

Conflict of Interest Policy Guide for Academic Medical Centers and Medical Schools



COI Toolkit on Pharmaceutical and Therapeutics Committees

This toolkit provides guidance to academic medical centers (AMCs) on how to design conflict of interest policies for pharmaceutical and therapeutics committees (PTCs) in order to eliminate or reduce the potential for bias in PTC decisions that may result from committee members' relationships with the pharmaceutical industry.*

I. Introduction

Pharmaceutical and therapeutics committees determine which drugs will be available for use in academic medical centers (AMCs).

It is the responsibility of PTC members to consider a medication's efficacy, safety and cost as they make decisions about its inclusion on the institution's formulary. The committee should arrive at its decisions through an unbiased review and analysis of the evidence in the scientific literature.¹ The committee strives to assure that its decisions put the best interests of the patients first and are based on the best available scientific evidence.

Over the last 50 years, the role of PTCs has evolved significantly from their initial work to address the logistics of adequate drug supplies on hand at a hospital. Today's complex health care systems and competitive economic environment demands an expanded role for PTCs encompassing technology assessment, cost-effectiveness analysis, and patient safety.^{2,3}

PTC members must possess sophisticated knowledge of medication as well as familiarity with the health economics methods used to determine the costs and benefits of one medication versus its alternatives. Equally important, committee members must carry out their duties free of outside influences that could bias their decisions in ways that are not beneficial to patients. Financial conflicts of interest (COIs) with pharmaceutical companies pose such a threat, but many AMCs may not have adequate COI policies in place.⁴

**This guide does not address medical device procurement policies, which may or may not be the responsibility of a PTC, depending on the institution. Furthermore, unlike the evaluation of drugs, decisions about the safety and efficacy of some devices may require hands-on experience and expertise that can only be gained by interactions with manufacturer representatives. As a result, approaches to addressing COI in device procurement may require different policies and/or more individual management.*

II. Arguments For and Against Different COI Management Approaches

Here are the arguments for and against different strategies that can be used in various combinations to eliminate or reduce the impact of financial COIs arising from financial interactions between the pharmaceutical industry and individual PTC members.

Broad prohibition of any COI by PTC members

The most effective way to eliminate the potential for bias from a COI is to prohibit anyone who has certain financial interests with a pharmaceutical company from serving on the PTC. For instance, an institution could preclude PTC membership for any candidate that received any funding above a certain amount from a drug manufacturer in the last 24 months.

The World Health Organization, in its training guide for hospital drug and therapeutics committees, asserts that it is essential to the committee's success to "permit no relationship of the committee or committee members with pharmaceutical manufacturers or suppliers."⁵

Yet strenuous arguments have been raised against a blanket prohibition of membership. Opponents argue that the committee may need individuals with special expertise in certain types of drugs or devices, yet be precluded from recruiting them to the PTC if they have financial relationships with industry. Finding individuals with this special expertise but with no financial ties is difficult, they argue, because the special expertise is often developed through paid collaborations with industry such as involvement in clinical trials. Alternatively, such special expertise often is of value to industry, and thus would have already led to prior consulting agreements, which would then disqualify the expert from PTC membership.

Proponents of a strong prohibition approach counter this argument by noting that the PTC could solicit the advice or input for the committee from persons with such special expertise. Including input from a conflicted experts in such a manner is highly preferable to allowing them to serve directly on the committee, because the PTC members are more likely to be made aware of the expert's conflicts, and can then discuss and evaluate the input in light of risks of potential bias.

An additional argument against banning PTC membership for persons with financial relationships with industry is that such a prohibition limits the pool of potential members. Depending on how many types of financial relationships that disqualify a candidate, and how far back in time the institution looks for relationships with industry, the pool of potential candidates within an institution could become too small for work that is already time-consuming and uncompensated. A 2007 survey of life science faculty in research-intensive universities showed that about half of the clinical faculty had some relationship with industry, principally as consultants, paid speakers, and scientific advisory board members.⁶

"Barring faculty with COIs from membership in the PTC is of paramount importance to UMMC in assuring the integrity of critical committee decisions that have hospital-wide impacts on patient safety and fiscal prudence."

*— Michael Todaro, PharmD,
Director of Pharmacy, University of
Mississippi Medical Center*

Furthermore, a strict prohibition would mean that committee members would either have to forego new opportunities for collaborations with industry, such as consulting or clinical research, or resign from the committee. The disqualifying conflicts would apply not only to themselves, but also to immediate family members. This requirement would cause transitions in the staffing, reducing the efficiency of the PTC. Finally, the prospect of that situation arising may deter individuals from serving on the committee in the first place.

