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CONFLICTS OF INTEREST IN MEDICINE: SHOULD WE CONTRACT, CONSERVE, OR EXPAND THE TRADITIONAL DEFINITION AND SCOPE OF REGULATION?

MARC A. RODWIN*

I. INTRODUCTION

One article reviewing the recent medical literature concluded that "Conflict of interest' seems to be one of those concepts that is recognized in a given situation, but for which no consensus definition exists." In fact, the conflict-of-interest concept has had a clear, agreed-upon meaning in both law and public policy for a long time. Nevertheless, in recent years, to help explain the concept, Dennis Thompson and the Institute of Medicine (IOM) developed alternative definitions which stray from standard legal usage and introduce potential sources

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^{1.} Teddy D. Warner, What Do We Really Know About Conflicts of Interest in Biomedical Research?, 171 PSYCHOPHARMACOLOGY 36, 37 (2003). Although there is a clear understanding of the term conflict of interest, often the concept is used without being formally defined. Neither the ABA Cannons of Professional Responsibility, the Code of Professional Responsibility, nor the Model Rules of Professional Conduct provide a formal definition. See CANONS OF PROF'L ETHICS (1908) (giving no formal definition but explaining that "a lawyer represents conflicting interests when in behalf of one client, it is his duty to contend for that which duty to another client requires him to oppose); MODEL CODE OF PROF'L RESPONSIBILITY Canon 5 (1980) (defining "differing interests" to include every interest that will adversely affect either the judgment or the loyalty of a lawyer to a client" including a conflicting interest); MODEL RULES OF PROF'L CONDUCT 1.7 (2017) (prohibiting representation involving a concurrent conflict of interest, which exists if the representation is "directly adverse to another client," or if there is a "significant risk that the representation will be materially limited by the lawyer's responsibility to another."). Although scholars have documented how the term has been used in the law, they sometimes call it an elusive concept. See, e.g., CONFLICT OF INTEREST IN GLOBAL, PUBLIC AND CORPORATE GOVERNANCE 4 (Anne Peters & Lukas Handschin eds., 2012) (defining conflict of interest as an "elusive concept").

of confusion.² Drawing on the IOM definition, other writers have proposed changes that would redefine the concept to include so-called *intellectual* conflicts and *non-financial* conflicts.³ These new definitions generally refer to situations that are quite different from what have been considered conflicts of interest until now. When redefined to include intellectual or non-financial conflicts, every potential source of bias would be deemed a conflict of interest, which would expand the concept in a way that reduces conceptual clarity and dissipates efforts to counter and cope with conflicts of interest.

Many writers who redefine conflict of interests to include intellectual conflicts have a policy agenda. Most propose greater tolerance for such conflicts.⁴ They argue that we should not avoid, regulate, or manage conflicts of interest because we tolerate intellectual conflicts.⁵ At least one writer takes the opposite position, holding that because we regulate financial conflicts of interest, we should also regulate intellectual conflicts, even though the law has not considered intellectual conflicts to be conflicts of interest.⁶

This article describes how the term *conflict of interest* has been traditionally used in the law and new uses of the term. Adopting the new definitions would proliferate the situations considered to give rise to conflicts of interest, introduce unneeded categories, and confuse analysis. We should conserve the traditional legal definition of conflict of interest and maintain policies to avoid and manage conflicts of interest in medicine.

II. THE LEGAL CONCEPT

Origins in Fiduciary Law

The concept of conflict of interest has its origins in fiduciary law. Although society now regulates conflicts of interests outside of fiduciary relationships, reviewing fiduciary law helps explain what conflicts of interest are, the problems

^{2.} INST. OF MED., CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE 46 (Bernard Lo & Marilyn J. Field eds., 2009) (stating that a conflict of interest is a set of circumstances that creates a "risk that professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest.").

^{3.} Lisa A. Bero & Quinn Grundy, Why Having a (Nonfinancial) Interest Is Not a Conflict of Interest, PLOS BIOL (2016) ("Focusing on interest such as personal beliefs, experience, or intellectual commitments can divert attention from financial conflicts of interest, which have the potential for widespread influence.").

^{4.} Richard S. Saver, *Is it Really All About the Money? Reconsidering Non-Financial Interest in Medical Research*, 40 J. L., MED. & ETHICS 467, 468 (2012).

See Kenneth J. Rothman, Conflict of Interest: The New McCarthyism in Science, 269 JAMA 2782, 2782 (1993) (arguing against mandated disclosures of conflicts of interest).

^{6.} Saver, supra note 4 at 468.

^{7.} See Marc A. Rodwin, Conflicts of Interest & The Future of Medicine: The United States, France, & Japan 251–56 (2011); The origins of fiduciary law are in the Roman law fideicommissa. See William L. Burdick, Principles of Roman Law and Their Relation to Modern Law

they pose, and the ways to cope with them.⁸ Fiduciaries are individuals entrusted with authority or powers over the property or affairs of another party; they are held to the highest legal standards of conduct and are regulated to reduce the risk that they breach their obligation.⁹ Fiduciaries exercise powers over or on behalf of parties that depend on them.¹⁰ This often places them in a position to act in ways that promote their own interests, or the interests of third parties, rather than the party they are designated to serve. Courts have therefore developed rules and procedures to hold fiduciaries accountable.

First, the law sets high standards for fiduciary conduct. It requires fiduciaries to be loyal to the party they serve, to act exclusively for that party's benefit, to perform their work with due diligence, to account for their own conduct, and to refrain from conduct that could compromise their loyalty or independent judgment. The law specifies these broad obligations in great detail within various contexts.

Second, in the event that a fiduciary breaches his or her client's trust, the law employs various remedies. These may include: holding the fiduciary liable for harm, requiring that the fiduciary pay restitution, or revoking the contracts that fiduciaries entered into on behalf of the entrusted party.

619–25 (1938) (discussing fideicommissa); *id.* at 379–83 (discussing fiduciary sale). *See generally* WILLIAM W. BUCKLAND, EQUITY IN ROMAN LAW (2002) (explaining how Roman law modified the law). However, there are differences in Roman law fiduciaries and Angle American law. *See generally* TAMAR FRANKEL, FIDUCIARY LAW (2011) (providing analysis of modern fiduciary law); Tamar Frankel, *Fiduciary Law*, 71 CALIF. L. REV. 795, 795–836 (1983) (discussing the importance of fiduciary law); Austin W. Scott, *Fiduciary Principle*, 37 CALIF. L. REV. 539, 539–55 (1949); J. C. SHEPARD, LAW OF FIDUCIARIES (1981) (discussing the history and development of fiduciary law). *See generally*, T. G. YOUDAN, EQUITY, FIDUCIARIES AND TRUSTS (1989); ERNEST VINTER, TREATISE ON THE HISTORY AND LAW OF FIDUCIARY RELATIONSHIP AND RESULTING TRUSTS (3d ed. 1955) (discussing the nature and origin of fiduciary law). Much of the law governing fiduciaries has grown out of the law of trusts. *See generally*, AUSTIN W. SCOTT & WILLIAM F. FRATCHER, SCOTT ON TRUSTS (2000); RESTATEMENT (SECOND) OF AGENCY: AGENCY AS A FIDUCIARY § 13 (AM. LAW INST. 1958); RESTATEMENT (SECOND) OF AGENCY: AGENCY AS A FIDUCIARY § 387 (AM. LAW INST. 1958); RESTATEMENT (SECOND) OF AGENCY: \$\$ 389–96 (AM. LAW INST. 1958):

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^{8.} See RODWIN, supra note 7 at 251–56; MARC A. RODWIN, MEDICINE, MONEY, & MORALS: PHY-SICIANS' CONFLICTS OF INTEREST 179–211 (1993).

^{9.} See Frankel, supra note 7, at 809, 829–31, 833; FRANKEL, supra note 7, at 8. ("Entrustors entrust property or power to fiduciaries not for the purpose of benefiting the fiduciaries but for the purpose of benefiting the entrustors (or their designates)."); see also Robert Cooter & Bradley J. Freedman, The Fiduciary Relationship: Its Economic Character and Legal Consequences 66 N.Y. L. REV. 1045, 1046 (1991) ("[A] beneficiary entrusts a fiduciary with control and management of an asset."); 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, 243 (1995) ("The law defines a fiduciary as a person entrusted with power or property to be used for the benefit of another and legally held to the highest standard of conduct.").

^{10.} Tamar Frankel, Fiduciary Law in the Twenty–First Century, 91 B.U. L. REV. 1289, 1293 (2011).

^{11.} See generally, Arthur R. Laby, Resolving Conflict of Duty in Fiduciary Relationships, 54 AM. U. L. REV. 75, 78, 81, 100–01, 109 (2004) (describing the two main branches of fiduciary duties—duty of care and duty of loyalty and how these duties require a fiduciary to work for the party's benefit, with due diligence and accountability, and to refrain from conflicts of interest).

Third, the law has developed prophylactic rules to reduce the risk that fiduciaries will abuse their trust, fail to exercise diligence, or fail to exercise independent judgment. ¹² These rules apply to situations now known as conflicts of interest. We will soon examine how the law has defined conflicts of interest. For the moment, it is sufficient to say that a conflict of interest is a situation that compromises the fiduciary's loyalty or independent judgment. ¹³

The law regulates conflicts of interest in several ways. To begin, the law often prohibits fiduciaries from entering into situations that create conflicts of interest. Furthermore, if a conflict of interest arises, the law typically requires that the fiduciary resolve the conflict by ceasing the activity which created the conflict.

The practice of requiring fiduciaries to disclose any conflicts of interest advances several goals. It notifies the party that the fiduciary serves (what some authors refer to as the entrustor and others call the fiducie) of the risk that the fiduciary may not serve their interests. ¹⁴ This makes it possible for the entrustor to end the relationship, to insist that the fiduciary cease the activity that creates the conflict of interest, or to take other measures to protect themselves. In addition, knowledge of the conflict of interest is necessary for courts or other parties in order to manage the conflict of interest by supervising the fiduciary's work.

The law sometimes permits fiduciaries to enter situations with conflicts of interest or even to continue to perform their work, despite the conflicts of interest or even to continue to perform their work, despite the conflicts of interest.¹⁵ The

^{12.} See Frankel supra note 10 at 1295–96 (describing mechanisms that are in place to prevent the fiduciary from abusing the power entrusted to him).

