah et al., Patient Anxiety, supra note 4, at 5.

verse effects.¹⁰⁷ When disclosure alerts a patient to his or her physician's chance for financial gain, the patient feels obliged to help the physician maximize the gain.¹⁰⁸ The patient is afraid to reject the physician's recommendation because rejection would signal distrust of the physician that would, in turn, endanger present as well as future care.¹⁰⁹

The paradoxical outcome is that the patient is uncomfortable rejecting the physician's advice even though he or she mistrusts the advice; thus, instead of encouraging patients to seek an independent opinion, disclosure of conflicts of interest makes it more likely that they will follow their physicians' untrustworthy advice. ¹¹⁰ In short, disclosure of financial interest might protect physicians against allegations by their patients of abuse of trust or fair dealing, but it does little to protect patients from the impact that financial interest has on a physician's—even an honest physician's—treatment decisions. ¹¹¹

V. POSSIBLE SOLUTIONS

If disclosure actually makes it harder for patients to protect themselves by challenging their physicians' advice or seeking alternative care, then one solution would be to prohibit physicians from disclosing their financial interests—which would, at least, remove the added pressure patients feel to help their physicians maximize their financial interests. ¹¹² Indeed, one observer has suggested that a patient who wants to be sure that he or she receives the best advice can hire an "advisor" who is free of financial ties to the machines, drugs, or location for the care the patient will ultimately receive and who could provide the patient with unbiased advice about what care to choose and where and whom to go to for that care. ¹¹³ This approach would treat patients similar to other consumers in a free market; however, it conflicts with the underlying premise that patients are not typical consumers but rather "captive" consumers lacking the bargaining power or understanding to protect themselves. ¹¹⁴

Keeping patients ignorant of their physicians' financial interests in recommended tools and services is also antithetical to the widely accept-

^{107.} Sah et al., *Patient Anxiety*, *supra* note 4, at 15; Sah et al., *The Burden of Disclosure*, *supra* note 4, at 32–33.

^{108.} Sah et al., *The Burden of Disclosure*, *supra* note 4, at 6 (describing a "panhandler effect" when a physician discloses his interest in financial gain and the patient feels obligated to help the physician obtain it).

^{109.} Id.; see also Sah et al., Patient Anxiety, supra note 4, at 6.

^{110.} Sah et al., Patient Anxiety, supra note 4, at 15.

^{111.} Sutton, *supra* note 1, at 23 (citing 139 CONG. REC. E1116–17 (daily ed. May 3, 1993) (statement of Rep. Stark)).

^{112.} See Sah et al., The Burden of Disclosure, supra note 4, at 6.

^{113.} Robertson, supra note 23, at 665.

^{114.} Hall & Schneider, supra note 23, at 652; see also Bloche, supra note 27, at 928.

ed principle that patients have the right to know all of the risks and benefits of any proposed treatment. 115 Consistent with a patient's right to know all information that may affect his or her care, current laws and ethical rules require that physicians disclose their financial ties to the tools and services they recommend to patients. 116 Medical societies have traditionally defined their own rules of disclosure, and allowing these societies to do so is consistent with "the collective belief that physicians are competent, compassionate professionals, acting solely for their patients' best interests."117 Indeed, until the last part of the twentieth century, medicine remained a largely self-governed enterprise and the centerpiece of this self-governance was a "fidelity to patients regardless of selfinterest" that was widely regarded as desirable from a social welfare perspective. 118 Self-regulation, alone, however, has proven not to be enough. As research has confirmed, when physicians can make more money by ordering certain tests or prescribing a certain course of treatment, they do—regardless of whether it is in the best interest of the patient to do so. 119

This empirical evidence, therefore, has justified governmental regulation. ¹²⁰ As already described, the PPACA requires, as the profession and existing law has long required, that physicians disclose their financial ties. ¹²¹ The Act goes further than the traditional disclosure rules because it not only requires a written disclosure that includes a list of alternative providers but also expands the Stark prohibitions on self-referrals by requiring physicians to report their ownership interests to the Secretary of Health and Human Services. ¹²² The law could go even further, as at least one insurer has done, and require a physician to withhold treatment until a patient actually receives a second opinion from someone on that list. ¹²³

Additionally, to inform patients fully, physicians ought to disclose not only their financial stake in the treatment decisions their patients

^{115.} See Moore v. Regents of Univ. of Cal., 793 P.2d 479, 483 (Cal. 1990).

