Conflicts of Interest on Pharmacy and Therapeutics Committees at Academic Medical Centers

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Dear Editors,

Pharmacy and Therapeutics (P&T) committees' decisions should ideally be guided by objective patient and institution centered factors including comparative efficacy and cost–benefit analysis [1]. However, the potential for institutional and personal conflicts of interest (COI) among committee members may have undue and adverse influence on the decision-making process. The focus on this issue is highlighted in the American Medical Student Association (www.amsascorcard.org) review of COI at Academic Medical Centers (AMC). In this initial survey, we sought to determine the mechanisms by which COI are defined and managed by P&T committees at AMCs. Our goal was to provide an overview of the practices to inform further investigation.

Methods We used an anonymous online tool to send and collate a survey concerning the institutional policy regarding COI for P&T committee members. Solicitation was sent electronically to members of the University Health Consortium Pharmacy, a group of AMC-based pharmacy directors, and to medical toxicologists via the Forum of the American College of Medical Toxicologists, the specialty's professional organization. The total number of survey recipients could not be tracked, although reminders were sent weekly over a 1-month period. The IRB waived the consent requirement.

Results We received a total of 39 responses representing 39 distinct organizations. Each respondent served on the hospital's P&T committee. The responses are mainly from individuals in urban (90%, 35/37), nonprofit (74%, 29/39), and or publicly funded (28%, 11/39) institutions. The identified P&T committees' functions included all of the following: formulary (100%, 38/38), medication use (92%, 35/38), and medication safety (87%, 33/38). A COI disclosure form was signed annually (59%, 23/39), only at the time of joining (15%, 6/39), biannually (8%, 3/39), or never (18%, 7/39); a few (5%, 2/39) required a declaration of relevant COI at the beginning of each meeting. Most (76%, 29/38) respondents stated that their P&T committees do not have formal COI guidelines or policies. When policies were present, the P&T chair adjudicated the COI 60% (23/37) of the time. Greater than 50% of P&T committees defined COI as: (1) financial (95% (35/37) for personal, 73% (27/37) for family member/significant other, 68% (25/37) for a business partner), (2) expert witness consultation (84%, 31/37), (3) research or clinical funding (76%, 28/37), (4) advisory board (78%, 29/37), and or (5) speaker bureau participation (84%, 31/37). Members of P&T committees at institutions where a COI policy exists were required to withdraw from discussion (64%, 25/39) and decision making (79%, 30/38) of relevant medications. Pharmaceutical representatives were nearly uniformly not allowed to attend P&T meetings 97% (36/37).

Limitations This survey was not designed to systematically sample pharmacy directors or P&T chairs, but rather as a pilot to determine the potential for a more comprehensive study.

Discussion COI in healthcare has received substantial attention in the last several years. Congress is considering a governmental website that requires physicians to register their personal COI [2]. Since P&T committee meetings are

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often conducted with little public or institutional oversight, the level of rigor for assessing and vetting potential biases must be sufficient to allay any concern for impropriety. The American Society of Health-System Pharmacists advises P&T committees to address all COIs, particularly financial ones, during the decision-making process [1]. The Institute of Medicine recommendations focus on full disclosure of COI for any industry associated with medical research, professional societies, patient advocacy groups, and medical journals [2].

A recent survey of Institutional Review Boards (IRBs) showed similar results to our survey of P&T committees. Nearly 75% (79/107 or 73.4%) of the chairs of IRBs reported a defined process for COI disclosure, and 80% of respondents identified the need to sign a COI declaration (15% at time of joining, 57% annually, and 3% biannually) [3]. About 66% (70/107) of IRB chairs stated that there was also a policy regarding the appropriate action for identified COI [3]. For the IRB chairs that identified a member COI in the past year, 100% of those members were not allowed to vote on a protocol while 63% of those members with COI were not allowed to discuss the protocol [3].

Although the liabilities associated with unidentified COI are difficult to assess, the discussion and vote of a charismatic, but conflicted, member could result in an inappropriate decision by the committee. P&T committees

should therefore have written, specific, and objective guidelines for adjudication of COI. At a minimum, these instructions should require COI declaration at each P&T committee meeting so members are aware of any potential bias. They should include the restriction of P&T members with COI from decision-making regarding relevant, including competitor, medications. By adapting this strict COI policy, P&T committees can help ensure that their recommendations are fair and objective.

Conclusion Explicit written guidelines for COI on P&T committees are often lacking, and the assessment and management of COI is highly variable.

References

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