Conflicts of Interest: Concepts, Conundrums, and Course of Action
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A Psychiatrist on Potential Conflicts of Interest

Consider these potential conflict of interest scenarios:

The slide set. Dr. A is an academic psychiatrist and well-regarded lecturer. She receives an invitation to speak on the topic of antidepressant use during pregnancy at a major medical school. The talk is sponsored by a pharmaceutical company that makes a popular antidepressant, and the stipend for Dr. A's participation is very generous. The pharmaceutical company representative contacts Dr. A and tells her, "We have a set of slides that our lecturers have found very helpful. There is no obligation, but we would be happy to send them to you."

To what extent does this scenario present Dr. A with a conflict of interest (COI)? What are her ethical obligations in this situation?

The pharmacy committee. Dr. B agrees to join a speaker's bureau for a large pharmaceutical company, in exchange for a regular monthly stipend. Dr. B then accepts a position at a large community mental health center, where he is appointed to the center's Pharmacy & Therapeutics Committee. It is the committee's job to decide which psychiatric medications to include in the center's formulary. The list of candidate medications includes several drugs produced by the company from which Dr. B receives a stipend.

What COI, if any, does this pose for Dr. B, and what are his ethical obligations?

The dependent patient. Dr. C is a psychiatrist in private practice providing individual psychotherapy to a 38-year-old unmarried woman, Ms. Y, who has been diagnosed with generalized anxiety disorder and "dependent personality traits." Ms. Y originally sought help for her generalized anxiety disorder and had no particular complaints with respect to interpersonal relationships or dependency issues. She has been in treatment with Dr. C for nearly 1 year, twice weekly, and regularly pays out-of-pocket, preferring not to involve any third-party payers.

Dr. C has used a combination of cognitive-behavioral and psychodynamically oriented approaches and has concluded that Ms. Y's anxiety disorder is now in full remission. He wonders whether it is appropriate to continue the therapy, even though Ms. Y has expressed the clear wish to continue seeing him.

We will return to consider these vignettes and the ethical issues they raise later in this article.

Conflict of Interest: Ethical Context

The term "conflict of interest" is bandied about quite loosely these days, often as a cudgel aimed at allegedly corrupt or unethical physicians. This is understandable, because COI is usually discussed in the context of a physician's failure to disclose a COI. Thus, the congressional hearings conducted by Sen Charles Grassley (R, Iowa) called attention to
a group of academic psychiatrists who allegedly failed to disclose income from pharmaceutical companies.[1]

From the standpoint of medical ethics, however, the pejorative connotation attached to the term "conflict of interest" is not entirely or necessarily warranted. As many medical ethicists understand COI, it is neither an action nor an ethical lapse; rather, it is a situation or set of conditions in which ethical decisions are incumbent upon the physician, and which may or may not eventuate in unethical or unprofessional behavior. The mere existence of a COI does not necessarily signify a breach of medical ethics.

Whereas ethicists, journals, and medical organizations define COI in various ways, the following general definition of COI is a reasonable starting point. According to Columbia University, a COI entails "...a situation in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity."[2]

Note that this definition does not require actual biased actions or decisions, on the part of the "conflicted" person; rather, the Columbia definition stipulates that "...a conflict of interest exists whether or not decisions are affected by a personal interest; a conflict of interest implies only the potential for bias, not a likelihood."[2]

Although the notion of COI often carries the connotation of self-interest, greed, or a desire for monetary gain, COI per se does not entail a "bad character" or "bad faith" on the part of the conflicted individual. As ethicist James DuBois[3] has pointed out, a conflict of interest "does not imply that a professional intends to put his or her personal interests first; it does not in itself imply any wrong-doing."

A Closer Look at COI

Conflicts of interest are sometimes dichotomized as conscious vs unconscious, inherent vs induced, or financial vs nonfinancial. An inherent COI might exist, for example, in any type of medical research, because the researcher almost always seeks to benefit mankind while also seeking to advance his or her own career. There is nothing unethical in this tension between altruism and self-interest. In contrast, an induced COI is said to exist when a researcher knowingly creates situations of financial or other types of dependency that may compromise judgment.[3]

Several writers have pointed out that physicians and other researchers are not always aware of their own COIs, and are truly surprised when an outside observer points it out to them; thus, not all COI is conscious or "knowing." With respect to nonfinancial COIs, this may arise, for example, if a physician is asked to review a study by a colleague whom he or she deeply dislikes, or whose paper strongly criticizes the would-be reviewer's own long-standing views.