^{13.} The concern with both loyalty and independent judgment is articulated in the rules governing the conflicts of lawyers. *See* MODEL CODE OF PROF'L RESPONSIBILITY Canon 5 (AM. BAR ASS'N 1980) ("The professional judgment of a lawyer should be exercised, within the bounds of the law, solely for the benefit of his client and free of compromising influences and loyalties."); MODEL CODE OF PROF'L RESPONSIBILITY DR 5–101 (AM. BAR ASS'N 1969) ("Except with the consent of his client after full disclosure, a lawyer shall not accept employment if the exercise of his professional judgment on behalf of his client will be or reasonable may be affected by his own financial, business, property, or personal interests."); *see also* MODEL RULES OF PROF'L CONDUCT r. 1.7 (AM. BAR ASS'N 2017) (prohibiting representation when employment is likely to adversely affect the lawyer's independent professional judgment or when it would involve the lawyer in representing *differing interests*).

^{14.} There are many terms for the party the fiduciaries serve in their individual relationships. For example, we speak of guardian and ward, principle and agent, or trustee and trustor. Others use the term fiducie, which follows more closely with the usage in Roman law. *See*, Frankel, *supra* note 7, at 800 n. 17 ("The term 'entrustor' has been coined here to refer to the other party in *any* fiduciary relation because there is no general term presently used to describe this party."); RODWIN, *supra* note 8, at 352 ("I have coined the term *fiducie*. It does not suggest any particular kind of fiduciary relationship and clearly links the fiduciary to the party on whose behalf he or she acts. Although the concept of fiduciary in law original in trust law . . . devices similar to trusts were also developed in Roman law"); FRANKEL, *supra* note 7, at 8 ("Entrustors entrust property or power to fiduciaries not for the purpose of benefiting the fiduciaries but for the purpose of benefiting the entrustors (or their designates).").

^{15.} See, e.g., Model Rules of Prof'l Conduct R 1.7, AM. BAR ASS'N (2006), http://www.americanbar.org/groups/professional_responsibility/publications/model_rules_of_professional_conduct/rule_1_7_conflict_of_interest_current_clients.html (explaining the circumstances when a lawyer can

law allows parties to proceed with conflicts of interest when prohibiting the conflicted transaction would preclude a particularly valuable activity and where there is reason to believe that the entrustor can take adequate measures to protect itself. In those circumstances, the fiduciary must fully disclose the conflict, and the party they serve must consent to proceeding, despite the conflict. In

For example, certain broker-dealers create markets, a valuable function that would cease if the law precluded combining these two roles, so the law allows the combination of broker-dealers in certain situations. In addition, in certain corporate transactions, the board or other parties acting for the corporation have the ability to assess whether the conflicted transaction is worth the risk. The law has moved away from prohibiting all forms of corporate self-dealing. It now allows self-dealing when an independent board of directors or a majority of shareholders knows of the conflict, approves of the transaction, and finds that the transaction is fair; courts may also find that a transaction is fair.

Although the law initially developed conflict-of-interest rules for fiduciaries, courts, legislatures, and governmental and private sector organizations subsequently applied many of these rules to other relationships. For example, such entities will apply these rules when an individual has a legal duty to serve the interest of a designated party or a legal duty to perform a specified role.²⁰ Today, the law regulates the conflicts of interests of public servants, financial professionals, officers of corporations and charitable foundations, lawyers, medical

medical ethics ").

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represent a client despite a conflict of interest); Joshua D. Margolis, *Professionalism, Fiduciary Duty, and Health-Related Business Leadership*, 313 JAMA 1819, 1820 (2015) (discussing fiduciary duties of physicians and business managers, and, the benefits of the tension between medicine and efficiency).

^{16.} See, e.g., Model Rules of Prof'l Conduct R 1.7, AM. BAR ASS'N (2006), http://www.americanbar.org/groups/professional_responsibility/publications/model_rules_of_professional_conduct/rule_1_7_conflict_of_interest_current_clients.html (requiring the consent of the client in order to receive legal representation when there are conflicts of interest).

^{17.} See id. (ensuring that the client consent to legal representation despite a conflict of interest with written informed consent).

^{18.} ROBERT C. CLARK, CORPORATE LAW § 5.1 160 (2d ed. 1986).

^{19.} Id. at 160-61.

^{20.} Sometimes writers refer to various actors as fiduciaries. Whether the law holds them accountable as fiduciaries is a separate matter. Often writers refer to individuals as fiduciaries as a metaphor rather than as a strict legal definition. See 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, 242 (1995) ("The idea that physicians are or should be fiduciaries for their patients, however, is a dominant metaphor in

professionals, clinical researchers, and organizational managers.²¹ Public policies, ethical codes, and private organizations also regulate the conflicts of *interest* of many professionals.²²

Legal Definition and Usage

A review of how the concept of conflict of interest is used in the law yields the following definition. A conflict of interest exists where an individual has an obligation to serve a party or perform a role and the individual has either: 1) *incentives* or 2) *conflicting loyalties*,²³ which encourage the individual to act in ways that breach his or her obligations.

Thus, there are two broad categories of conflicts of interest, though they are not mutually exclusive. These are:

1) Conflicts between an individual's obligations and their financial self-interest or other self-interest;

^{21.} See, e.g., Ethics in Government Act of 1978, 5 U.S.C. App'x at 549 (2012) (expanding regulation of federal government employees); Securities Act of 1933, 15 U.S.C. § 77a et. seq. (2012) (regulating of broker dealers and investment advisors). See id. § 80a-1 et. seq. (regulating investment companies); id. § 80b-1 et. seq. (regulating of broker dealers and investment advisors); A.B. 8072, 236th Leg., 2013 Sess. (N.Y. 2013) ("[E]very corporation shall adopt a conflict of interest policy to ensure that its directors, officers and key employees act in the corporation's best interest and comply with applicable legal requirements."); MODEL RULES OF PROF'L CONDUCT (2006) (regulating lawyers conduct); 42 U.S.C. § 1395nn (2012) (regulating physicians' conflicts of interest); 42 C.F.R. § 50.601 (2016) (regulating researchers' conflicts of interest).

^{22.} See, e.g., CANONS OF PROF'L ETHICS Canon 6 (1908) (recommending regulation of lawyers); MODEL CODE OF PROF'L RESPONSIBILITY Canon 5 (1969) (recommending regulation of lawyers); MODEL RULES OF PROF'L CONDUCT (2006) (recommending regulation of lawyers). See R.C. CLARK, ROBERT CHARLES, CORPORATE LAW (1986), for regulation of corporate officers and directors. See also, e.g., Securities Act of 1933, 15 U.S.C. § 77a et. seq. (2012) (regulating of broker dealers and investment advisors); 17 C.F.R. § 230 (2016) (supplementing rules and regulations to the Securities Act of 1933); Investment Company Act of 1940, 15 U.S.C. § 80a-1 et. seq. (2012) (regulating of investment companies); Investment Advisers of 1940, 15 U.S.C. § 80b-1 et. seq. (2012) (regulating of broker dealers and investment advisors); TAMAR FRANKEL & ANN T. SCHWING, REGULATION OF MONEY MANAGERS: MUTUAL FUNDS AND AD-VISERS § 14.01 (2d ed. Supp. 2015) (describing conflicts of interest). See also, e.g., Conflicts of Interest, 18 U.S.C 201 et. seq. (2012) (regulating of federal government employees and appointed officials); Roswell B. Perkins, The New Federal Conflict-of-Interest Law, 76 HARV. L. REV. 1113, 1113-69 (1963) (discussing 18 U.S.C. 201 et seq.); BAYLESS MANNING, FEDERAL CONFLICT OF INTEREST LAW (1964) (discussing conflict of interests among federal employees); Ethics in Government Act of 1978, 5 U.S.C. App'x at 549 (2012) (expanding regulation of federal government employees); DENNIS F. THOMPSON, POLITICAL ETHICS AND PUBLIC Office 82 (1987) (discussing the Ethics in Government Act); ANDREW STARK, CONFLICT OF INTEREST IN AMERICAN PUBLIC LIFE 36 (2003) (describing types of conflicts among government positions).

^{23.} See Kenneth Kipnis, Legal Ethics 40 (1986) (denoting two kinds of conflicts of interest (1) dealing with conflicting obligations and (2) questionable loyalty); see also Roy A. Schotland, Introduction to Abuse on Wall Street: Conflicts of Interest in the Securities Market 3, 4 (1980) ("Conflict of Interest...denotes a situation in which two or more interests are legitimately present and competing or conflicting.... The individual (or firm) making a decision that will affect those interests may have a larger stake in one of them that the other(s) but he is expected—in fact, obligated—to serve each as if it were his own, regardless of his own actual stake.").

2) Conflicts arising from an individual's conflicting or divided loyalties, or dual roles or duties.²⁴

Self-interest conflicts of interest are usually referred to as *financial conflicts* of interest because they typically involve financial stakes in the matter. However, an individual can receive rewards other than financial compensation. Inkind goods, sexual favors, or an official position of authority, honor, or employment are all examples of such rewards. For most purposes, however, financial interests are a good proxy for self-interest conflicts of interest. I will refer to the financial and other self-interest conflicts of interest as financial conflicts of interest.

As an example of a financial conflict of interest, consider the physician who dispenses medication. This physician has a financial interest in prescribing medicines in a way that promotes his income, for example, by increasing the number of prescriptions or, when there is a choice of medications, by prescribing the most profitable medications. Combining the role of prescribing and dispensing medications creates a risk that the physician's role as a dispenser will compromise the physician's obligation to consider the patient's best interests when prescribing medication. The physician's incentive to earn money can compromise his judgment regarding what his patients need.

The law also typically imputes to an individual the financial interest of his close family members, friends, or affiliates. ²⁶ As a result, the law deems a person to have a financial conflict of interest when the individual has a close family member, friend, or business associate with a financial interest. ²⁷ Family and friends are considered an extension of the person, presuming that the individual stands to receive indirect benefits from their family members or close affiliates. ²⁸ The law deduces that when an individual in a position of authority makes an official decision that directly affects her family, friends, or business associates, the official is tempted to act this way in order to favor his or her own interests.

Dual or divided loyalties can arise either because an individual has competing official obligations or because of conflicts between the individual's obligations and his or her loyalty to other parties. First, they occur when an individual performs two or more roles or activities whereby the performance of one can

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^{24.} See CONFLICT OF INTEREST IN GLOBAL, PUBLIC AND CORPORATE GOVERNANCE 3-4 (Anne Peters & Lukas Handschin eds., 2012).

^{25.} See Barbara A. Noah, The Invisible Patient, 2002 U. ILL. L. REV. 121, 146 (2002) (referring to financial conflict of interest as an example of self-interest).

