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### Attempts to Redefine Conflicts of Interest

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## **Attempts to Redefine Conflicts of Interest**

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## **Abstract**

The traditional legal concept of conflict of interest is a practical tool to regulate conduct. In recent years several medical authors have defined *conflicts of interest* in ways that stray from its original legal meaning. The new definitions cause conceptual confusion and will result in policies that cannot be implemented effectively. We should not follow recent attempts to redefine conflicts of interest because doing so deviates from the legal concept and will lead to deregulation of financial conflicts and overregulation of so-called intellectual conflicts.

*Conflict of interest* has a long agreed-upon meaning in law and public policy. Nevertheless, recently medical writers have developed alternative definitions that muddy the waters and impede focused, effective regulation of conduct. This article explains the traditional legal concept and why we should not use the revised definitions.

### **The Legal Concept**

The concept of conflict of interest has its origins in the law used to regulate fiduciaries—individuals entrusted to serve the interest of another party or to serve a designated mission—who are held to the highest legal standards of conduct. The law does not permit fiduciaries to promote their own interests, or the interests of third parties. It requires fiduciaries to be loyal to the party they serve, to act prudently and diligently, and to account for their conduct. To advance these goals the law regulates certain situations—designated as conflicts of interest—that increase the risk that fiduciaries will betray their trust. It often prohibits fiduciaries from entering into situations that create conflicts or require that they cease the activity that creates a conflict or that they disclose their financial interests so that third parties can identify and manage the conflict and thereby reduce the risk of misconduct. (Rodwin, 1993; Rodwin, 2011). Today, public policy also regulates the conflicts of interest of parties who are not fiduciaries.

According to standard legal usage, a conflict of interest arises whenever activities or relationships compromise the loyalty or independent judgment of an individual who is obligated to serve a party or perform certain roles. Multiple interests often pull people in different directions but only when they compromise fulfilling *obligations* is there a conflict of interest. Conflicts of interest can influence action, but they are not acts and do not constitute a breach of duty.

There are two broad types of conflicts of interest: 1) conflicts between an individual's obligations and their financial or other self-interest; 2) conflicts resulting from an individual's divided loyalties, dual roles or conflicting duties, sometimes referred to as conflicts of commitments (Peters, 2012). For example, a physician who dispenses medication has a financial conflict: the incentive to increase income through prescribing clashes with the obligation to prescribe for the patient's best interest. A physician who enrolls one of her patients in a clinical trial has a divided loyalty conflict: the duty to act in the patient's interest diverges from the goal of research, which is to advance scientific knowledge (Angell, 2015a,b). The two types of conflict arise from different sources and reflect different sorts of problems but are not mutually exclusive. The policies and interventions used to cope with conflicts of interest vary with the institutional context and the particular conflict of interest.

Most dictionaries distinguish between financial and dual loyalty conflicts (Random House Webster's Unabridged Dictionary, 2001), but some do not (American Heritage Dictionary, 2016). 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. See Table 1: Definitions of Conflicts of Interest in dictionaries and organization policies.

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

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....<sup>1</sup> OGE (1993 &2017)

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.” (Internal Revenue Service, 2006).

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. (Thomson Reuters, 2015, § 1:3)

Another treatise on finance defines conflicts of interests as:

A situation in which a person or institution is caught between opposing concerns, loyalties, or objectives that prejudice impartiality. A conflict of interest may be between self-advantage and the benefit of an organization for which somebody works, or it could arise when somebody is connected with two or more companies that are competing... A conflict of interest may also arise when an institution acts for parties on both sides of a transaction and could derive an advantage from a specific outcome. (QFinance, 2010).

## **New Definitions**

### *The Thompson-IOM Definition*

In 1993, Professor Dennis Thompson analyzed conflict-of-interest policies and proposed an alternative definition, now widely used (Thompson, 1993, 573). He wrote: “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 secondary interest (such as financial gain).” He explained:

The primary interest is determined by the professional duties of a physician, scholar, or teacher. [T]here is normally agreement that ... they should be the primary consideration in any professional decision.... The secondary interest is usually not illegitimate... Only its relative weight... is problematic. The aim is ... to prevent these secondary factors from dominating ... the relevant primary interest. (Thompson, 1993, 573).

Thompson's formulation differs from legal definitions. It focuses on bias to *professional judgment* and neglects the actor's compromised *loyalty* to the party or mission she is supposed to serve. It refers to conflicts between primary and secondary *interests* rather than conflicts between *obligations* and interests, which diminishes the conflict's significance. Secondary interests are deemed a problem only when they *dominate* or *unduly influence* "primary interests," yet it is difficult to know when there is *undue* influence. Thompson does not distinguish between financial conflicts and dual loyalty conflicts.