A COI can occur in many professional contexts, ranging from a physician's ties to industry (eg, speakers' bureaus, stipends for lectures, research support) to bias in the publication of research studies (eg, failing to publish negative outcome studies) and COI stemming from the physician/patient relationship. Often, these areas overlap or interact to produce the COI. In a seminal article, Dennis Thompson defined a COI as "...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)."[4]

Thompson's definition emphasizes the likelihood or probability of a bias developing
tends to be unduly influenced”) and includes a semiquantitative specifier; that is, there must be an *undue degree* of influence from a secondary interest. This is important, because it implies that a COI may not be present if the degree of influence remains modest or moderate (for example, within some unspecified parameters of acceptability). In Thompson’s view, not every situation in which bias might occur -- or be perceived by others as existing -- would be an actual, full-blown COI (in contrast to the Columbia definition of COI).

Similarly, the International Committee of Medical Journal Editors (ICMJE), in their Uniform Requirements for Manuscripts Submitted to Biomedical Journals, state that:

Conflict of interest exists when an author (or the author’s institution), reviewer, or editor has financial or personal relationships that inappropriately influence (bias) his or her actions (such relationships are also known as dual commitments, competing interests, or competing loyalties). *These relationships vary from negligible to great potential for influencing judgment. Not all [financial or personal] relationships represent true conflicts of interest* (italics added).

In short, the ICMJE does not see a COI as an all-or-none phenomenon; there is a wide range of circumstances that create a continuum of COI.

**Conflict of Interest vs Vested Interest**

It is also important to distinguish a COI from a vested interest. For example, Dr. A, in the first vignette, has a legitimate, vested interest in educating her audience about the risks associated with antidepressant use during pregnancy. A psychiatrist also has a legitimate vested interest in seeing his or her practice grow and flourish. There is no COI in either case, unless and until the vested interest bumps up against a competing interest.

To understand this, let’s suppose that in the interest of growing your psychiatric practice, you create a Website that provides information about you, your education, areas of expertise, how to set up appointments, and so on. There is no COI in any of this. But now, suppose you have been treated recently for a significant and chronic mood disorder. Do you disclose this on your Website?

It could be argued, on various grounds, that such disclosure is in the best interests of your current and prospective patients. On the other hand, some potential patients may find this personal disclosure worrisome and seek help elsewhere, even though you are perfectly capable of treating them effectively. This, of course, could reduce your net income. Thus, over and above the legitimate vested interest, there is at least a potential COI.

**Psychiatric Medication, Big Pharma, and Publication Bias**

In recent years, concern has been increasing that psychiatric research has been unduly biased by its ties to the pharmaceutical industry, and that this bias is often unrecognized in published research articles. In a frequently cited study of publication bias, Perlis and colleagues found that among 397 clinical trials of psychiatric drugs, 239 (60%) reported receiving funding from a pharmaceutical company or other interested party. In 187 studies (47%), at least 1 author reported a financial COI.

Among the 162 examined randomized, double-blind, placebo-controlled studies, those that reported a COI were nearly 5 times more likely to report positive results -- and this
association was significant only among the subset of pharmaceutical industry-funded studies. Perlis and colleagues concluded that "author conflict of interest appears to be prevalent among psychiatric clinical trials and to be associated with a greater likelihood of reporting a drug to be superior to placebo."

These findings are often cited by critics of psychiatry as evidence that industry-supported studies of psychotropic medications can't be trusted or are inherently corrupt. Yet this was not the conclusion of the study authors, who provided alternative interpretations of their data. For example:

Industry sponsorship may allow larger and better-designed studies, with greater statistical power to identify significant differences if such differences exist. Indeed, the median number of subjects was larger among studies in which conflict of interest was present. Industry-funded trials would naturally examine drugs already suggested to have efficacy in earlier-stage trials.\(^6\)

In short, at least some industry-funded trials may produce more positive outcomes because they are based on better preliminary information about the drug in question. More fundamentally, Klein and Glick\(^7\) have argued that the best defense against an inaccurate and misleading scientific paper lies in the accurate, scientific scrutiny of the article's methods, design, statistical analysis, and conclusions. As these authors observe, "...the important issue is whether the presentation truthfully reflects the known scientific facts and draws justifiable conclusions..."\(^7\)

According to Klein and Glick,\(^7\) if a study or article meets this test, the issue of financial underwriting is not of great public health importance. If the study fails this test, the research is not redeemed by its independent funding source. Indeed, in principle, a researcher utterly without COI may still produce an atrocious and misleading piece of research. Conversely, a researcher or writer who has a COI may produce an article or study that is accurate, meticulously designed, and scrupulously analyzed.