In response, proponents of a strong prohibition argue that insulating drug selections and recommendations from industry influence is a top priority, because it directly impacts patient care and safety. A very early study by Chren and Landeman found that physicians with financial relationships with a particular company were much more likely than other physicians to make requests that specific drug products from that company be added to a hospital formulary.⁷ The American Society of Health System Pharmacists warns that a COI “may interfere with professional’s ability to make evidence-based decisions” and even the appearance of a COI by a PTC member can “undermine a formulary decision.”¹

In addition, any asserted difficulty in finding qualified personnel for a PTC should never preclude a stronger COI approach. While, as noted above, an average of half of clinical faculty has relationships with industry, half do not. The director of pharmacy at the University of Mississippi Medical Center—an AMC that strictly bans faculty with COIs from serving on PTCs—reports no difficulty in finding qualified faculty to serve on the committee. (Personal communication, Michael Todaro, August 26, 2014)

Finally, the rules to prohibit membership can be more nuanced. For example, the committee can decide that clinical research supported by industry would not preclude membership on a PTC if that research were bona fide scientific research with safeguards to assure its integrity—for instance, guaranteeing the investigators the right to publish regardless of the outcomes, full access to all data, and independence in the design, conduct, and analysis of the study.

Disclosure and recusal requirements for PTC members

Prohibiting PTC membership by those with certain financial relationships with industry has not become widespread among AMCs, although it is practiced by some public programs.⁸ More often, AMCs attempt to manage potential COIs through *disclosure* and *recusal* – i.e., by having members of the committee first *disclose* any potential financial interests, and then be *recused* from either the committee’s discussion, or the committee’s voting on the drug or device. Some argue that disclosure and recusal can achieve the same results as a ban on COIs among PTC members. Yet disclosure and recusal are imperfect solutions.

First, disclosure can be in the eye of the beholder. Sometimes the requirements for disclosure are vague and open to interpretation. Sometimes they are too limited, because they do not include financial relationships of immediate relatives, or financial relationships in the

recent past. Disclosures may be required too infrequently, not revealing new financial relationships that emerged since an individual first joined the committee. Even if disclosures are comprehensive and detailed, individuals may inadvertently misinterpret the disclosure requirements.

Next, disclosure itself does not solve conflict of interest; paradoxically, it may even make it worse. Lowenstein et al. describe two mechanisms by which disclosure may actually exacerbate bias: *strategic exaggeration* (the tendency to provide more biased advice to counteract anticipated discounting) and *moral licensing* (the often unconscious feeling that biased advice is justifiable because the advisee has been warned). Added to that is the tendency on behalf of the recipients of biased information to discount the bias so as not to convey a sense of distrust to their colleague who has made the disclosure. Lowenstein et al. conclude, “the most significant likely pitfall of disclosure is ... the likelihood of a kind of moral licensing on the part of the profession as a whole—the rationalization that, with disclosure, the profession has dispensed with its obligation to deal with conflicts of interest.”⁹

Under any recusal policy, PTCs should pay close attention to the scope of industry relationships by PTC members and the scope of products potentially impacted by a particular decision. Recusal practices must consider which parts of the PTC process a conflicted committee member should be excluded from, including discussions and deliberations, communications with other committee members, and final voting. Such considerations are important, because potential bias on the part of the individual with financial interests may be completely unconscious. Simply recusing the conflicted committee member from voting doesn’t remove the biased information from the minds of other voting PTC members. Even the strongest recusal policy that excludes a conflicted member from all PTC action related to a product may not fully eliminate that conflicted member’s possible influence on other committee members, due to their unconscious desire for collegiality.

In addition, the PTC should establish standards so that the scope of products subject to a recusal should be appropriately broad. For instance, shouldn’t recusal include not only a specific product that a member has a financial COI about, but also any competing products, and/or to any other products sold by the same manufacturer? (See the recommendations below for recusal policies.)

III. Policy Considerations

Timely disclosure

All PTCs should have written policies governing COI, which should be available on a public website. A disclosure form reflecting the committee’s policies must be completed by all committee members when they first become members of the committee and annually thereafter. Before each meeting, the chair should inquire if any member has new relationships with industry to disclose. Appropriate action, such as withdrawal from membership or recusal from activities, would then be taken depending on the institution’s policy.

“The COI policy for our P&T committee requires full disclosure of any COIs, yet allows experts in the field to have input on matters where they do not have significant financial interests. We believe this is a balanced and reasonable policy.”

*— Neal J. Thomas, MD, MSc,
Chair, COI Review Committee,
Pennsylvania State University
College of Medicine*

A ban on membership

Optimally, the COI policy should prohibit individuals from becoming members of the committee if they have a disqualifying relationship or interaction with any industry whose products might be reviewed by the committee or have had such disqualifying relationships within the last two years. Disqualifying relationships should include “high-risk” interactions with the pharmaceutical industry, such as direct payments for participation in a speakers bureau, consulting, or gifts, and also direct or indirect payments such as the provision of travel, lodging or food.

