

Professional Medical Associations and Their Relationships With Industry

A Proposal for Controlling Conflict of Interest

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PROFESSIONAL MEDICAL ASSOCIATIONS (PMAs), bringing together physicians in the same specialty or subspecialty, make many distinctive contributions to advancing the quality of medical care. In the first instance, PMAs play a vital role in medical education. Their meetings, publications, journals, and continuing medical education (CME) courses inform members of new and established diagnostic and treatment procedures. The PMAs also issue detailed practice guidelines that set the standards for efficient and effective patient care. Moreover, PMAs define ethical norms for their members, promulgating codes of conduct for professional behavior. At the same time, PMAs pursue a public agenda. They advocate for the particular interests of their members, for patients, and for what they believe to be the best interests of society.¹⁻³

Professional medical associations (PMAs) play an essential role in defining and advancing health care standards. Their conferences, continuing medical education courses, practice guidelines, definitions of ethical norms, and public advocacy positions carry great weight with physicians and the public. Because many PMAs receive extensive funding from pharmaceutical and device companies, it is crucial that their guidelines manage both real and perceived conflict of interests. Any threat to the integrity of PMAs must be thoroughly and effectively resolved. Current PMA policies, however, are not uniform and often lack stringency. To address this situation, the authors first identified and analyzed conflicts of interest that may affect the activities, leadership, and members of PMAs. The authors then went on to formulate guidelines, both short-term and long-term, to prevent the appearance or reality of undue industry influence. The recommendations are rigorous and would require many PMAs to transform their mode of operation and perhaps, to forgo valuable activities. To maintain integrity, sacrifice may be required. Nevertheless, these changes are in the best interest of the PMAs, the profession, their members, and the larger society.

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As the range and importance of these activities suggest, PMAs represent expertise and authority to those inside and outside of medicine. Physicians and the general public rely on PMAs to provide evidence-based information and recommendations. Therefore, any compromise of scientific integrity or of unqualified commitment to patient well-being must be anticipated and avoided.^{4,5}

During the past decade, the relationship between medicine and industry, specifically involving pharmaceutical and medical device companies, has come under intense scrutiny. The overriding concern is that industry ties cre-

ate conflicts of interest, both real and perceived.⁶⁻⁸ The attention to this issue reflects, first, an increasing awareness of the extent of the financial links between pharmaceutical and medical device companies and medical practitioners and institutions.⁹⁻¹² Second, an extensive literature has documented the influence of gifts on individual physicians.¹³⁻¹⁵ The fear, expressed by physician leaders, public officials, and the media, is that industry influence may

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compromise clinical decision making, adversely affecting health care delivery and undermining the reputation of the profession.^{2,16}

The problem has exceptional relevance for PMAs because industry funding of their activities, although varying in degrees, is pervasive. Contributions from pharmaceutical and medical device companies often subsidize annual meetings by their purchase of booths in the exhibit halls at which they distribute pamphlets and branded items.^{17,18} These companies sometimes underwrite physician attendance through grants for travel, meals, receptions, and other social activities. Industry frequently provides honoraria for plenary sessions and lectures, and purchases mailing lists and advertising space from PMAs to increase attendance at their satellite symposia paralleling the PMAs' meetings. In many instances, industry also funds the accredited CME offered by the PMAs and supports publication of practice guidelines and information booklets, often stamping these materials with their company logo.^{3,19,20}

Although many PMAs have issued guidelines on conflict of interest, there is little uniformity among them. Some critics suggest that these guidelines are not sufficiently stringent or detailed enough to prevent the appearance or reality of undue industry influence and bias.^{2,16,21,22} To address this situation, model guidelines on conflict of interest, as proposed herein, may serve to bring both consistency and efficacy to the governance of PMAs. The proposals in this article discuss conflicts of interest as they pertain to the activities, leadership, and members of PMAs. The scope and specificity of the recommendations point to the intricacy of ties between industry and PMAs.

