# **Conflict: A Catalyst for Institutional Change**

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#### **Author's Note**

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#### **Abstract**

This article focuses on perceptions and behaviors surrounding potential conflicts of interest and/ or commitment on both personal and institutional levels. It references past cases, public reaction and subsequent policy decisions. Most people believe conflict to be negative, something to be avoided. While conflict might make one feel stressed, angry, scared, or confused, it can offer new and positive opportunities for change, learning, and growth. In that same vein, a potential conflict of interest or commitment is not inherently a bad thing. Conflicts within science are almost to be expected. In fact, often it means there is good work happening that will contribute to generalizable knowledge and benefit society. Therefore, there is no shame or crime in having external financial relationships. The shame is in allowing those relationships to potentially bias the work, create false presumptions and distort decision-making, or in hiding the fact that they exist in the first place. This paper endorses a proactive approach for dialoguing and developing effective conflict of interest policies that will ultimately lead to changes in people's perceptions as well as their behavior in conflict of interest situations.

Keywords: Conflict of interest, conflict of commitment, significant financial interest, equity holdings, conflict management, rebuttable presumption, commercialization of intellectual property, peer review

#### Introduction

Conflict, simply defined, is a state of disharmony between incompatible or opposing persons, ideas, or interests. When asked to close their eyes and envision a recent conflict, most people will experience a disheartening feeling. They may notice physical or emotional signs of distress (e.g., palpitations, rapid breathing, sweaty palms, shaking, tearing, etc.). Therefore they tend to assign

a negative connotation to conflict as a general concept. They view conflict as something to be avoided at all costs. But conflict is natural, and even when one acquires the skills to deal with it more effectively it continues to exist (ESR, 1998). It surrounds us on a daily basis, and while it might make us feel stressed, frustrated, angry, scared, or confused, it can offer new and positive opportunities for change, learning, and growth.

The same holds true for conflicts of interest and/or commitment within an organization. Again, by simple definition, a conflict of interest and/or commitment exists when there is a state of disharmony between one's responsibilities as an employee/member of a specific institution/organization and an outside entity. Both the American Association of Medical Colleges (AAMC) and the American Association of Universities (AAU) have adopted this definition: "The term individual conflict of interest in science refers to situations in which financial considerations may compromise, or have the appearance of compromising, an investigator's professional judgment in conducting or reporting research" (Broccolo & Klanica, 2006). Yet, dealing effectively with the conflict of interest situation can also lead to positive opportunities for change, learning, and growth.

In essence, a potential conflict of interest or commitment is not inherently a bad thing. Often it means there is good work happening that will contribute to generalizable knowledge and benefit society. External or extramural financial interests often drive the research in ways that internal funding alone cannot by providing a direction to research that will result in the largest possible positive impact on society. Kalichman and Macrina (2001) state that conflicts encountered through the scientific profession are to be expected, it is how they are handled that can lead to untoward, inappropriate, or bad outcomes. Therefore, there is no shame in having external financial relationships, whether as an individual or an institution as a whole. The shame is in allowing those relationships to potentially bias the work, create false presumptions and distort decision-making, or in hiding the fact that they exist in the first place.

Maintaining even minimal standards of research integrity is dependent upon protecting and preserving not only the integrity of the science, but that of the researcher and the institution. There is also a fundamental obligation to preserve and sustain the public trust. The public trust is a fragile thing and once shattered it is almost impossible to repair (Schaller-Demers, 2006). Bradley (2005) says there is a concern that an escalating climate of secrecy and economic competition is contributing to the public's loss of confidence in the integrity of science and scientists, if not an actual deterioration in the quality of the science. If one accepts that public trust is what drives public funding, it may be logical to assume that once public trust is eroded, public funding will erode as well (Cohen, 2002).

Broccolo and Klanica (2006) state that instances of research misconduct can be motivated by the types of financial and associational (non-financial) interests that give rise to potential conflicts of interest and that the media and the public cannot distinguish the difference between actual conflict and perceptions of conflict. That is why perception and appearances are so important. Hiding is never the answer, because upon close examination, it may be determined that an actual conflict of interest doesn't even exist. When conflicts are revealed after-the-fact, especially in cases where misconduct is alleged or unanticipated adverse events occur, the perceptions can be more damaging than the reality.