^{26.} See, e.g., 42 U.S.C. § 1395nn (2012) (regulating physicians' conflicts of interest relating to family members).

^{27.} *Id.*; see also Mark Barnes & Patrick S. Florencio, *Investigator, IRB and Institutional Financial Conflicts of Interest in Human-Subjects Research: Past, Present and Future*, 32 SETON HALL L. REV. 525, 531 (2002) (describing regulations that apply to family members and research staff of clinical investigators).

^{28.} Conflict of Interest Policy California Nonprofit Public Benefit Corporation, PUBLIC COUNSEL (2010), http://www.publiccounsel.org/tools/publications/files/coi_policy.pdf.

conflict with the performance of the other.²⁹ For example, a lawyer that represents two clients with conflicting interests might be able to advance the interest of one client by harming the interest of the other client.³⁰ Dual loyalty conflicts also occur when an individual has personal loyalties to family, friends, or another party affected by the actions they take to fulfill their duties. The desire to help their family or friends can also bias the conduct of public officials. For example, when a public servant's official duties require that they act on matters that affect the welfare of a friend, family member, life-companion, sexual partner, or other close relation, the public servant's loyalty is divided between performing his official duties and acting in ways that benefit his close associates.

Physicians who treat patients and also perform clinical research often have divided loyalty conflicts of interest. For example, consider the physician who enrolls one of her patients as a research subject in a clinical trial to test the efficacy of a drug. The physician's duty as a clinician is to act in the patient's interest by treating his medical condition.³¹ In contrast, the physician's role as a researcher is to advance scientific knowledge, conduct research that might yield new therapies, and publish articles.³² The role of the clinician is quite different from the role of the researcher, and the two can easily conflict.³³ While research might help address medical problems on a broader scale, it is not designed to promote the best interests of the research subjects. Indeed, human research subjects often bear risks to their health and might receive therapy that is less effective than either the standard therapy or receiving no treatment at all. Both patients and physicians can confuse these roles and think that the physician is working to advance the patient's interest when enrolling the patient in the clinical trial.³⁴

^{29.} See, e.g., Margaret E. McLean, Employee Stock Ownership Plans and Corporate Takeovers: Restraints on the Use of ESOP's by Corporate Officers and Directors to Avert Hostile Takeovers, 10 PEPPERDINE L. REV. 731, 746–50 (1983) (explaining dual and divided loyalty issue between the duties of officer and trustee of an Employee Stock Ownership Plan).

^{30.} See, e.g., State v. Goode, 171 N.W.2d 733, 735 (1969) ("No attorney should be placed in a position of divided loyalty 'where he may be required to choose between conflicting duties or to be led to an attempt to reconcile conflicting interests rather than to enforce, to their full extent, the rights of the party whom he should alone represent."").

^{31.} See Rodwin, supra note 20, at 245 (explaining that as clinicians, physicians examine, diagnose, and advise patients on their medical conditions).

^{32.} See David A. Lenrow, *The Treating Physician as Researcher: Is Assuming This Dual Role a Violation of the Nuremberg Code?* TEMP. J. OF SCI. TECH. & ENVTL. L, 15, 30–31 (2006) (discussing how research as compared with treatment, is geared toward the advancement of knowledge and the potential benefit of society as a whole).

^{33.} Franklin G. Miller & Donald L. Rosenstein, *The Therapeutic Orientation to Clinical Trials*, 348 New Eng. J. Med. 1383, 1383–85 (2003).

^{34.} This is often referred to as the therapeutic misconception. See Marcia Angell, Medical Research: The Dangers to Human Subjects, N. Y. REVIEW (Nov. 19, 2015), http://www.nybooks.com/articles/2015/11/19/medical-research-dangers-human-subjects/; Marcia Angell, Medical Research on Humans: Making It Ethical, N. Y. REVIEW (Dec. 3, 2015), http://www.nybooks.com/articles/2015/12/03/medical-research-humans-making-it-ethical/. The aim of the clinical trial is not to treat patients, but to develop knowledge about medical therapies. Sometimes patients enroll in clinical trials

It is worth emphasizing two points to avoid frequent misunderstandings. First, conflicts of interest do not necessarily constitute a breach of duty or misconduct, although the law may sometimes prohibit public officials from entering into situations that create conflicts of interest as a means of reducing the risk that the individual will breach their obligations. Although law or ethical codes may require that individuals not enter into conflict-of-interest situations, this is only a measure to prevent acts considered wrong in themselves. Conflicts of interest can influence action, but they are not the unlawful acts. Second, conflicts of interest are not the same as conflicting interests. Multiple interests often pull people in different directions. Unless such conflicting interests compromise an individual or party's *obligations*, no conflict of interest exists. 37

Conflicts of interest constitute a problem for two reasons: (1) they compromise an actor's *loyalty* to her mission or to the parties she is supposed to serve, and (2) they compromise the actor's *independent judgment*.³⁸ Consequently, conflicts of interest increase the risk that individuals will either not perform their duties as they should, or even cause them to breach their obligations. A conflicted individual might not perform at his customary high level of competence, diligence, or effectiveness in such a situation. At its most egregious, individuals with conflicts of interest might knowingly exploit their position for personal interest. Extreme disloyalty obviously presents more dramatic dangers, making it easier to identify. Situations that compromise independence, loyalty, or judgment more subtly, or even unintentionally, occur more frequently but are harder to recognize.

Conflicts of interest also arise in organizations and/or institutions. An *institutional conflict of interest* exists when an organization performs two or more

when existing therapies are not effective or when they hope they will fare better by receiving the experimental therapy. However, we conduct clinical trials precisely because we do not know whether they are safe or effective. There is no way of knowing if there will be benefits or what risks patients will bear from receiving the experimental therapy. Moreover, typically in clinical trials, only some patients receive the experimental therapy and the others receive either a placebo or an alternative therapy. Patients who enter clinical trials therefore do not even know whether they will receive the experimental therapy. *See* Miller & Rosenstein, *supra* note 33, at 1384–85.

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^{35.} Ravindra B. Ghooi, *Conflict of Interest in Clinical Research*, 6 PERSPECT. CLINICAL RES. 10, 10–11 (2015).

^{36.} See CONFLICT OF INTEREST IN GLOBAL, PUBLIC AND CORPORATE GOVERNANCE 6 (Anne Peters & Lukas Handschin eds., 2012) (explaining that conflicting interests come up all the time in day to day management of many things).

^{37.} Likewise, a conflict of interest is not a conflict between competing interest groups or organizations that have conflicting interests.

^{38.} There are many other problems that follow. Conflicts of interest undermine the trustworthiness of conflicted actors and public trust in individuals and institutions. *See* Lo & Field, *supra* note 2, at 2 – 28 (other problems exist such as, conflicts of interest undermine the trustworthiness of conflicted actors and public trust in individuals and institutions); Bradford H. Gray, *Trust & Trustworthy Care in the Managed Care Era*, 16, HEALTH AFFAIRS 34, 35 (1997), https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.16.1.34. *See generally* RUSSELL HARDIN, TRUST & TRUSTWORTHINESS (2002) (discussing trust as an individual-level problem, and, an individual-institution problem).

conflicting roles.³⁹ This typically occurs when the institution has financial interests that cut against its institutional mission or activity. ⁴⁰ In the United States, academic medical centers and many private, not-for-profit universities and hospitals sometimes have joint ventures with for-profit firms to conduct research, commercialize the resulting products, and share profits or royalties.⁴¹ Meanwhile, universities have a mission of promoting inquiry and public access to knowledge. They also have obligations to oversee the integrity of university researchers, thus requiring them to monitor their individual financial conflicts of interest. Alternatively, the university itself may have a financial interest in the outcome of the research that can conflict with its mission as an educational and research institution.⁴² For example, if an institution conducts research to evaluate a medication while earning income from the product's sale, those two activities create an institutional conflict of interest.

Definitions in Dictionaries, Legal Texts, Treatises and Organizational Policies

Dictionaries typically define conflicts of interest in ways that follow the standard legal usage as discussed above. Still, there are some variations.

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^{39.} Ezekiel J. Emanuel & Daniel Steiner, *Institutional Conflict of Interest*, 332 NEW ENG. J. MED. 262, 263 (1995); *Managing Conflict of Interest in the Public Service: OECD Guidelines and Country Experiences*, OECD, https://www.oecd.org/gov/ethics/48994419.pdf (last visited Oct. 26, 2018).

^{40.} Some writers also hold that when an institution's senior official has financial interests that can affect the institutional policies, that situation also creates an institutional conflict of interest. However, the financial interests of senior officials in an organization can be analyzed as reflecting individual conflicts of interest, so there is no need to define these as institutional conflicts of interest. See, ASS'N OF AM. U., REPORT ON INDIVIDUAL & INST. FINANCIAL CONFLICT OF INTEREST (2001) (The Association of American Universities defined institutional conflicts of interest to include those of both the institution itself and its senior officials); Lo & Field, supra note 2, at 218 ("Institutional conflicts of interest arise when an institution's own financial interests or those of its senior officials pose risks of undue influence on decisions involving the institution's primary interests. For academic institutions, such risks often involve the conduct of research within the institution that could affect the value of the institution's patents or its equity positions or options in biotechnology, pharmaceutical, or medical device companies. Conflicts of interest may also arise when institutions seek and receive gifts or grants from companies, for example, a gift of an endowed university chair or a grant for a professional society to develop a clinical practice guideline. In addition, institutional conflicts of interest exist when senior officials who act on behalf of the institution have personal financial interests that may be affected by their administrative decisions. For instance, a department chair or dean who has a major equity holding in a medical device company could make decisions about faculty appointments and promotions or assignment of office or laboratory space in ways that favor the interests of the company but compromise the overall research, educational, or clinical mission of the institution. Similarly, a hospital official with such a holding would be at risk of undue influence in making decisions about the use of the company's products for patient care. In situations like these, an individual's financial relationship also implicates the institution's interests.").

^{41.} Bradford H. Gray, For-Profit Enterprise in Health Care 1–10 (Nat'l Academies Press, 1986).

^{42.} Emanuel & Steiner, *supra* note 39, at 262–67.