Thompson served on the Institute of Medicine (IOM) committee that wrote a 2009 report, *Conflicts of Interest In Medical Research, Education, and Practice*, (Field and Lo, 2009) which adopted Thompson's definition with minor revisions. It wrote, "a conflict of interest is 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." (Field and Lo, 2009, 46) Many subsequent authors used the Thompson-IOM formulation and some expanded the concept.

### *Intellectual and Non-Financial Conflicts*

Several authors drew attention to *intellectual* or *non-financial* conflicts, which include situations that the law does not regulate as a conflict of interest (Rothman, 1993a; Rothman, 1993b; Maj, 2008; Marshall, 1992; Levinsky 2002; Rothman and Cann, 1997; Rothman, 1991; Rosenbaum, 2015a; Rosenbaum, 2015b). Some writers use the first term; others employ the second. I use these interchangeably or the term used by the author I discuss. Writers employing the new definitions argue that intellectual conflicts can bias judgment so that we should treat them the same as we treat financial conflicts. Most such writers say that because we do not regulate intellectual conflicts, we should not restrict activities that create financial conflicts (Rothman, 1991a, Rothman, 1991b; Rosenbaum, 2015a, Rosenbaum, 2015b). In contrast, some writers conclude that because we already regulate financial conflicts we should regulate intellectual conflicts (Saver, 2014; Sollitto et al., 2003). Some organizations have adopted policies for intellectual conflicts, most notable for clinical practice guidelines (Steinberg et al., 2011).

These new definitions, which are not compatible with the traditional legal definition but fit with the Thompson-IOM definition, lack conceptual clarity or limiting principles. They are therefore less precise or useful as a policy instrument so it is preferable to use the traditional legal definition.

### **Should we Include Intellectual Conflicts as a Conflict of Interest**

#### *Can everything be a Conflict of Interest?*

Typical definitions and examples of intellectual / nonfinancial conflicts reveal that the concepts are amorphous, which reduces their usefulness (Bero, 2014); Krimsky, 2006; Steinbrook et al., 2015; Loder et al., 2015; Brody, 2008). See, Table 2: Comparison of Legal and New Definitions.

Richard Saver penned one of the most articulate discussions of nonfinancial conflicts (Saver, 2014). Following the IOM, he defines *non-financial interests* as "any non-financial source of bias that can unduly influence primary research goals." (Saver,

2014, 468) Just as we regulate financial conflicts of interest, he says, we should regulate “any non-financial source of bias that can unduly influence primary research goals.” (Saver, 2014, 468).

His list of conflicting nonfinancial interests includes: 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, investigative zeal...,” a reluctance to antagonize powerful faculty and “social relationships formed in...research..., ranging from collegial to competitive to hierarchical...” (Saver, 2014, 468). This list is breathtakingly large.

The 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” (Steinberg et al., 2011,78). It suggests that we should regulate such conflicts.

Eliot Marshall writes that many scientists can’t be objective due to their intellectual commitments. They become advocates for a preferred hypothesis, which compromises their assessment of evidence (Marshall,1992). Gordon Guyatt writes that scientists who have published a study have an intellectual investment in the conclusion of certain scientific questions, and this conflicts with their impartial evaluation on the same or related issues (Guyatt et al., 2010).

Professor Maj argues that allegiance to a school of thought 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” (Maj, 2008, 92). He adds that certain political commitments create a conflict of interest. Richard Horton describes academic *rivalry* as another conflict of interest (Horton, 1997).

In contrast, some writers invoke the absence of regulation of intellectual conflicts as grounds to end regulation of financial conflicts. Lisa Rosenbaum asks whether “by focusing on these pecuniary biases, are we overlooking others that are equally powerful?” (Rosenbaum, 2015a 1961). Kenneth Rothman argues that we should not regulate financial conflicts more strictly than intellectual conflicts because both are sources (Rothman, 1991; Rothman 1993a; Rothman 1993b). Thomas Stossel argues that individuals can never be totally disinterested and that we should not regulate financial conflicts more than intellectual commitments (Stossel, 2008).

Some authors use the term intellectual conflicts for what are better described as financial conflicts of interest. For example, radiologists earn income from mammography screening and conduct many of the studies that evaluate screening. Critics contend that these studies reflect the authors’ intellectual interests and so are biased in favor of non-symptomatic breast cancer screening (Lederer, 2007). It would be more apt to describe the bias as arising from radiologists’ financial interest in supporting sources of revenue. Similarly, when a professional group opposes recommendations for a clinical practice guideline that *fundamentally jeopardizes* its work (Steinberg et al. 2011, 79) that affects its economic interests, not merely its intellectual interests.

### *Are All Intellectual Interests and Biases Conflicts of Interest?*

Even if certain intellectual interests can cause bias, as in the preference for certain theories or etiologies of disease, this does not mean that they constitute a conflict of interest. The law does not define conflicts of interest as anything that creates bias nor does it regulate most biases. Including intellectual conflicts within the definition of conflict of interest would unmoor the concept from its original meaning and make it merely another phrase for bias.