An elemental question is to what extent financial incentives affect professional judgment. Barnes and Florencio (2002) state that financial incentives can and do exert significant influence over human behavior. Sadly, when individuals' reputations and/or livelihoods are at stake, good judgment can succumb to avarice. Institutional judgment can become clouded when reputations and/or finances hang in the balance. Bradley (2005) says that universities have a strong sense of self-preservation when confronted with these types of situations. Therefore, they may be reluctant to cancel lucrative contracts or prohibit or restrict certain studies even though a faculty member may have a potentially serious conflict of interest. The University of Oklahoma and the University of Toronto are two examples of institutions where professional judgment was overpowered by financial considerations to the detriment of reputation and research (Barnes & Florencio, 2002). At St. John Medical Center in Tulsa, Oklahoma, there was a study that investigated an experimental vaccine for malignant melanoma. Both the Institutional Review Board (IRB) chair and the dean allegedly concealed from both the IRB and the Food and Drug Administration (FDA) a report from an outside consulting firm that found severe deficiencies with the melanoma vaccine study. They eventually halted the study, but not because of these negative findings, and stated in an annual report that there were no significant safety issues related to the melanoma vaccine.

At the University of Toronto, the former university president urged the Canadian Prime Minister and four other cabinet ministers to withdraw proposed drug patent regulations or Apotex, a pharmaceutical giant, would rescind its multi-million dollar donation earmarked for the University and its affiliated teaching hospitals.

Barnes and Florencio (2002) point out that even high-level officials like an IRB chair, a dean of medicine, or a university president can be distracted from their primary responsibilities due to the influence of financial interests. One would automatically assume that safeguarding human research subjects and preserving the integrity of research, researchers, and the institution would be paramount. Yet even those held in the highest esteem may misstep while chasing evershrinking research dollars.

Objectivity through self-reflection can be difficult to achieve and/or maintain. Doctors, researchers, and other academic professionals might question whether "gifts" from a pharmaceutical company or consulting agreements could influence them to prescribe that company's drugs, use a particular device, or contract for a certain service (Gilbert, 2006). As professionals, people do not want to believe that they can be subconsciously bribed. It is almost impossible to judge one's own behaviors or motivations accurately and without bias. Gilbert (2006) says that the brain cannot see itself fooling itself. Therefore, he thinks that the only reliable method for avoiding bias is to avoid the situations that produce it in the first place.

Avoidance and elimination are ways to handle conflict of interest situations. However, in the scope of scientific research that is not always what is in the best interest of the science (see rebuttable presumption). As is the case with most learned professionals, scientists are generally strong in their beliefs and will stand long by a hypothesis. Understandably this mindset might tempt them to hold tight to a particular research plan, especially when it has become their life's work. However, as we have now seen by the misjudgments of others, strong beliefs can sometimes lead to disaster – as proven by more than one now-infamous example.

In 2005, researcher James Wilson and the University of Pennsylvania (UPENN) were found complicit in the case of Jesse Gelsinger, a teenage volunteer who died in a gene therapy trial. In addition to numerous research misconduct violations, it was discovered after-the-fact that Wilson, the principal investigator (PI), held a 30% equity interest and UPENN a 3.2% equity interest in the sponsor of the trial. When another corporation acquired the sponsor, the PI reportedly made a return of \$13.5 million and the university reportedly earned \$1.4 million (Lemonick & Goldstein, 2002).

Paul Gelsinger (2001), Jesse's father, says that when he met with the head researcher for the first time after his son's death he asked him about his financial position in the trial. The researcher's response was that he was an unpaid consultant to the biotech company behind the research effort. Gelsinger accepted his word and continued to support him and his work. He now contends that the over-enthusiasm of the clinical investigators painted an unrealistic picture of the study's safety and efficacy. That enthusiasm blinded them to the ill effects that they were witnessing. Therefore, Gelsinger says "... I still support our need for clinical trials, but with this caution: Informed consent is only possible if all facets of the research endeavor are ethical and in the open." The death of Jesse Gelsinger stands as a tragic reminder that transparency and full disclosure serve to protect us all – the public-at-large (all potential subjects), the researchers, the sponsors, and the institutions.