Many dictionaries distinguish between the two types of conflicts of interest: 1) financial and other self-interested conflicts of interest, and 2) conflicts of interest arising from dual loyalties.⁴³ They typically explain that these two types of conflicts arise from conflicts regarding an individual's performance of his or her official duties (these official duties may involve public servants or of private sector actors such as lawyers, agents, and financial managers).⁴⁴ Sometimes dictionaries refer to the conflict as arising from *personal* interests rather than financial interests.⁴⁵ For example, the 2001 Random House-Webster's Unabridged Dictionary contains this definition:

Conflict of Interest:

- 1. The circumstance of a public office holder, business executive, or the like, whose personal interests might benefit from his or her official actions or influence. *The Senator placed his stocks in trust to avoid possible conflicts of interest.*
- 2. The circumstance of a person who finds that one of his or her activities, interests, etc. can be advanced only at the expense of another of them.⁴⁶

However, some dictionaries define conflicts of interest in ways that do not distinguish between the two categories of conflict of interest; they focus instead on financial conflicts of interest.⁴⁷ These definitions describe conflicts of interest as a conflict between the actor's duty and their financial or other private interest.⁴⁸ For example, the 2004 American Heritage Dictionary defines conflicts of interest as "A conflict between a person's private interests and public obligations."⁴⁹

Legal texts, treatises, and organizational policies typically define conflicts of interest similarly to dictionary definitions or employ the term in ways consistent with such definitions.

The federal government's Office of Government Ethics (OGE), which oversees the conflicts of interest of public employees, states that:

^{43.} See infra "Box 1 Definitions of Conflicts of Interest in Dictionaries, Treatises, and Organizational Policies," in Appendix.

^{44.} See infra "Box 1 Definitions of Conflicts of Interest in Dictionaries, Treatises, and Organizational Policies," in Appendix.

^{45.} RANDOM HOUSE – WEBSTER'S UNABRIDGED DICTIONARY 2001; *see also* MERRIAM-WEBSTER'S DICTIONARY OF LAW 1996 (referring to a conflict between *private interests* and professional responsibilities).

^{46.} RANDOM HOUSE – WEBSTER'S UNABRIDGED DICTIONARY 2001.

^{47.} See infra "Box 1 Definitions of Conflicts of Interest in Dictionaries, Treatises, and Organizational Policies," in Appendix.

^{48.} See infra "Box 1 Definitions of Conflicts of Interest in Dictionaries, Treatises, and Organizational Policies," in Appendix.

^{49.} See infra "Box 1 Definitions of Conflicts of Interest in Dictionaries, Treatises, and Organizational Policies," in Appendix.

A criminal conflict of interest statute, 18 U.S.C. § 208, prohibits an employee from participating personally and substantially, in an official capacity, in any "particular matter" that would have a direct and predictable effect on the employee's own financial interests....⁵⁰

The Internal Revenue Service requires charitable organizations that seek tax exemptions to have a conflict-of-interest policy. The IRS writes "A conflict of interest arises when a person in a position of authority over an organization, such as a director, officer, or manager, may benefit personally from a decision he or she could make."

A treatise on Conflicts of Interest in Business and the Professions states:

A conflict of interest thus contemplates something more than two interests that conflict with or tend to impair one another... [B]efore a conflict of interest arises, one must be in a relationship of trust or a fiduciary relationship or otherwise have a duty to the other.... Second, one must have some interest that interferes or tends to interfere with one's exercise of judgment on behalf of the person with whom one is in the relationship of trust.⁵²

Several international organizations have conflict-of-interest policies for their employees and consultants that treat their actors as public servants. The Organization for Economic and Cooperative Development (OECD) says that:

a 'conflict of interest' is: a conflict between the public duty and private interests of a public official, in which the public official has private-capacity interests, which could improperly influence the performance of their official duties and responsibilities.⁵³

For other examples of definitions and usage that are variations of the types discussed, see Box1: Definitions of Conflicts of Interest In Dictionaries, Treatises and Organizational Policies.

III. NEW DEFINITIONS

The Thompson-IOM Definition

In 1993, Professor Dennis Thompson, a political philosopher who has written about politics, government, and ethics, published an influential article titled

^{50.} Employees Entering Government, U.S. OFFICE OF GOV'T ETHICS (Mar. 31, 2017), https://www.oge.gov/web/oge.nsf/Financial%20Conflicts%20of%20Interest/E07A0C541EF92CF385257E96006364E1?opendocument.

^{51.} Instructions for Form 1023 (12/2017), INTERNAL REVENUE SERV., https://www.irs.gov/instructions/i1023/ch02.html#d0e2126>%20(last%20visited%20July%2012,%202016 (last visited Oct. 26, 2018).

^{52.} THOMSON REUTERS, CONFLICTS OF INTEREST IN BUSINESS & PROFESSIONS: LAW AND COMPLIANCE § 1:3 (2016), Westlaw.

^{53.} The Org. for Econ. and Cooperative Dev., Managing Conflict of Interest in the Public Service: OECD Guidelines and Country Experiences 15, https://www.oecd.org/gov/ethics/48994419.pdf (last visited Oct. 26, 2018).

"Understanding Financial Conflicts of Interest" in the *New England Journal of Medicine*. ⁵⁴ The article drew on Thompson's previous work to explain why conflicts of interest are a significant problem in medical practice and to counter some of the criticism for those policies which were developed to counter conflicts of interest. ⁵⁵ The article discussed reasons for regulating conflicts of interest, standards for assessing conflicts of interest, and remedies. ⁵⁶ His article is a succinct and lucid summary of law and policy that has developed to manage and cope with conflicts of interest. The article has been most influential for its brief definition of conflict of interest and its short explanation of key terms. Many people writing about medical conflicts of interest have since adopted Thompson's definition.

Thompson defined conflicts of interest as follows:

A conflict of interest is a set of conditions in which professional judgment concerning a primary interest (such as a patient's welfare or the validity of research) tends to be unduly influenced by a secondaryinterest (such as financial gain).⁵⁷

Thompson follows with this explanation:

The primary interest is determined by the professional duties of a physician, scholar, or teacher. Although what these duties are may sometimes be controversial (and the duties themselves may conflict), there is normally agreement that whatever they are, they should be the primary consideration in any professional decision that a physician, scholar, or teacher makes. In their most general form, the primary interests are the health of patients, the integrity of research, and the education of students.

The secondary interest is usually not illegitimate in itself, and indeed it may even be a necessary and desirable part of professional practice. Only its relative weight in professional decisions is problematic. The aim is not to eliminate or necessarily to reduce financial gain or other secondary interests (such as preference for family and friends or the desire for prestige and power). It is rather to prevent these secondary factors from dominating or appearing to dominate the relevant primary interest in the making of professional decisions.⁵⁸

The Thompson definition differs from standard legal definitions in several ways. First, the Thompson definition does not distinguish between the two types of conflicts of interest included in traditional legal definitions, namely: a) financial

^{54.} Dennis F. Thompson, *Understanding Financial Conflicts of Interest*, 329 New Eng. J. Med. 573 (1993); *Dennis F. Thompson*, HARV. KENNEDY SCH., https://www.hks.harvard.edu/faculty/dennis-thompson (last visited May 16, 2018).

^{55.} Thompson supra note 54.

^{56.} See id. at 573–76 (rebutting criticisms of established methods of combating conflicts of interest and defending their utility through various examples).

^{57.} Id. at 573.

^{58.} Id.

conflicts and b) dual loyalty conflicts. It is often useful to specify both types or to distinguish between them.

Second, the Thompson definition focuses on conflicts of interest as a source of undue influence or bias on professional judgment. It does not discuss the other risk from conflicts of interest, such as compromising the actor's *loyalty* to the party or mission he or she is supposed to serve.

Third, while traditional legal usage speaks of conflicts between the actor's obligations and his or her interests, Thompson refers to conflicts between the actor's primary and secondary interests.⁵⁹ The Thompson definition substitutes the term primary interests for legal or official obligations though it does not mention legal obligations or the law. This diminishes the significance of the conflict of interest because there are merely two competing interests rather than a conflict between an individual's *obligations* and interests.

Fourth, secondary interests are deemed to be a problem only when they dominate primary interests or when the primary interests "tends to be unduly influenced by a secondary interest...."60 This formulation tends to minimize regulation, because it is difficult to know when an interest dominates or produces undue influence. In contrast, the traditional legal approach does not limit regulation to situations where there is undue influence. There is no need for an empirical test or investigation to determine whether the interest tends to unduly influence. Under the traditional legal definition, a conflict of interest exists in situations that compromise loyalty or independent judgment. Of course, once a conflict of interest is identified, there is a need to analyze the costs and benefits of alternative potential regulatory responses.

In 2009, the Institute of Medicine (IOM) published a report, Conflicts of Interest In Medical Research, Education, and Practice.⁶¹ Dennis Thompson served on the IOM committee that oversaw the study. The committee adopted the Thompson definition of conflict of interest, but made some modifications to its phrasing.⁶² The IOM held that "A conflict of interest is a set of circumstances

^{59.} Id. at 573–76.

^{60.} Id. at 573; THE OXFORD TEXTBOOK OF CLINICAL RESEARCH ETHICS 763 (Ezekiel J. Emanuel et al. eds., 2008).

^{61.} See Lo & Field, supra note 2.

^{62.} The IOM report notes that its discussion of conflicts of interest draws on Thompson supra note 54 and Emanuel supra note 60 at 767-76 (discussing research-specific conflicts and institutional conflicts). The committee also consulted other definitions and frameworks, including: ASS'N OF AM. MED. COLLS., PROTECTING SUBJECTS, PRESERVING TRUST, PROMOTING PROGRESS – POLICY AND GUIDELINES FOR THE OVERSIGHT OF INDIVIDUAL FINANCIAL INTERESTS IN HUMAN SUBJECTS RESEARCH 3, 10 (2001), https://www.aamc.org/download/75302/data/firstreport.pdf; Ass'N of AM. Med. Colls. - AAU, Pro-TECTING PATIENTS, PRESERVING INTEGRITY, ADVANCING HEALTH: ACCELERATING THE IMPLEMENTA-TION OF COI POLICIES IN HUMAN SUBJECTS RESEARCH 7, 9, 10, 13 (2008), https://mem $bers. a amc. org/eweb/upload/Protecting \% 20 Patients, \% 20 Preserving \% 20 Integrity.pdf; \ T.L. \ BEAUCHAMP Protection of the property of$ & J. F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS (6th ed. 2009). See generally CONFLICT OF IN-TEREST IN THE PROFESSIONS (Michael Davis & Andrew Stark eds., 2001) (explaining the importance of conflict of interest in professions); Peter Lurie, Presentation to the Institute of Medicine Committee on

that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest." After the IOM study adopted the Thompson definition, many authors of articles on medicine adopted the Thompson-IOM definition. ⁶⁴

Because the Thompson-IOM definition does not distinguish between financial-self-interest and dual loyalty conflicts, subsequent writers sometimes made their own distinctions. However, the distinctions of subsequent writers often used categories that confused or expanded the conflict-of-interest concept, most notably by including intellectual or non-financial conflicts.