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**Full Disclosure: The Ethical Standard?**

Nonetheless, full disclosure is now considered the ethical standard in research, articles, and lectures. Typically, this disclosure is proffered with respect to the material presented in the study, article, or lecture.

Under this standard, owning stock in a pharmaceutical company on the part of the author would not be relevant to an article on, for example, the spiritual dimensions of psychotherapy. However, Daniel Carlat, MD,\(^8\) advocates a more sweeping kind of disclosure, one that:

...require[s] authors to disclose all financial ties to any healthcare-related company, whether seemingly relevant or irrelevant to the topic of the article. It would then be up to the readers to decide whether these ties represented true conflicts.

So far, this more stringent standard does not seem to have been adopted by most journals, but it is arguably more transparent and informative than the typical subject-specific disclosure. In contrast, in a recent study of COI disclosures in psychiatric review articles, Kopelman and colleagues\(^9\) concluded that:

Disclosures seemed to be of limited utility in helping readers assess possible biases because the nature and the extent of the relationships being disclosed were often unclear. Efforts to screen out authors with significant financial relationships pertaining
to the topic under review may be more effective than are disclosures, in protecting the integrity of the medical literature.

This proposal, of course, places a substantial "screening burden" on journal editors.

Of interest, Kopelman and colleagues\[9\] found that reviews in the psychiatric journals were significantly less likely to include industry-related disclosures than were reviews in general medical journals. This led to the conclusion that "...psychiatry does not have a particular problem"\[9\] with COI, at least with respect to review articles. This, of course, assumes that COI was accurately and honestly reported by the authors of the reviews.

The Clinical Vignettes

Reasonable observers and medical ethicists are likely to reach various conclusions about the ethical issues raised in the 3 vignettes described at the beginning of this article. The following comments represent my own views as a psychiatrist, researcher, and bioethicist. I have also interpolated some additional remarks from my colleague, medical ethicist Cynthia M.A. Geppert, MD, PhD.

**Dr. A and the slide set.** Appelbaum and Gold\[10\] state that continuing medical education (CME) is "heavily supported by industry funding and anecdotal accounts by physicians, including psychiatrists, who have been paid by industry to deliver promotional talks, indicate that they often face considerable pressure to shape their presentations to the companies' needs."

In my view, Dr. A is already dealing with a COI, merely by presenting a talk on antidepressants that is sponsored by a company that markets a particular antidepressant. (This would be a more obvious COI if Dr. A planned to discuss only or primarily the specific drug marketed by the company). There is nothing inherently unethical in Dr. A's actions, but the COI does require careful management. The level of the COI is raised by the large stipend Dr. A is receiving, which might predispose her to go easy on the company's antidepressant with respect to its risks during pregnancy.

As long as (1) the presentation's pharmaceutical sponsor is adequately disclosed to the audience and (2) Dr. A discloses that she is receiving a stipend from this company, this COI may be adequately addressed, without compromise of medical ethics on Dr. A's part or on the part of the institution hosting her talk.

However, accepting prepared slides from the sponsoring company would pose an undue biasing influence on Dr. A's presentation and should therefore be avoided. Even if the slides are entirely accurate and objective (by no means a sure bet), accepting them sets a bad didactic precedent, and at the very least creates the appearance of bias. This can detract from an otherwise useful presentation.

Finally, Dr. A should discuss several different antidepressants in her talk, pointing out the pros and cons of each agent.

**Dr. B and the pharmacy committee.** If Dr. B, who was receiving monthly stipends for participation in a pharmaceutical company's speakers bureau, did not inform his institution's Pharmacy Committee of this situation before accepting a position on the committee, he could be faulted for not disclosing a potential COI. (Whether this is a potential or an actual COI depends, in part, on whether the Columbia University definition or Thompson's definition of COI is used). The COI would exist, in my view, even if Dr. B
did not know that drugs marketed by the company would be candidates for inclusion in the pharmacopeia.