Underlying Principles and Premises

Several premises underlie these recommendations. First, the pharmaceutical and medical device industries

make important contributions to medical progress. Their role in the development and testing of new compounds and instruments is essential for the diagnosis and treatment of disease and disability. It may be appropriate in given instances for PMAs to join with industry in research and evaluation of new products. Resolving issues of conflict of interest is not best accomplished by avoiding all relationships.²³

Second, both quantitative and qualitative research demonstrates the power of gifts to bias physicians' choices. Beyond the monetary value of the exchange, the very fact of the exchange creates a conflict of interest. Even gifts of modest value foster a need to reciprocate, which then affects treatment decisions.^{24,25}

Third, education must be carefully distinguished from marketing. Professional medical associations have a duty to bring to their members the best scientific evidence on the efficacy and suitability of drugs and devices. These efforts must be separate from and not affected by industry promotions.

Fourth, individual as well as the PMAs' organizational ties to industry take a variety of forms so the guidelines for PMAs must reckon with each of them. For some individuals, industry support for their research is a major component of their salaries; for others, industry honoraria and consulting fees supplement their salaries. In many instances, it is not the individual physician but the medical school division or department that receives industry funding. Conflict-of-interest policies for PMAs, particularly as they affect the selection of the organization's leaders and committee members, should reflect these distinctions and differences, weighing the nature of the conflict, the type of activity, and its relevance to industry.^{10,26,27}

Fifth, PMAs must set their own agendas and priorities and remain faithful to them. Proposed industry support for a project should not alter the agendas of PMAs. To allow commercial funding to dictate a PMA's activities is, in

effect, to put the organization up for sale.²³

Proposed Recommendations for Controlling Conflict of Interest

The following sections explore the activities most relevant to relationships between PMAs and industry and propose recommendations and policies to help reduce or eliminate conflicts of interest.

1. General Budget Support From Industry. The general budget of PMAs covers a wide range of activities, including not only operational costs but annual meetings, research sponsorship, journal publication, and development of practice guidelines. The costs associated with these activities are substantial and at present are not supported exclusively by membership fees or even advertising revenues from journals. Without greater transparency, it is impossible to know how much industry funding supports these activities. In the absence of legal reporting requirements, the extent of each PMA's dependency on industry remains indeterminate.

This industry funding raises vital questions about the standing and operations of PMAs. How can the public and the profession be certain that a PMA dependent on industry for support is being faithful to its mission of conducting educational programs and setting practice guidelines that reflect only the best scientific knowledge? Such a dependency inevitably creates the perception and reality of conflicts of interest and jeopardizes public trust.

Accordingly, PMAs should work toward a complete ban on pharmaceutical and medical device industry funding (\$0), except for income from journal advertising and exhibit hall fees. Although attracting advertising and exhibit hall fees might possibly bias the activities of PMAs, officers and members can easily distinguish these marketing activities from educational presentations and are free to ignore them. Pellegrino and Relman²¹ have urged that membership dues and grants from the govern-

ment and foundations should underwrite the activities of PMAs. Recognizing that a goal of \$0 support from industry cannot be achieved overnight without causing great disruption of PMAs' services, a number of interim policies should be implemented to govern the acceptance or refusal of industry support.

All funds from industry should be truly unrestricted—given for the purpose of supporting the mission of the PMA. The donated funds should be pooled and administered by each PMA through a central repository. A PMA must have the freedom to set its own course and to modify both its goals and priorities, including the freedom to take positions on health-related issues that may be unfavorable to its funders.

Professional medical associations should immediately move to restrict total support from industry (except for journal advertising revenue and exhibit hall fees) to no more than 25% of their operating budgets. Although the choice of this percentage is necessarily arbitrary, meeting this goal would begin to wean PMAs from industry support without putting their survival into jeopardy. If that percentage is exceeded, the PMA should immediately reassess its policies to reduce its dependency and protect the integrity of its agenda. No single industry source should be responsible for the majority of total industry funding to an individual PMA, although limited and temporary exceptions may have to be made for small and specialized societies.