Intellectual and Non-Financial Conflicts

After publication of the Thompson article and the IOM report on conflicts of interest in medicine, several authors called attention to what they referred to either as *non-financial* conflicts of interest or *intellectual* conflicts of interest.⁶⁵ Although they used these terms in similar ways, some writers use the first term while others employ the second. I am unaware of any writer that distinguishes *intellectual* from *non-financial* conflicts, so I will use these terms interchangeably. When discussing an author in particular, I will employ the term the author uses. Some writers discuss these issues using slightly different terminology.⁶⁶

Conflict of Interest in Medical Education, and Practice (Nov. 5, 2007), http://www.citizen.org/Page.aspx?pid=720; CONFLICTS OF INTEREST: CHALLENGES AND SOLUTIONS IN BUSINESS, LAW, MEDICINE, AND PUBLIC POLICY (Don A. Moore et al. eds., 2009) (explaining conflict of interest for professional between professional responsibilities and self-interest); NAT'L INSTS. OF HEALTH, REPORT OF THE NATIONAL INSTITUTES OF HEALTH BLUE RIBBON PANEL ON CONFLICT OF INTEREST POLICIES 26–36, 65–66 (2004), http://acd.od.nih.gov/reports/ethics_COI_panelreport.pdf; William M. Sage, Some Principles Require Principals: Why Banning "Conflicts of Interest" Won't Solve Incentive Problems in Biomedical Research, 85 Tex. L. Rev. 1413, 1420–21, 1445, 1451 (2007). See Lo & Field, supra note 2, at 45 n 1

63. Lo & Field, supra note 2, at 45–46; Thompson, supra note 54, at 573.

64. Google scholar reports that as of May 4, 2018, the Thompson article has been cited in 933 publications and that the IOM report has been cited in 457 publications.

65. See Rothman, supra note 5, at 2782–84; Mario Maj, Non-financial Conflicts of Interests in Psychiatric Research and Practice, 193 BRITISH J. PSYCHIATRY 91, 91–92 (2008); Elliott Marshall, When Does Intellectual Passion Become Conflict of Interest?, 257 SCIENCE 620, 620–21 (1992); Norman G. Levinsky, Nonfinancial Conflicts of Interest in Research, 347 New Eng. J. Med. 759, 759–61 (2002).

66. A few writers also use the term *intrinsic* conflicts of interest to refer to similar issues. See e.g., Sharmon Sollitto et al., Intrinsic Conflicts of Interest in Clinical Research: A Need for Disclosure, 13 KENNEDY INST. OF ETHICS J. 83, 85–87 (2003). The authors draw attention to what they describe as intrinsic conflicts of interest, "conflicts of interest inherent in all clinical research." Id. at 83. These interests "arise automatically" and "are unavoidable" Id. at 86. The authors argue that researchers dismiss intrinsic conflicts of interests, but they should be acknowledged and disclosed. Unfortunately, intrinsic conflicts of interest "are almost impossible to reduce, prohibit, or regulate. They are simply too embedded in clinical research." Id. at 87. They offer several examples:

Medical investigators strive to obtain noteworthy findings through their research studies and to publish their results in prestigious academic journals. The quality, placement, and number of the researcher's publications will affect national reputation and eligibility for academic advancement. Other examples of intrinsic influences are the hope of being the first to fulfill the promise of a new technique, the satisfaction of vindicating intellectual biases and the wish to receive accolades from

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In general, so-called intellectual conflicts consist of situations that the law has not yet classified or regulated as conflicts of interest. Nevertheless, several writers argue that both financial and intellectual conflicts can bias judgment so that we should treat them the same way. Most suggest that because we do not restrict or manage intellectual conflicts, we should not prohibit engaging in activities that create financial conflicts of interest or manage these conflicts.⁶⁷ In contrast, other writers conclude that we should regulate intellectual conflicts because we already regulate financial conflicts.⁶⁸

peers or to win research prizes. *Id.* at 85. Sollitto et al. explicitly include certain financial conflicts of interest as intrinsic conflicts of interest when the financial incentives "are integral to the clinical research endeavor[and] arise automatically and they are unavoidable."

Id. at 85–86. They therefore implicitly acknowledge that intrinsic conflicts and financial conflicts of interest are not mutually exclusive. They also include as extrinsic conflicts of interest a researcher's interest in publishing, which other authors describe as an intellectual conflict of interest. *Id.*

67. Kenneth Rothman has written extensively in opposition to mandated disclosure of researchers' conflict of interests. See, e.g., Rothman, supra note 5, at 2784 (arguing that conflicts of interest are a "nearly universal circumstance" and the label deprives researchers of having their findings judged on the merits); cf. Kenneth Rothman, The Ethics of Research Sponsorship, J. CLINICAL EPIDEMIOLOGY 44 Supp. I 25S (1991) (pointing out that "virtually all" epidemiological research is sponsored, whether government or industry, and every researcher is interested in the outcome); cf. Kenneth Rothman & Cristina Cann, Judging Words Rather than Authors, 8 EPIDEMIOLOGY 223, 223-25 (1997) (justifying an editorial policy which places the impetus for disclosure solely at the discretion of the author submitting the work); cf. Kenneth Rothman, Letter to the Editor, Journal Policies on Conflict of Interest, 261 SCIENCE 1661 (1993) (further arguing that policies that broadly require authors to disclose an array of potential conflicts are "ethically questionable" themselves for impugning "wrongdoing without evidence"). Lisa Rosenbaum has argued that working with industry promotes medical advancement. See Lisa Rosenbaum, Understanding Bias - The Case for Careful Study, 372 N. ENG. J. MED. 1959, 1959-1960 (2015) (arguing that "94% of physicians have relationships with industry," but these relationships rarely impact patient health). See also Lisa Rosenbaum, Reconnecting the Dots—Reinterpreting Industry—Physician Relations, 372 N. ENG. J. MED. 1860, 1860-61, 1863 (2015) (raising concern that "stories about industry greed" distract from industry-sponsored research's benefits to the public); see also Lisa Rosenbaum, Beyond Moral Outrage-Weighing the Trade-Offs of COI Regulation, 372 N. ENG. J. MED. 2064, 2064–68 (2015) (describing an evolution of policy more driven by reaction to scandal than "careful data gathering and analysis").

Other writers that critique the concept of conflict of interest include:

Richard Epstein, Conflicts of Interest in Health Care: Who Guards the Guardians? 50 PERSPECTIVES IN BIOLOGY AND MEDICINE 72, 73, 82–84, 86 (2007) (arguing that regulations designed to curb the influence of conflicts of interest can have the effect of chilling beneficial research); Peter Eichacker et al., Special Letter to the Editor, Separating Practice Guidelines from Pharmaceutical Marketing, 35 CRITICAL CARE MED. 2877, 2877 (2007); Laurence Hirsch, Conflicts of Interest, Authorship, and Disclosures in Industry-Related Scientific Publications: The Tort Bar and Editorial Oversight of Medical Journals, 84 MAYO CLINIC PROCEEDINGS 811, 812–16 (2009) (arguing that journals employ haphazard standards to root out perceived conflicts of interest, unfairly and untenably ignoring industry-sponsored research); Michael Weber, Academic Physicians Confront a Hostile World: The Creation of ACRE, 11 J. OF CLINICAL HYPERTENSION 533, 533–36 (2009) (arguing that major research and improvements in health outcomes have been stalled by "the growing tension between industry and academia").

68. Cf. Saver, supra note 4, at 467 (cautioning that attempts at regulation should not "[dismiss] non-financial interests" because these frequently "raise misaligned incentives problems"); cf. Sharmon Sollitto et al., Intrinsic Conflicts of Interest in Clinical Research: A Need for Disclosure, 13 KENNEDY INST. OF ETHICS J. 83, 86–87 (2003) (rejecting the premise that because many, if not all, researchers have some indirect nonfinancial conflict that these should not be considered, but rather, "because they are part of the

Some organizations have adopted policies to manage intellectual conflicts. Several organizations that develop clinical practice guidelines have policies which cover both intellectual and financial conflicts of interest.⁶⁹ Some journals have also developed similar policies.

Can everything be a Conflict of Interest?

The definitions and examples of intellectual and nonfinancial conflicts reveal that the concepts are amorphous and lack clear boundaries. As a result, it is not clear what does or does not constitute an intellectual or nonfinancial conflict.⁷⁰

Richard Saver penned one of the most articulate discussions on the concept of nonfinancial conflicts. ⁷¹ He contends that current practices have inappropriately reduced "conflicts of interest to financial conflicts." Following the language of the Thompson-IOM definition, he defines *non-financial interests* as "any non-financial source of bias that can unduly influence primary research

familiar academic landscape," they "maybe be more insidious" than financial conflicts and require disclosure to avoid potential harm).

69. See INST. OF MED., NAT'L ACADEMIES PRESS, CLINICAL PRACTICE GUIDELINES WE CAN TRUST 78 (Robin Graham et al. eds., 2011) (explaining that the American Heart Association, American Thoracic Society, American College of Chest Physicians, American College of Physicians, and World Health Organization all have Conflict of Interest (COI) policies covering "financial and intellectual conflicts"). For explanations of professional society's decision-making and guidance-setting in regard to COIs, see Holger J. Schünemann et al., An Official American Thoracic Society Policy Statement: Managing Conflict of Interest in Professional Societies, 180 Am. J. RESPIRATORY CRITICAL CARE MED. 564, 564 (2009); Amir Qaseem et al., The Development of Clinical Practice Guidelines and Guidance Statements of the American College of Physicians: Summary of Methods, 153 Annals Of Internal Med. 194, 195 (2010).

For studies and critiques of professional associations' COI policies, see Gordon Guyatt et al., The Vexing Problems of Guidelines and Conflict of Interest: A Potential Solution, 152 ANNALS OF INTERNAL MED. 738 (2010); Ignacio Neumann et al., Low Anonymous Voting Compliance With the Novel Policy for Managing Conflicts of Interest Implemented in the 9th Version of the American College of Chest Physicians Antithrombotic Guidelines, 144 CHEST 1111, 1111–12, 1115–16 (2013).