Other transfers of value, such as research, free product samples, or meals at independent scientific meetings might not disqualify a person from PTC membership if the AMC determines that in general they present a low risk of undue influence upon a PTC member’s decision-making.

While a low-risk relationship or interaction with industry may not disqualify a PTC member, it certainly could require their recusal from some PTC decisions. (See below)

Recusal from participation

If the AMC does not wish to adopt a stringent policy that disqualifies people from membership based on high-risk relationships with industry, it should consider adopting a COI policy that incorporates the following provisions, which are adapted from Nguyen & Bero:⁸

1. Define the nature of relationships with industry that need to be disclosed, including equity ownership other than mutual funds, royalty payments, paid positions on advisory boards, commercial speaking (“speakers bureaus”), consulting, research support, educational support, travel support, gifts, meals and samples. Ideally, no *de minimis* should be specified; that is, any amount of, no matter how small, will require disclosure.
2. Include first-degree relatives (spouse, parents, siblings, and children) in the requirements for disclosure.
3. Require that members with a qualifying financial relationship be recused in relation to (i) any product related to their financial relationship; (ii) any competing product¹⁰; (iii) and all products sold by any manufacturer with which they have a financial relationship.
4. Specify which financial relationships with industry, both current and in the recent past, warrant recusal from PTC activities, and if so, how broadly. Factors of importance include the type of relationship, and when it occurred. For example:
 - a. Individuals that have engaged in commercial speaking for industry in the last two years should be recused from PTC activities related to the products of any manufacturer that paid them, and any competing products.

- b. PTC members who received industry funding for bona fide research approved through the AMC's institutional review board should be recused for any products related to their research for one or two years, but might be able to participate in decisions on other, unrelated products.
 - c. PTC members with current investment interests (stocks or bonds) in a manufacturer should be recused in relation to that manufacturer, but PTC members who have divested of such investments perhaps should not be recused.
5. Recusal requires that conflicted members have no communications with other committee members about the deliberation, and physically leave the meeting during the discussion and vote.
 6. Require PTC members or other staff communicating with the PTC to disclose if they have been asked by anyone from industry to submit a request for review of a product, regardless of whether the person has received any payment, gift, or any quid pro quo for doing so.
 7. Designate who on the committee is charged with reviewing disclosure forms and the process for performing the review and taking actions after the review.
 8. Define the consequences for committee members found to have not disclosed financial relationships, such as immediate dismissal from the PTC, and swift review of decisions on any related product, with a new vote.

The PTC bylaws should preclude industry sales representatives from participating in or observing committee meetings. PTCs should try to include clinical pharmacists, clinical pharmacologists, and medical toxicologists on the committee as expert sources of input.¹¹ Members with expertise in pharmacoconomics should also be sought.³

IV. Model Policies

A. Ban on membership for those with financial conflicts of interest

UNIVERSITY OF MISSISSIPPI MEDICAL CENTER (UMMC)

UMMC's workforce who are involved in institutional decisions regarding the purchase or approval of medications or equipment, or the negotiation of other contractual relationships with industry must not have any financial interest (e.g., equity ownership, compensated positions on advisory boards, a paid consultancy or other forms of compensated relationship) in the companies that might benefit from the institutional decision.

B. Recusal from discussion and votes for those with financial conflicts of interest

UNIVERSITY OF NEW MEXICO HEALTH SCIENCE CENTER (HSC)

HSC faculty or staff who are involved in institutional decisions concerning the purchase or approval of medications or equipment, or the negotiation of other contractual relationships with industry, must disclose any relevant financial interest (e.g., equity ownership, compensated positions on advisory boards, a paid consultancy or other forms of compensated relationship) in an industry that might benefit from the institutional decision. Where actual or potential conflict of interest exists, the individual should recuse him/herself from the process.

V. References

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The Toolkit is a publication of Community Catalyst, a national, nonprofit consumer advocacy organization dedicated to making quality affordable health care accessible to everyone. Among its prescription drug initiatives, Community Catalyst combats pharmaceutical marketing that creates conflicts-of-interest and threatens the safety and quality of patient care. We provide strategic assistance to medical schools and teaching hospitals seeking to improve their conflict-of-interest policies as part of the Partnership to Advance Conflict-Free Medical Education (PACME), a collaboration of Community Catalyst, The Pew Charitable Trusts, the American Medical Student Association and the National Physicians Alliance. PACME is supported by a grant from the Attorney General Consumer and Prescriber Grant Program, which was funded by the multi-state settlement of consumer fraud claims regarding the marketing of the prescription drug Neurontin.