Today's media, fortified by intensified government review, focus an easily influenced public's attention on misconduct. In this atmosphere, potential biomedical research conflicts receive heightened scrutiny – especially when human subjects are involved. Broccolo and Klanica (2006) say that the current challenge to institutions is to establish and maintain a conflicts of interest infrastructure that achieves the right balance between promoting and supporting a spirit of innovation (as supported by Bayh-Dole) on the one hand and adapting to the best practice standards that are emerging through society's call for reform on the other. Cohen (2002) reminds us that it is critical for relationships between academic medicine and industry to remain principled, protective of subjects, respectful of scientific integrity, and capable of withstanding public scrutiny. In other words, it is not sufficient to know your heart is pure, your science is impeccable, and your motives are completely altruistic — you must be able to prove it on the front page of The New York Times.

Although federal (i.e., PHS, FDA, DHHS) conflict of interest laws and regulations may fall short of emerging best practices, it is still important to be cognizant of them as a basic foundation for developing institution-specific policies and procedures (Broccolo & Klanica, 2006). Understandably, institutions are concerned about the increasing administrative burdens placed on them by legislators and regulators who expect them to implement unfunded mandates, especially when these mandates may put the institutions at odds with their own faculty or scientists (Bradley, 2005). Yet, the bigger picture is obvious – without clear policies and procedures, the price to pay would be even higher.

Most institutions and organizations have some requisite set of procedures, guidelines, or policies that dictate how potential conflicts of interest and/or commitment should be handled. The problem is not that policies do not exist, but that communicating their expectations or improving the implementation of those policies might be improved. Commonly accepted methods for

handling a potential financial conflict of interest involve managing (disclosure), reducing, or eliminating.

Managing financial conflicts of interest has become more important in recent years as the emphasis on commercialization of intellectual property has increased. Researchers are now encouraged to commercialize and thereby increase their opportunity to benefit personally (Cohen, 2002). As researchers benefit, so do their institutions. Universities now regard technology transfer as an important revenue stream needed to bolster or replace decreasing support from state and/or federal agencies (Bradley, 2005). Developing an organizational culture that appreciates the urgency of compliance, while balancing its enthusiasm for innovation and discovery is the key to financial longevity, brand-name recognition, and public trust.

The AAMC's guidelines for managing individual and institutional financial conflicts of interest were developed in recognition of the unique challenges faced by medical schools and teaching hospitals. The central focal point of the guidance is the rebuttable presumption that no one with a significant financial interest in the outcome of a study can be allowed to conduct that research, unless there are compelling circumstances why the research cannot be otherwise conducted as safely or effectively (Cohen, 2002). Typically, these financial interests exceed a certain dollar amount or value threshold and/or involve a competing fiduciary obligation (Broccolo & Klanica, 2006). Since it is rare that the rebuttable presumption can be argued successfully, there are several other alternatives that can be used to reduce or eliminate the conflict.

To further confuse the issue, there are varying definitions of the word "significant" in terms of reporting external or extramural financial interests (consulting fees, honoraria, gifts, in-kind compensation, equity interests, royalties, etc.). The National Institutes of Health (NIH - PHS) defines significant as having aggregate value greater than \$10,000 or a 5% equity ownership in a single entity, while the FDA has set the significance threshold at \$25,000. This leads to confusion on the part of many researchers. Most investigators report what is required and necessary, but others may feel that they are suspect because they are being asked to disclose.

The Office of the Inspector General's (OIG) report (January 2008) on the NIH and Conflicts of Interest in Extramural Research has focused new attention on this growing concern. Its findings clearly illustrate a disconnect between what is reported to the institution in the first instance and to the federal government and the public in the second. NIH policy simply requires that an institution report that a significant (meaning of high value) conflict exists and that it is being dealt with when NIH funding is involved. The OIG found that the information being reported to NIH is incomplete, as it lacks sufficient details regarding the conflict and how it is being managed. NIH counter-argues that it is incumbent on the institution - not NIH -- to "police" and guarantee this process. Note: NIH has stated that institutions must disclose to them significant conflicts as defined by the institution's policy if the institution has a lower dollar value definition than NIH does.

It is this lack of specificity or unwillingness to take an authoritative stand that leads to confusion on the part of investigators and their institutions. The days of "don't ask, don't tell" are over. There is too much at stake. Years of ground-breaking research are now suspect because funding sources and equity or intellectual property rights were not reported with enough transparency.