70. For critiques of the new definitions of conflicts of interest and proposals to reduce regulation of conflicts of interest see, Lisa Bero, What is in a name? Nonfinancial influences on the outcomes of systematic reviews and guidelines, 67 J. OF CLINICAL EPIDEMIOLOGY 1239, 1239–41 (2014); Sheldon Krimsky, Autonomy, Disinterest, and Entrepreneurial Science, 43 SOCIETY 22, 25–27 (2006); Robert Steinbrook et al., Justifying Conflicts of Interest in Medical Journals: A Very Bad Idea, 350 THE BMJ (June 2, 2015, https://www.bmj.com/content/350/bmj.h2942); Elizabeth Loder et al., Revisiting the Commercial-Academic Interface in Medical Journals, 350 BMJ (June 2, 2015, https://www.bmj.com/content/350/bmj.h2957); Howard Brody, A Reply to Thomas Stossel on the AMA-CEJA Draft Report, 10 MEDSCAPE J. MED. 154 (2008). See Table 1: Conflicts of Interest Definitions: Comparison of Legal Definitions to New Definitions.

71. See Saver, supra note 4, at 467 (describing the negative consequences of "under-prioritiz[ing] non-financial interests" in conflict of interest disclosure by positing that "[c]oncern about financial ties crowds out consideration of other influences that may bias research conduct").

^{72.} *Id*.

goals."⁷³ He says that just as we regulate financial conflicts of interest, we should similarly regulate non-financial interests when they conflict with the primary goals of research. ⁷⁴ Saver notes that conflicting nonfinancial interests also include: an individual's interest in career advancement, tenure and promotion, enhanced reputation, professional honors and prestige, access to power, as well as "intellectual or political predispositions, intellectual passion, and investigative zeal...."⁷⁵ They also include a reluctance to antagonize powerful faculty and "social relationships formed in...research..., ranging from collegial to competitive to hierarchical...."⁷⁶ This list is breathtakingly large. The social relations he refers to—hierarchical, collegial, and competitive—include prevailing types of work relations.

Other writers have focused on some of the particular interests mentioned by Richard Saver. For example, Professor Maj argues that *allegiance to a school of thought* or *political commitments* constitutes a conflict of interest that can unduly influence physicians. There are physicians, he says, "with a strong prejudicial attitude against the use of medications in psychiatry and the hospitalization of psychiatric patients." Tracking the language of the Thompson-IOM definition, Maj claims that writers who have certain political commitments have a conflict of interest because their views constitute secondary interests that unduly influence their primary interests, specifically, the welfare of their patients.

Eliot Marshall also draws analogies between intellectual conflicts and financial conflicts of interest.⁸⁰ He writes that the editors of the journal, *Science*, have repeatedly heard from scientists that money conflicts are "simple compared to the intellectual conflicts of interest that scientist have always to deal with."⁸¹ The scientists said that due to their intellectual commitments, many scientists

^{73.} *Id.* at 468. Saver uses the term "non-financial interest" rather than "non-financial conflict of interest," because "often the non-financial interests do not pose a stark conflict with primary research goals, but they can still present misaligned incentives problems"). *Id.* Saver notes that non-financial interests are sometimes referred to as intellectual or intrinsic conflicts of interest. *Id.*

^{74.} *Id.* at 469–70. Saver finds unpersuasive the reasons traditionally offered to regulate financial interests, though not used for non-financial interests. *Id.* at 477.

^{75.} Id. at 468

^{76.} *Id*.

^{77.} Maj, supra note 65, at 91–92.

^{78.} See *id.* (noting that physicians are free to hold certain viewpoints, however, it is problematic when these prejudicial attitudes endanger patients' welfare).

^{79.} See id. (arguing that a conflict arises, for example, when a psychiatrist holds a strong prejudicial attitude against the use of medication, denies pharmacological treatment to a severely depressed patient who later commits suicide). See Thompson, supra note 54 (explaining conflict of interest definition); see also INST. OF MED., supra note 69 (explaining Institute of Medicine definition of conflict of interest).

^{80.} Eliot Marshall, Special News Report, When Does Intellectual Passion Become Conflict of Interest?, 257 SCIENCE 620, 620–23 (1992).

^{81.} Id. at 620.

have difficulties being objective. 82 They become advocates for a preferred hypothesis, which compromises their assessment of evidence. Marshall maintains that scientific research is characterized by passionate individuals, who champion competing ideas, not by individuals who dispassionately pursue truth. 83

In a similar vein, David Horobin argues that "fanaticism about a single issue" constitutes a nonfinancial conflict far more serious than financial conflicts.⁸⁴

Gordon Guyatt suggests that the intellectual commitments demonstrated in previous work sometimes conflicts with an objective assessment of the evidence. According to Guyatt, important intellectual conflicts of interest arise where:

[A]uthorship of original studies and peer-reviewed grant funding by such institutions as the government or nonprofit organizations that directly relate to a recommendation. For example, an author of a randomized trial comparing 2 anticoagulant regimens for acute treatment of venous thromboembolism would have a conflict for any recommendation related to acute anticoagulant therapy for venous thromboembolism.⁸⁵

Less important intellectual conflicts include one's "participation in previous guideline panels...." In short, he says that scientists who have published a study on a subject have an intellectual investment in the conclusion of certain scientific questions. This intellectual investment will conflict with their impartial evaluation on the same or related issues.

Some writers describe *rivalry* as another conflict of interest. For example, in an editorial for *The Lancet*, Richard Horton writes:

^{82.} See id. (explaining that intellectual conflicts stem from scientists' deep investments to a hypothesis and the innate difficulty humans have in viewing their work objectively).

^{83.} Id. at 621.

^{84.} David F. Horrobin, *Non-financial Conflicts of Interest are More Serious than Financial Conflicts*, 318 BRITISH MED. J. 466, 466 (1999) (describing three other examples of non-financial conflicts: political commitment, philosophical bias, and commitment to a particular theoretical framework).

The first is fanaticism about a single issue. Certain causes attract people who become so committed that they cannot ever evaluate research fairly. Smoking and salt are two of these. I know of at least two senior academics who would never put their name to a research report describing any beneficial effect from smoking. Just as researchers . . . should declare any funding from, say, tobacco . . . or food or drink companies, so researchers should also declare whether they are members of antismoking or anti-alcohol pressure groups The second is political commitment. I know of one Marxist academic who could never admit that any action of any pharmaceutical company was beneficial. Antagonism to capitalism or . . . pharmaceutical industry should be declared, as should . . . funding from industry. The third is philosophical bias [S]ome medical scientists cannot admit that nutrition is beneficial to health, while others believe [it] can do everything The last is commitment to a particular theoretical framework.

Id.

^{85.} Guyatt, supra note 69, at 739.

^{86.} Id.

^{87.} Id.

Financial conflicts may be the easiest to identify but they may not be the most influential. Academic, personal, and political rivalries and beliefs are less easily recognized, but each may affect an interpretation.... [They] render the declaration "conflict of interest: none" an impossibility.⁸⁸

A few writers have recognized the vast scope of so-called intellectual conflicts and have developed definitions or typologies for them. Though these writers provide a crisp summary, they do not rule out any of the examples provided. For example, the Institute of Medicine (IOM) report, *Clinical Practice Guidelines We Can Trust*, defines intellectual conflicts as "academic activities that create the potential for an attachment to a specific point of view that could unduly affect an individual's judgment about a specific recommendation." 89

Are All Intellectual Interests and Biases Conflicts of Interest?

Richard Saver argues that we should regulate "any non-financial source of bias that can unduly influence primary research goals" because they can compromise research in the same way that financial conflicts of interest can. 90 He lists multiple nonfinancial interests that create bias. 91 Similarly, in discussing conflicts of interest, the IOM report, *Clinical Practice Guidelines We Can Trust*, warns of bias from "an attachment to a specific point of view that could unduly affect an individual's judgment about a specific recommendation."92

Professor Maj writes that physicians sometimes have "a strong prejudicial attitude against the use of medications in psychiatry" and that their deep-seated views or allegiance to a school of thought constitute secondary interests that unduly influence their primary interests regarding the welfare of their patients. Senneth Rothman also argues that financial interests are just one factor that can bias results and that we should not treat them differently than we treat other interests. Thomas Stossel argues that there are many biases in medicine, including the intellectual commitment of researchers and that individuals can never be

^{88.} Richard Horton, Commentary, Conflicts of Interest in Clinical Research: Opprobrium or Obsession?, 349 LANCET 1112, 1112 (1997).

^{89.} INST. OF MED., supra note 69, at 78 (quoting Guyatt, supra note 85, at 739).

^{90.} See Saver, supra note 4, at 467–68. Saver notes that non-financial interests are sometimes referred to as intellectual conflicts of interest or intrinsic conflicts of interest. He finds unpersuasive the reasons traditionally offered to regulate financial interests, though not for non-financial interests.

^{91.} *Id.* at 468. These nonfinancial interests include an individual's interest in career advancement; tenure and promotion; enhanced reputation; professional honors and prestige; access to power; "intellectual or political predispositions," "investigative zeal . . . and intellectual passion"; and reluctance to antagonize powerful faculty and certain social relationships including collegial, competitive, and hierarchical.

^{92.} INST. OF MED., supra note 69, at 78 (quoting Guyatt, supra note 69, at 739).

^{93.} Maj, *supra* note 79 65, at 91–92.

^{94.} See Rothman, supra note 5, at 2782, 2784 (explaining that while concerns about conflicts of interests focus primarily on money, the discussion should not be limited solely to financial influences). Further, while Rothman does not argue "in favor of suppressing" disclosures of any type, he believes the

totally disinterested in their research.⁹⁵ He says that total objectivity is an unattainable goal and that it is a mistake to be more concerned with financial conflicts of interest than with any other source of bias.⁹⁶

These authors argue that intellectual interests are an important source of bias. However, we should question whether *all* the interests and activities referred to as intellectual conflicts constitute a significant source of bias. Why should we consider "intellectual passion" or interest in career promotion a source of bias? If these interests do sometimes create bias, it is likely that this will occur only in the presence of certain additional circumstances rather than as an inherent feature of having intellectual passion or an interest in career promotion.

More importantly, why would these intellectual interests create risks that characterize conflicts of interest, namely, the risk that a professional will breach his or her loyalty to the party they are supposed to serve or will not exercise independent judgment? For example, consider an individual's interest in career promotion. Typically, professionals advance their careers by performing their work as they are supposed to or by meeting higher standards than required. Without specifying something more, we should not assume that having an interest in career enhancement compromises one's loyalty or judgment.

Consider a researcher's interest in publishing and receiving recognition. Does that interest compromise independent judgment or loyalty? Is the interest in publishing articles (which can be fulfilled whatever the study concludes), equivalent to having a financial interest in having a study finding that a drug is safe and effective? Unlike financial interests in having the study draw a certain conclusion, an individual's interests in recognition for publishing will not affect the researcher's conclusion. Researchers can advance their career by publishing, whatever their conclusion.