^{116.} See supra Part IV.

^{117.} See Morris, supra note 14, at 253 (citing Steven D. Pearson et al., Ethical Guidelines for Physician Compensation Based on Capitation, 339 New Eng. J. Med. 689 (1998)).

^{118.} Bloche, supra note 27, at 924.

^{119.} See Candeub, supra note 8, at 47; Rodwin, Physicians' Conflicts of Interest, supra note 8, at 1405.

^{120.} Candeub, supra note 8, at 46-47.

^{121. 42} U.S.C. § 1395nn(b)(2)(B) (2012).

^{122.} Id. §1395nn(b)(2).

^{123.} See Robertson, supra note 23, at 663 (noting an example where a health insurer required a patient to obtain a second opinion before following the advice of a physician with financial ties to the treatment he suggested (citing Damare v. Occidental Petroleum Corp. Med. Care Plan, No. 92-1779, 1993 WL 92503, at *3 (E.D. La. Mar. 24, 1993))).

make but also the empirical studies proving that physicians who own diagnostic tools and treatment services recommend them to their patients more often than physicians who do not have that same financial stake. 124 Currently, no disclosure rules require physicians who own testing and other services to which they refer their patients to disclose that they are more likely to recommend these tests and services simply because they own those services, even though that fact has been proven time and time again. 125 Actually, to be "fully" informed, in addition to knowing that their physicians have a financial interest in the recommended services, "patients need to know that virtually every major study indicates that physicians who make referrals to medical facilities they own recommend more (or more expensive) medical tests and procedures than physicians without ownership interests." 126 Armed with this information, patients might be less likely to agree to submit to a certain procedure or test, or at least more likely to seek a second opinion. 127

If disclosure does not protect patients against their physicians' interest in maximizing financial gain, then the law could prohibit physicians from having that financial stake, as the AMA once attempted to do. Although federal antitrust laws prevented the AMA from continuing to impose this prohibition, medical research scientists instituted such a prohibition and abolished all ties to industry in an attempt to avoid industry interference. Industry interference, Industry interf

^{124.} Candeub, *supra* note 8, at 47; Rodwin, *Physicians' Conflicts of Interest, supra* note 8, at 1406.

^{125.} See supra note 63 and accompanying text.

^{126.} Rodwin, Physicians' Conflicts of Interest, supra note 8, at 1406.

^{127.} Id.

^{128.} See supra note 46 and accompanying text.

^{129.} Thomas P. Stossel, Regulating Academic-Industrial Research Relationships—Solving Problems or Stifling Progress, 353 New Eng. J. Med. 1060, 1060 (2005).

^{130.} Id.

^{131.} *Id.* (citing President and Fellows of Harvard College, Policy on Conflicts of Interest and Commitment (2004)).

Such efforts at self-regulation, however, were met with strong opposition. 132 As already noted, the AMA's definition of appropriate sources of income for physicians was found to violate federal antitrust laws. 133 In addition to these legal impediments, there are also cogent arguments for why physicians should be able to invest in the tools and services they recommend, including the fact that ownership creates the incentive, as in any competitive market, to offer the highest quality care. 134 In the research science area, it was argued that bans on industry support were counterproductive and interfered with progress. 135 One critic of the NIH rules stated, "Had these rules been in force in the 1970s and 1980s, they would have prevented the scientists who were founding the biotechnology industry from making their breakthrough contributions." ¹³⁶ In fact, a complete ban in industry as well as in medical practice may not be advisable, and in the physician–patient context, a complete prohibition of financial ties is unlikely to be widely accepted, even if it was not a restraint of trade. 137