Writers that draw attention to intellectual conflicts argue that physicians cannot be totally objective and that we should not distinguish among various sources of bias or personal interests. In order to evaluate these propositions, consider this typology of interests, only 7 through 11 of which the law defines as potential sources of conflicts of interest:

- 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 maintaining good relations with firms and organizations that can provide future research funding.
- 7) Income or gifts from a commercial interest that will gain income if one makes professional decisions in ways that favor their 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 interests are not equivalent (Krimsky 2006); Bero, 2014; Brody, 2011a; Brody, 2011b). While a predilection for a particular hypothesis or commitment to a school of thought and a point of view can affect research design and data interpretation, these tendencies are disclosed through publications. Scholars can easily learn that a researcher has these interests and understand how they can affect their work (Lenzer, 2016; Krimsky, 2006). Scientists typically debate and criticize competing theories and interpretations, which is an effective way to address bias arising from points of view. In contrast, it is often not possible to learn that a researcher has financial interests, and scientific debate is insufficient to address problems arising from financial conflicts. And studies provide evidence that some financial conflicts of interest, such as industry supported research that evaluates industry products, influence research outcomes (Lundh et al., 2017).

Furthermore, scientific inquiry benefits from having researchers with diverse theoretical perspectives; there is no reason to eliminate intellectual interests. In contrast, financial and dual loyalty conflicts are an extraneous and unnecessary source of bias.

Moreover, while desire for recognition can affect a researcher's conduct in undesirable ways, these interests cannot be eliminated. In contrast, it is possible to conduct research without having a financial interest in reaching a particular conclusion.

Furthermore, our legal and social institutions distinguish between financial and intellectual interests. Society has long regulated the financial conflicts of interest for public servants, judges, lawyers, and financial professionals, but it has not regulated intellectual conflicts. Just because other activities can compromise medical practice and research does not mean that we should cease to regulate conflicts of interest. For these reasons several scholars follow the traditional legal approach and distinguish financial conflicts of interest from other sources of bias (Bero and Grundy, 2016).

### *Is There a Practical Way to Regulate Nonfinancial Conflicts?*

Expanding the conflict-of-interest definition to include all potential sources of bias would make the concept a less practical tool. There is no effective way to eliminate most intellectual conflicts. Furthermore, nonfinancial interests are widespread, so the scope of regulation would greatly increase. It is hard to conceive of professionals ever lacking an interest in their reputation, career advancement, promotion, job security, or receiving honor. Regulating these potential sources of bias using a conflict of interest framework will impose heavy burdens on professionals and institutions.

It makes sense to consider a person's intellectual qualities, temperament, and potential biases when we choose who should be selected as peer reviewers, committee members and researchers but the conflict of interest concept is not a tool to evaluate all questions regarding selecting personnel.

### **Conclusion**

Efforts to include so-called intellectual or nonfinancial conflicts as conflicts of interest blur the concept. Moreover, the new definitions can be used to reduce legal oversight of financial conflicts or expand regulation of other activities. We should conserve the traditional legal definition. Public policy should seek to preclude or mitigate and manage conflicts of interest in medicine.

## **Table 1: Conflicts of Interest: Legal Definition**

*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 in 5<sup>th</sup> 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.

The Ethics & Compliance Initiative, 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. (Ethics & Compliance Initiative, 2016)

Large for-profit firms typically have policies to oversee the employee conflicts of interest. For example, the pharmaceutical firm, Novartis, states that there are conflicts of interest "when Associate s' personal interests either influence, have the potential to influence, or are perceived to influence their decision making at Novartis..." (Novartis, 2015, 1). Common examples of conflicts of interest include "personal workplace relationships (e.g., hiring or supervising a closely related person), external mandates

(e.g., serving on the board of directors or scientific advisory board of a Novartis competitor), outside employment (e.g., having a second job with a Novartis customer, supplier, or competitor), promoting personal financial interests (e.g., owning a substantial share of a Novartis supplier while in a position to steer Novartis business towards it), and receiving fees, commissions, discounts, gifts, entertainment, or services (e.g., receiving cash from a Novartis business partner)” (Novartis, 2015, 1-2)

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’ involves 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. (OECD, 2003, 24).

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. (World Bank, 2004, 3-4).

## Table 2: Comparison of Legal and 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.

Includes interests in:

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

## Notes

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<sup>1</sup> The regulations promulgated under the statute specify various financial interests that disqualify federal employees from participating in a matter. The OGE also imputes to the individual the financial interests of family members and affiliates. It therefore includes as prohibited financial interests “the financial interests of: the employee’s spouse or minor child; a general partner of a partnership in which the employee is a limited or general partner; an organization in which the employee serves as an officer, director, trustee, general partner, or employee; or a person with whom the employee is negotiating for or has an arrangement concerning prospective employment.” See, Office of Government Ethics, *Employees Entering Government*. OGE (1993 & 2017)

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