Even if certain intellectual interests are a source of bias, this does not necessarily mean that they constitute a conflict of interest.⁹⁷ The law does not regulate most biases as conflicts of interest or define conflicts of interest as anything that creates a bias. Including intellectual conflicts as a conflict of interest would

decision should be up to a larger community, after peer review, to question biases based on the substance of the work, not the individuals submitting it.

^{95.} See Thomas P. Stossel, Response to AMA's Council on Ethical and Judicial Affairs Draft Report on "Ethical Guidance for Physicians and the Profession With Respect to Industry Support for Professional Education in Medicine", 10 MEDSCAPE J. MED. 137 (2008), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2491684/ (describing that it is impossible to find a completely disinterested researcher, as some set of biases are inherent in any researcher).

^{96.} See id. (assuming that because it is impossible to eliminate all bias or to be totally objective, it therefore does not make sense to restrict or regulate conflicts of interest); but see Brody, supra note 70, at 154 (critiquing Stossel's assumptions regarding total objectivity). Brody argues that Stossel "confuses an achievable goal," severely limiting financial conflicts of interest, with the unachievable goal of eliminating all bias and "making medicine and science completely objective enterprises."

^{97.} See Brody, supra note 70 (arguing that critics wrongfully classify all possible sources of bias and subjectivity within science and medicine as "conflicts of interest").

unhinge the concept from its original meaning and make it merely another phrase for bias. Holding that nonfinancial conflicts constitute a conflict of interest conflates what the law defines as a conflict of interest with other risks of good medical practice and research.

These writers argue that researchers cannot be totally objective and that there is no reason to distinguish between various sources of bias and an individual's various personal interests. 98 In order to analyze this proposition, consider this typology of interests that can affect a physician's work:

- 1) Intellectual commitments (e.g., working within a theoretical framework or school of thought, being a proponent of a hypothesis, and holding philosophical or ideological views).
- 2) Interest in a positive outcome to a study because that will support the researcher's previous findings.
 - 3) Interest in maintaining a good professional reputation.
 - 4) Interest in career advancement and promotion.
 - 5) Interest in finding potential practical applications of applied research.
 - 6) Interest in obtaining research funding.
- 7) Income or gifts from a commercial interest that will produce income if one makes professional decisions in ways that favor commercial interests.
 - 8) Income from being a consultant related to one's research expertise.
 - 9) Intellectual property in fruits of research.
 - 10) Financial interest in a firm sponsoring one's research.
 - 11) Equity interest in a firm that commercializes one's research.

These eleven types of interests are not equivalent or fungible and they each pose different kinds of risks.⁹⁹ Under certain circumstances, the law considers interests 6 through 10 (but not the others) as creating a conflict of interest. There are several differences among these ten types of interests.

First, while an individual's predilection for a particular hypothesis or commitment to a school of thought can affect his or her interpretation of data and

^{98.} See Rothman, supra note 5, at 2782–84 (discussing how both financial and personal factors may influence conflicts of interest, including a researcher's sexual orientation, religious affiliation, or "tenaciously held belief" in a certain scientific theory); see also Stossel, supra note 95 (explaining that "scientific objectivity" is an oxymoron, since subjective interpretations inevitably come into play).

^{99.} See Krimsky, supra note 70, at 25 (discussing a list of interests held by researchers, including receiving an academic promotion, securing a grant, ethical motives, and equity interests in a company); see also Brody, supra note 70 (discussing how the presence of a particular bias by itself does not indicate a conflict of interest); Howard Brody, Clarifying Conflict of Interest, 11 Am. J. BIOETHICS 23, 24 (2011) (discussing how the concept of conflict of interest is wide and varied); Howard Brody, "Intellectual Conflict of Interest" Rides Again, HOOKED: ETHICS, MED., PHARMA (Dec. 9, 2011, 8:22 AM), http://brody-hooked.blogspot.com/2011/12/intellectual-conflict-of-interest-rides.html (distinguishing between three concepts related to researchers, including disinterest, conflicts of interest, and the disclosure of conflicts of interest).

research, these tendencies are generally made known by the individual's publications and work. Other researchers either know or can easily learn that a researcher has these interests and understand how they can affect a researcher's work. Until recently, it was usually not possible to learn that a researcher has financial interests that could affect their work. Moreover, the community of scholars are in the best position to draw attention to the assumptions and limitations of an intellectual framework. The scientific community typically debates, criticizes, and tests competing theories and interpretations. The usual process of scientific inquiry is an effective way to address bias and other problems arising from assumptions, ideas, points of view, and intellectual orientations. However, scientific debate about assumptions, theory, or the limitations of a framework are not sufficient to address the problems arising from financial conflicts of interest.

Second, scientific inquiry benefits from having researchers who represent diverse theoretical perspectives and who work within different schools of thought, so there is no reason to try to eliminate such intellectual interests. ¹⁰¹ In contrast, financial and dual loyalty conflicts of interest are an extraneous and unnecessary source of problems. Such biases can often be avoided or eliminated without interfering with what is essential to scientific inquiry.

Third, while a researcher's desire for recognition, advancement, and promotion can affect their conduct in both undesirable and desirable ways, these interests cannot be easily eliminated. In contrast, it is possible to conduct research without researchers having a financial interest in reaching a particular conclusion. Furthermore, there is no loss to scientific enterprise by removing such financial conflicts of interest.

Fourth, our legal, political, and social institutions distinguish between financial and other individual interests. Experience shows that financial interests often compromise judgment or loyalty, thus affecting conduct. Society has long regulated the financial conflicts of interest for public servants, judges, lawyers, and financial professionals, in order to reduce the risk that these professionals will act inappropriately. However, it has not regulated intellectual conflicts. Just because other unregulated activities can compromise medical practice and research does not mean that we should cease to regulate financial and dual loyalty conflicts of interest.

^{100.} See Jerome P. Kassirer & Marcia Angell, Financial Conflicts of Interest in Biomedical Research, 329 New Eng. J. Med. 570, 570 (1993) (explaining that while many intellectual conflicts are "inherent to the endeavor", they are usually apparent, well appreciated and therefore do not need to be disclosed); Krimsky, supra note 70, at 26 (discussing a number of interests held by contemporary researchers, including prediction to a hypothesis or theory, that can affect a scientist's judgement).

^{101.} See Douglas L. Medin & Carol D. Lee, *Diversity Makes Better Science*, OBSERVER (Apr. 27, 2012), https://www.psychologicalscience.org/observer/diversity-makes-better-science#.WPakvlMrIdW (discussing how scientific inquiry benefits from diverse perspectives).

Is There a Practical Way to Regulate Nonfinancial Conflicts?

The concept of conflict of interest helps address certain kinds of problems. It is useful because it has a clear focus and constitutes a practical tool. The focus and practical application would be greatly diminished if the concept included intellectual conflicts or other sources of bias because there is no effective way to limit the scope of regulation, to eliminate most intellectual conflicts, or even to manage them.

Nonfinancial interests are widespread, perhaps even present everywhere; if we seek to regulate them, there would be an enormous scope of new rules and procedures. It is hard to conceive of any work situation in which professionals lack an interest in their good reputation, their career advancement, promotion, job security, or receiving honor. Furthermore, most scholars and researchers have points of view that can color their assessment of evidence, often working within a school of thought. If we consider professional achievement to be a conflict of interest, then most researchers are conflicted.¹⁰² If we try to regulate all these sources of bias, we will target an enormous range of activities and regulation will impose heavy burdens with little benefit.

There is no doubt that point of view affects an individual's analysis and decisions, and we should take those into account. When we choose who should peer review a manuscript or serve on a committee that awards grants or that evaluates a project, it makes sense to consider the candidate's intellectual qualities, character, temperament, and potential biases. Moreover, in selecting individuals to serve on committees, it often makes sense to include people with diverse points of view. It is better to use the term conflict of interest in ways that are relatively clear than to use it as an umbrella concept to evaluate all questions regarding an individual's suitability.

Are Some Activities Labeled as Intellectual Conflicts Better Described as Financial or Dual Loyalty Conflicts of Interest?

Writers sometimes use the terms intellectual and nonfinancial conflicts to refer to situations that have always been considered either financial or dual loyalty conflicts of interest. In so doing, they have created unneeded categories and made unhelpful distinctions.

Authors often use the term intellectual conflicts for what are better described as financial conflicts of interest, especially when financial interests overlap with practice specialty, points of view, and intellectual interests. For example, radiologists earn their income from mammography screening and conduct many of the studies that evaluate screening. Critics contend that these studies are

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^{102.} See Maj, supra note 65, at 91 (discussing how some professional career moves could result in an "allegiance effect" where similar "mechanisms" to those that induce financial bias unduly influence a researcher to generate research that serves the interest of a public agency or particular school of thought).

biased in favor of routine, non-symptomatic screening for breast cancer, thus reflecting the authors' intellectual interests. 103 It would be more helpful to describe the bias as arising from radiologists' financial interest in supporting their profession's traditional revenue source.

Some writers use the term intellectual conflicts to describe dual loyalty conflicts of interest. Eliot Marshall, for example, describes how researchers who serve on committees that evaluate grant applications submitted from their home institutions have an intellectual conflict. 104 No doubt, these reviewers are in a position to favor grants of their colleagues and friends or to disfavor grants submitted by their competitors, but this is aptly described as dual loyalty or financial conflict.

The IOM report on clinical practice guidelines maintains that attachment to a specific point of view, demonstrated by a publication "directly related to a recommendation under consideration" constitutes an intellectual conflict. 105 The IOM explains that these intellectual conflicts occur when "a person whose work or professional group fundamentally is jeopardized, or enhanced, by a guideline recommendation..." However, a recommendation that fundamentally jeopardizes the work of an individual or professional group affects its economic interests, thus creating a financial conflict. Moreover, when a researcher evaluates a framework conceptually close to her own work, then the researcher is effectively judging her own work, a situation that constitutes dual loyalty conflict.