The debate about whether or not to accept funding from certain industries and how much it might influence the outcome of the research is not new... If tobacco companies or "Big Pharma" sponsor research, will the results be automatically suspect? Many institutions take a hard stance against acceptance of funding from the tobacco industry. As reported in 2006, the University of California had received close to \$2 million in grants and contracts from tobacco companies. As a result, a movement began to ban the university system from accepting such funding. Jaschik (2006) reports that the argument is not that the smoking industry promotes harmful products, although most would concur that it does, but that it uses university research to "deceive the public to such an extent that the research harms the university system." The opposing viewpoint says that any absolute ban on support from tobacco, or for that matter, any other specific source, would violate the tenets of academic freedom. This would create an untenable situation where university officials would be constantly put in the position of having to decide which sources were acceptable and which were not (Jaschik, 2006).

The American Cancer Society (ACS, 2008) maintains a policy in regard to the acceptance of funding from tobacco companies. It states that those who are funded by the tobacco industry for any project, or whose named mentors in the case of mentored grants are funded in the same vein, may not apply and will not be eligible for ACS research and training grants activated on or after July 1, 2005. It states further that those who accept tobacco funding during the tenure of an ACS grant must inform ACS of such funding and subsequently the ACS grant will be immediately terminated.

Might drug company dollars be perceived as influencing research results in much the same way as those of tobacco? Abramson and Starfield (2005) suggest that universities have little choice but to turn to commercial sources of funding, a notion supported by the numbers, which show that between 1977 and 1990, drug expenditures on research and development (R & D) increased sixfold. A large portion of these expenditures went to support university-based research.

Certainly there are strict regulatory controls overseeing pharmaceutical development as compared to the oversight mechanisms that exist within the tobacco industry. Therefore society's trust level is supported when it comes to drug R & D. Yet this dramatic increase in funding over the years certainly speaks to the possibility of biased or skewed results. The increase in spending alone is not an indicator of how the funding was used or if any of the researchers or institutions involved may have had a potential conflict of interest with the sponsoring company or agency. Additionally, if financial relationships did exist, there is no way to know from just the numbers if there were any contractual restrictions on publishing negative results. Yet, it is this very lack of explicit reporting and monitoring that helps foster negative perceptions. In the end, without much needed transparency, the process can become tainted and a lifetime of valuable research can become unnecessarily suspect.

The controversy becomes more intense as the loudest voices position themselves to be heard. Who should be the final arbiter of what is right when it comes to funding the scientific enterprise? How does policy, such as the one established by the ACS, reflect on the worthiness and validity of the scientific peer review process? As stated by Dovey (2004), the rigors of the peer review process, even in the most renowned science and medical journals, in addition to full disclosure requirements, aren't enough to convince some that published studies aren't tainted by

the dollars that made them possible. Dissatisfied with results that might undermine or contradict their own belief system, activists and politicians claim bias, and otherwise prestigious biomedical institutions and organizations are forced to backtrack, opting in some instances to "appease the advocates," rather than allow the established scientific method to determine good science from bad (Dovey, 2004).

While Dovey (2004) and others hold the peer review process in high regard, others (Abramson & Starfield, 2005) feel that the medical journals are "ill-equipped to withstand the drug companies' financial pressure, research and statistical capacity, commercial ties with the most recognized experts, and lack of transparency in the research they fund." Neal, Schwartz and Bowman (2005) concur, and say that a major limitation of the peer review process is its inability to effectively deal with conflicts of interest, especially in a context when "prestigious scientists may have similar biases." Therefore, they fear that reliance on the peer review process may allow damaging distortions to become ingrained in clinical practice and health policy.

Each of us, despite our role as members of a society dependent on those in the know in the research community, has to be able to determine what is "real" from what is "real, but paid for." Following the money trail allows us to be cognizant of the influences that may be at work behind the scenes. This is essential to understanding the motivations of those performing, interpreting, and reviewing the research. Readers, potential subjects, patients, and colleagues need to be able to make their own judgments about the likelihood that conflicts (real or potential) may have introduced bias in the research report or practice guideline (Neal, Schwartz, & Bowman, 2005).

This is further evidence that a clear and transparent process for disclosure is important. The science must be above any suspicion of hidden (or not so hidden) agendas. Everyone must be considered equally and subject to the same reporting mechanisms. It is prudent to require disclosure of any amount, and not be persuaded by a presumption that only significant amounts need to be reported. Broccolo and Klanica (2006) recommend abandoning the use of financial thresholds as triggers for disclosure and support requiring disclosure of interests of any value, using the thresholds instead as a guideline for the conflict committee (or other appropriate oversight body) when assessing management options.