The most appropriate solution, therefore, may rest on a clearer focus on the problem. When considering how to handle a physician's financial ties that impact patient care, one must note that "[a] conflict of interest does not necessarily result in harm to a patient; whether the outcome of a conflict is good or bad depends on how it is managed." An appropriate solution need not eliminate the prospect of financial investment but should prevent physicians' interests in financial gain "from dominating or appearing to dominate the relevant primary interest in the making of professional decisions." Even though the law regulates but cannot, and probably should not, ban physician ownership of the business of medicine, lawmakers and physicians must identify the best way to protect patients from their physicians' interest in financial gain. "Just because we cannot do much about the other secondary interests, it does not follow that we should do little about financial gain." ¹⁴¹

^{132.} David J. Rothman et al., *Professional Medical Associations and Their Relationships With Industry: A Proposal for Controlling Conflict of Interest*, 301 J. AM. MED. ASS'N 1367, 1368 (2009); Stossel, *supra* note 129, at 1064; Thompson, *supra* note 31, at 573.

^{133.} See Goldfarb v. Va. State Bar, 421 U.S. 773, 786 (1975).

^{134.} Thompson, supra note 31, at 573.

^{135.} Stossel, supra note 129, at 1060; Thompson, supra note 31, at 573.

^{136.} Stossel, supra note 129, at 1060.

^{137.} Rothman et al., *supra* note 132, at 1368 (citing David Wofsy, *Living in a Different World*, 52 ARTHRITIS & RHEUMATISM 395 (2005)).

^{138.} See Sutton, supra note 1, at 48 (noting the importance of targeting the "specific relationships and practices prone to abuse").

^{139.} Mack & Sade, supra note 22, at 1335.

^{140.} Thompson, supra note 31, at 573.

^{141.} *Id*.

If the problem is that physicians act to maximize their financial gain when they are given the opportunity, the law should remove that incentive by requiring physicians who own tools and services to charge a flat fee for the entire course of their patients' care, regardless of how many of their own tests or services their patients use. 142 This model could mimic either Medicare's diagnosis-based system, where government advisors recommend appropriate fees, or the more recently defined concierge-like medical practices, where fees are based on what the market will bear. 143 While choosing the most appropriate flat-fee model will present its own challenges, the model would avoid antitrust violations that a complete ban on ownership could not avoid and, at the same time, would remove entirely the temptation to overutilize diagnostic tools and services owned by treating physicians. 144 Requiring physicians to charge a flat fee would remove all risk that they are recommending any test or treatment for their financial self-interest because, no matter how many tests they order or treatment alternatives they suggest, their financial gain would remain the same. 145

VI. CONCLUSION

Because the U.S. Supreme Court has upheld the constitutionality of those PPACA provisions that are relevant here and that strengthen the disclosure requirements, it is time for the legal and medical professions to rethink how to best protect the interests of patients in receiving the best possible health care. Recent research suggests that patients feel compelled to help their physicians reach their financial goals once they are aware of their physicians' financial interests, even though these patients lose trust in their physicians' advice. Thus, medical, legal, and ethics scholars and decision makers should confront these realities. Instead of imposing additional disclosure requirements, they should remove the incentive by adopting a flat-fee billing model. This approach will restore the proper balance between a patient's best interest and a physician's interest in financial gain.

^{142.} See Carnahan, supra note 33, at 122 (examining the quality of health care based on a flat-fee concierge service model); Sutton, supra note 1, at 48 (suggesting payments based on "an episode of care").

^{143.} See Carnahan, supra note 33, at 122.

^{144.} Sutton, supra note 1, at 48.

^{145.} See Carnahan, supra note 33, at 121-22.