Viswanathan et al. proposed a typology of four main sources of nonfinancial conflicts of interest, which arise from:

(1) the individual through personal beliefs, (2) others through personal relationships, and (3) the institution through institutional relationships. Interests related to career advancement, and (4) others with a personal relationship with the individual (such as mentors), and the institution.107

All but the first category includes dual loyalty or financial conflicts. Personal relationships can give rise to both financial and dual loyalty conflicts of interest. Under the legal definition, an individual can have a financial conflict of interest

^{103.} See Susan L. Norris et al., Author's Specialty and Conflicts of Interest Contribute to Conflicting Guidelines for Screening Mammography, 65 J. CLINICAL EPIDEMIOLOGY 725, 731 (2012); see also Eleanor D. Lederer, Development of Clinical Practice Guidelines: Are We Defining the Issues Too Narrowly?, 2 CLINICAL J. AM. SOC'Y NEPHROLOGY 207, 207 (2007) (noting possible bias towards personal intellectual predilections in the context of phosphate metabolism); Levinsky, supra note 65, at 759 (discussing how the pursuit of academic prestige and advancing one's career is often a secondary motive for researchers).

^{104.} See Eliot Marshall, NSF Deals With Conflicts of Interest Every Day, 257 SCI. 624, 624 (1992).

^{105.} See INST. OF MED., supra note 69, at 78-79.

^{107.} Meera Viswanathan et al., A Proposed Approach May Help Systemic Reviews Retain Needed Expertise While Minimizing Bias from Nonfinancial Nonflicts of Interest, 67 J. CLINICAL EPIDEMIOLOGY 1229, 1232 (2014).

arising from the economic interests of a family member, a close friend, affiliate, or another personal relationship. *Institutional relationships* can create institutional conflict of interest, which include financial and dual loyalty conflicts. Personal relations with individuals and institutions also include financial and dual loyalty conflicts.

CONCLUDING OBSERVATIONS

The concept of conflict of interest originated in fiduciary law and has an expanding sphere of influence. It has been used in philosophy and bioethics and has become part of the language used by laymen. The concept also has practical uses in regulating the conduct of public officials and private sector actors. Language and concepts change over time and so the term *conflict of interest* might change. However, not all new ways of using a term reflect consensus on the changed meaning, nor do they improve understanding or clarify thinking. Sometimes people use commonly understood terms in ways that are unhelpful or that produce confusion.

Recent efforts to redefine conflicts of interest in new ways would include so-called *intellectual* or *nonfinancial* conflicts. The term *intellectual conflict* generally refers to situations that are quite different from what have been considered conflicts of interest until now. If generally adopted in our public discourse, this attempt at redefinition would confuse our traditional understanding of conflicts of interest. This redefinition of would also introduce new categories to refer to activities that are adequately analyzed using the traditional concept of conflict of interest. In addition, some advocates of redefining conflicts of interest also seek to reduce legal oversight. They argue that we should not avoid or manage conflicts of interest because we lack similar oversight for intellectual conflicts. This article concludes that we should conserve the traditional legal definition and regulation of conflicts of interest. Public policy should reduce the incidence of conflicts of interest in medicine and when that is not feasible, it should at the least mitigate these conflicts.

TABLE1: CONFLICTS OF INTEREST DEFINITIONS: COMPARISON OF LEGAL DEFINITIONS TO NEW DEFINITIONS

Legal Definition

Situations where an individual has an obligation to serve a party or perform a role and the individual has either: 1) *incentives* or 2) *conflicting loyalties*, which encourage the individual to act in ways that breach his or her obligations.

Thompson-IOM Definition

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.

- Does not distinguish between a) financial conflicts and b) dual loyalty conflicts.
- Does not mention risks to loyalty and focuses on risks to professional judgment.
- Substitutes *primary interests* for conflicts with legal or official obligations.
- Includes conflicts with ethical norms, not just conflicts with legal duties.
- Secondary interests are a problem only when they *unduly influence* primary interests.

Intellectual/Non-Financial Conflicts Definitions

Includes as a secondary interest various, non-financial or intellectual sources of bias on professional judgment. Does not discuss risks to loyalty.

Includes:

- Intellectual or political predispositions or commitments and personal beliefs
- Allegiance to a school of thought or point of view, hypothesis, or theory.
- Activities that create the potential for an attachment to a specific point of view.
- Academic, personal, and political rivalry.
- Intellectual passion or investigative zeal.
- Reluctance to antagonize powerful faculty.
- Social relationships formed in the research process, ranging from collegial to competitive to hierarchical.
- Authorship of original studies that directly relate to a recommendation.
- Peer-reviewed grant funding by government or nonprofit organizations.
- Personal relationships.
- Institutional relationships.

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Includes interests in:

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- Career advancement.
- Tenure and promotion.
- Enhanced reputation.
- Professional honors and prestige.
- Access to power.

BOX 1 DEFINITIONS OF CONFLICTS OF INTEREST IN DICTIONARIES, TREATISES, AND ORGANIZATIONAL POLICIES

1) Dictionaries Distinguishing Between Financial and Dual Loyalty Conflicts.

Random House-Webster's Unabridged Dictionary 2001

Conflict of Interest:

- 1. The circumstance of a public office holder, business executive, or the like, whose personal interests might benefit from his or her official actions or influence. *The Senator placed his stocks in trust to avoid possible conflicts of interest.*
- 2. The circumstance of a person who finds that one of his or her activities, interests, etc. can be advanced only at the expense of another of them.

Merriam-Webster's Dictionary of Law 1996

Conflict of interest

- 1. A conflict between the private interests and the official or professional responsibilities of a person in a position of trust
- 2. A conflict between competing duties (as in an attorney's representation of clients with adverse interests)

Black's Law Dictionary, 8th ed., 1999

Conflict of Interest

- 1. A real or seeming incompatibility between one's private interests and one's public or fiduciary duties.
- 2. A real or seeming incompatibility between the interests of two of a lawyer's clients, such that the lawyer is disqualified from representing both clients if the dual representation aversively affects either client or if the clients do not consent.

The Oxford English Dictionary definition speaks of "two or more interests" being incompatible, tracking the idea of dual loyalties while also providing an example of a financial conflict of interest.

Oxford English Dictionary 2003

"(b) (chiefly in Business, Polit., and Law) a situation whereby two or more of the interests held by, or entrusted to, a single person or party are considered incompatible or breach prescribed practice; spec. a situation in which an individual may profit personally from decisions made in his or her official capacity."

2) Dictionaries that Do Not Distinguish Between Two Types of Conflicts of Interest

<u>The American Heritage Dictionary of the English Language 4th ed., 2004</u> Conflict of interest: A conflict between a person's private interests and public obligations.

Webster's Third International Dictionary, 2002

Conflict of interest: A conflict between the private interests and the official responsibilities of a person in a position of trust (as a government official)."

The New Dictionary of Cultural Literacy, 3rd ed., 2002

Conflict of interest: A situation in which someone who has to make a decision in an official capacity stands to profit personally from the decision. For example, a judge who rules on a case involving a corporation in which he or she owns stock has a conflict of interest.

Random House Webster College Dictionary, 2000

Conflict of Interest: The circumstance of a public officer holder, corporate officer, etc. whose personal interests might benefit from his or her official actions or influence. [1950-1955].

Black's Law Dictionary in 5th ed., 1979

Conflict of interest: Term used in connection with public official and fiduciaries and their relationship to matters of private interest or gain to them. Ethical problems connected here are covered by statutes in most jurisdictions and by federal statutes at the federal level. Generally, when used to suggest disqualifications of a public official from performing his sworn duty, term "conflict of interest" refers to a clash between public interest and the private pecuniary interest of the individual concerned.

The World Book Dictionary Millennium Edition, 2000

Conflict of Interest: The actual or potential conflict arising when a person holds an interest in a company doing business with his employer; The conflict of interest statutes bar government officials who are appointed to their jobs from receiving stock or other interests in a concern that does business with the federal agency the official works for.

<u>The Ethics & Compliance Initiative</u>, a non-profit organization that aims to serve as a resource for ethics compliance for industry, defines conflicts of interest this way:

Directors are considered to be in a "conflict of interest" whenever they themselves, or members of their family, business partners or close personal associates, may personally benefit either directly or indirectly, financially or otherwise, from their position on the Board. ¹⁰⁸

108. MEL D. GILL, GOVERNING FOR RESULTS: A DIRECTOR'S GUIDE TO GOOD GOVERNANCE (2005).

Large for-profit firms typically have policies to oversee the employee conflicts of interest. For example, the pharmaceutical firm, Novartis, states that: "Associates are expected to recognize when they have, potentially have, or could be perceived as having, a conflict of interest. Associates should consult their Manager if in doubt about what circumstances might create a conflict of interest." ¹⁰⁹

The World Bank consultant guidelines address financial and dual loyalty conflicts:

Conflict of Interest:

1.9 Bank policy requires that consultants provide professional, objective, and impartial advice and at all times hold the client's interests paramount, without any consideration for future work, and strictly avoid conflicts with other assignments or their own corporate interests. Consultants shall not be hired for any assignment that would be in conflict with their prior or current obligations to other clients, or that may place them in a position of not being able to carry out the assignment in the best interest of the Borrower.... [C]onsultants shall not be hired under the circumstances set forth below:

(a) A firm which has been engaged by the Borrower to provide goods or works for a project, and any of its affiliates, shall be disqualified from providing consulting services for the same project. Conversely, a firm hired to provide consulting services for the preparation or implementation of a project, and any of its affiliates, shall be disqualified from subsequently providing goods or works or services related to the initial assignment (other than a continuation of the firm's earlier consulting services....)

(b) Consultants or any of their affiliates shall not be hired for any assignment which, by its nature, may be in conflict with another assignment of the consultants. As an example, consultants hired to prepare engineering design for an infrastructure project shall not be engaged to prepare an independent environmental assessment for the same project, and consultants assisting a client in the privatization of public assets shall not purchase, nor advise purchasers of, such assets.¹¹⁰

109. Novartis, Conflicts of Interest Policy 1, 3–4 (2015), https://www.novartis.com/sites/www.novartis.com/files/Conflict_of_Interest_Policy_Final_en.pdf?utm_source=dru-pal%20&utm_medium=redirect&utm_campaign=drupalredirect&utm_content=www.novartis.com/downloads/corporateresponsibility/resources/conflictofinterestpolicyfinalen.pdf ("Associates should avoid conflicts of interest with Novartis. Some conflicts of interest, however, represent an especially high risk to the reputation or business interests of Novartis and Associates must avoid these." It adds "Avoiding' a conflict of interest means Associates take decisions or actions to ensure a conflict of interest does not occur, or does not have the potential to occur, in the first place.").

 $^{110.\ \ \}textit{See}\ GUIDELINES: SELECTION\ AND\ EMPLOYMENT\ OF\ CONSULTANTS,\ WORLD\ BANK\ BORROWERS,\ http://pubdocs.worldbank.org/en/894361459190142673/ProcurementConsultantHiringGuidelinesEngJuly2014.pdf.$