Too often investigators get lulled into a false sense of security by thinking that their monetary gain is not significant enough to warrant reporting, or could not influence their results. This has led to many controversies of late, and a media frenzy of pointing fingers, opposing testimonies, and restrictive policies, such as the ACS ban on tobacco funding referenced above.

In any case where bias is in question, the benefits of conducting the research by the conflicted investigator and/or at the conflicted institution must be weighed against the risks of what that bias might incur (Barnes & Florencio, 2002). Conflict advisory panels or committees to oversee the reporting and make compliance recommendations are an important first screening mechanism to have in place before even Institutional Review Boards (IRBs) or Institutional Animal Care and Use Committees (IACUCs) evaluate a proposed project. It then becomes essential to both the financial survival and scientific reputation of the research institution to ensure that its conflict of interest policies, procedures, and practices are clear, effective, enforceable, and can stand up to any scrutiny.

#### Conclusion

To preserve, maintain, and foster research integrity and the public trust, academia will need to prove that it values the advancement of human knowledge more than short- or even long-term profit (Barnes & Florencio, 2002). Having policies and procedures to actively manage both individual and institutional conflict of interest situations earns good faith points in the eyes of those served by the research enterprise. Federal regulations are just the starting point and, as witnessed by the recent OIG audit of the NIH, even the government is taking a hard look at its own biases and weaknesses in this regard. The public, the courts, the media, and industry trade associations have all made it clear that just meeting the minimum standard is no longer acceptable (Broccolo & Klanica, 2006).

Regardless of the oversight mechanisms employed, education, training, and communication among all the constituents are vital. Conflicts of interest should not be treated like secrets, but disclosed and reported with consistency and regulated with parity.

Building an organizational environment that will support, sustain, protect, and give a voice to staff, faculty, and students alike is critical to the process. A culture that embraces the ideals of research integrity will allow for open venues to actively discuss conflict situations. These days, most comprehensive Responsible Conduct of Research (RCR) programs have a module on conflicts of interest and commitment, but learning does not begin and end in college or graduate school. Sometimes the most seasoned faculty members and top-level administrators need refresher lessons and reinforcement. Even mentors need mentors. If people feel they are a part of the solution and not just the problem, compliance rates should increase, as doing the right thing becomes the only way to do what needs to be done. Ideally, accurate and timely disclosure would become an automatic standard operating procedure.

Electronic database systems have made reporting and tracking less onerous and allow those responsible for compliance to have the most up-to-date information at hand. Yearly disclosure is standard, and the immediate reporting of changes that might occur during the year is critical to maintaining compliance.

Enforcing sanctions for noncompliance with the research conflicts policy can be challenging. While no one wants to interfere with good science, there are compliance standards that must be met for the protection of everyone involved. Creating clear procedures for reporting in an accurate and timely fashion on both an annual and on-going (study specific) basis will serve to bolster the enforceability and effectiveness of the policy. If sanctions are delineated in the policy, the institution must consistently enforce them. Broccolo and Klanica (2006) suggest that ties to annual renewals of medical staff or faculty status can be effective, as can suspension or termination of such status. On a study-by-study basis, IRB and IACUC approval can be held in abeyance until disclosure statements are complete and accurate, as can the execution of pending grants and/or contracts.

FASEB (2007) offers these three guiding principles: 1) Investigators must conduct research activities objectively; 2) Investigators must operate with transparency; 3) Investigators must be accountable to all stakeholders. We may also go one step further, and say that investigators are not the only ones who must operate in this forthright manner.

Institutions and all of the stakeholders (including the public, the media, regulators, students and trainees, technicians, legal counsels, technology transfer personnel, compliance officers, committee chairs/members, administrators, coordinators, and other research support staff) engaged in or affected by the research enterprise must embrace and internalize responsible conduct of research on many levels. It must become an ingrained part of the mission, the virtual raison d'être. Conflicts of interest issues dwell at the base of this ethical core. Allowing them to remain hidden or untouched will eventually erode the entire foundation of trust in the integrity of science. Dealing with them openly and actively will allow them to rise up and filter out into the mainstream where they belong. The result is a research enterprise above reproach – one that is responsible, accountable, and indisputably ethical.

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