In any case, having accepted a position on the pharmacy committee, Dr. B is obligated to disclose the potential (or actual) COI to the committee chairperson. That might result in Dr. B’s being asked to leave the committee or, more likely, to recuse himself from any committee decisions about drugs produced by the company. Dr. Cynthia Geppert adds, "The highest standard now would require Dr. B to announce his COI at the beginning of every meeting, so [this would be] included in the minutes" (Personal communication; October 27, 2013).

**Dr. C and the anxious, dependent patient.** When assessing the ethical responsibilities of this physician, keep in mind the 4 cornerstone principles of medical ethics:

- Autonomy;
- Benevolence (or beneficence);
- Nonmalefeasance (or nonmaleficence); and
- Justice.¹¹

As Dr. Geppert observes, "The core of medical ethics is to place the interests of the patient above all others -- yet there are limits" (Personal communication; October 27, 2013).

There is a probable COI for Dr. C, whose primary interest is the emotional well-being of his patient -- but who also stands to lose a regular and substantial source of income (the "secondary interest," in Thompson's formulation of COI⁴). It could be argued that continuing therapy after resolution of the presenting problem risks exacerbating Ms. Y's dependence traits. To that extent, continuing the sessions risks undermining Ms. Y's autonomy, even though she is perfectly happy to continue psychotherapy. Arguably, continuing treatment under these circumstances would also violate the principles of benevolence and nonmalefeasance.

This, of course, assumes that continuing treatment would worsen Ms. Y's dependence traits and perhaps contribute to interpersonal difficulties outside of the therapeutic relationship. This is the preeminent consideration in the case, and any financial repercussions associated with termination of therapy must be set aside.

One approach to this COI would simply be to terminate Ms. Y's treatment, but this might risk a reemergence of her generalized anxiety, and perhaps an unintended worsening of her symptoms. Another option would involve Dr. C discussing his concerns with Ms. Y, so that she is fully informed of the risks -- and also potential benefits -- of continuing treatment. For example, Dr. C might say:

You have made great progress over the past year, in terms of your anxiety. I understand your wish to continue seeing me, and I have some concerns about that. Because the problem you sought help for -- the anxiety -- has been resolved, I am concerned that continuing to see me might lead to you becoming overly dependent on psychotherapy. In the short run, this might seem fine, but it might undermine your ability to handle things on your own in the long run. On the other hand, there might be other issues for us to work on in treatment, such as how much you rely on others in your everyday life. What are your feelings about continuing to see me, given what I
am saying?

One compromise might be to reduce the frequency of sessions to once per week over a period of a few months, with a plan to terminate treatment within a specified interval, assuming that Ms. Y remains stable. Dr. Geppert adds that "Some therapists also allow check-ins for a period of time [during] crises..." and that Dr. C might consider referring Ms. Y to a support group, either as a transitional step or as a new treatment modality (Personal communication; October 27, 2013). Some of the difficulties of terminating psychotherapy -- made famous in Freud's 1937 classic paper, "Analysis Terminable and Interminable" -- are discussed in a useful article by psychologist Dr. Ryan Howes.[12]

Conclusion

The definition of a COI remains somewhat contested, but this much seems clear: If a physician feels uncomfortable because his or her professional obligations are in persistent tension with his or her personal advantage, it's best to assume that a COI exists and address it responsibly. Indeed, as Dr. Geppert observes, "Even the appearance of a COI can itself cause harm" (Personal communication; October 27, 2013). This is true whether the COI is financial or personal, and whether within, or outside, the doctor/patient relationship.

Academic and research-oriented psychiatrists must pay particular attention to the integrity and transparency of their teaching and publications. COIs are not at all uncommon and by themselves do not represent a breach of medical ethics. In fact, as Dr. Geppert comments, COIs "...are really another form of the classic ethical dilemma in which one must choose from among several 'goods.' COIs are unavoidable; what matters is their disclosure and management." (Personal communication; October 27, 2013). Ironically, as David Healy has commented, "The only people with no conflicts of interest when it comes to clinical care are those with nothing to offer. But these biases must be open to scrutiny for which access to data is critical."[13]

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