Even this level and distribution of industry support has the potential to bias a PMA because pharmaceutical companies often share common interests, for example, legislation affecting Medicare Part D or drug importation from Canada. However, PMAs will learn how best to move to a \$0 position by adopting these interim guidelines.

2. Annual National Conferences and Periodic Regional Meetings. Almost all PMAs conduct an annual meeting for members, and many also hold regional conferences. Industry supports these meetings in a variety of ways, providing substantial funding to the PMA.

A. Industry Sponsorship of Conference Programs. It is common practice for industry to fund conference programs, including CME courses. Although the Accreditation Council for Continuing Medical Education expressly prohibits industry influence over the choice of speakers and content of programs, PMAs should establish additional safeguards to ensure compliance with the spirit of this prohibition. Each PMA might establish a CME committee whose members, free of all industry ties, would have the responsibility to distribute unrestricted, educational grants from industry. This committee would have exclusive authority to select program topics and speakers; industry would not be allowed to fund or be identified with specific lectures or individuals. Alternatively, PMAs may turn to independent foundations or to relevant programs by the National Institutes of Health to fund specific courses or endow lectureships. In addition, it may be necessary to pass more of the CME costs to individuals, rather than depend on contributions from interested parties.

B. Conflict-of-Interest Standards for Program Committee Members. Because of their ability to influence the content of educational programs, members of program committees for PMAs should adhere to strict conflict-of-interest guidelines. The choice of topics and speakers is so essential to the integrity of conference offerings that independence of choice must be fully preserved. At a minimum, members of the program committee should disclose any financial ties with industry to the committee chair, the PMA's legal counsel, or both, who should, in turn, request recusal of the committee member when a relevant area is under discussion. All PMAs should strongly consider going beyond this standard. They might select program committee members who are completely free of financial ties to industry, and consider making conflict-of-interest disclosures from officers and speakers at CME meetings public through their Web site or through other means.

C. Gifting of Promotional Items at Meetings. To distance PMAs from industry marketing activities, and in light of the data on the power of gifts to influence treatment choices, conference meetings should not serve as a setting for industry to distribute branded items to members. No company logos should appear on tote bags, lanyards, pens, notebooks, and publications distributed to members at conferences. In 2009, the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Advanced Medical Technology Association (AdvaMed) are adopting this standard, but their codes are entirely voluntary and make no provision for enforcement.^{28,29}

A PMA may choose to permit industry to purchase and occupy booths in adjoining exhibit hall space at conferences. However, these booths should not be in the obligate path to a scientific or educational session, and must be clearly delineated so that attendees understand that they are entering a marketing site, and are free to do so or not to do so as they choose. Just like some readers skip the advertising pages in a journal, attendees can avoid exhibit hall booths. The PMAs should also set standards for the conduct of an exhibit booth, including a ban on all gifts and food.

D. Satellite Symposia. It is common for pharmaceutical and medical device companies to hold satellite symposia in conjunction with PMA meetings. Some of these symposia may provide CME credit. The information disseminated at these satellite events is not necessarily incorrect, but the satellite programs often appear to be designed to serve a marketing agenda. To gather an audience, some companies have paid PMAs to obtain members' addresses or to have the symposia listed in the conference agenda.^{2,30}

Under no circumstances should PMAs collaborate in industry marketing activities or profit from them. To maintain scientific integrity and to ensure that educational programs are evidence based, PMAs must distance themselves completely from industry

promotions. Although PMAs cannot prohibit companies from running satellite programs, it must be made clear to all participants that the PMA is not endorsing the industry's programs, facilitating their operation, or profiting from them.

Accordingly, PMAs should not endorse, facilitate, or accept funding for satellite symposia. This may be accomplished by not allowing satellite symposia to take place immediately before, during, or immediately after the conference, by not sharing the names and addresses of members, and not sharing conference space. To enforce this policy, PMAs may ban a company that violates these rules from exhibiting at future meetings.

3. Industry Funds for Research by PMAs and Members. Many PMAs fund research projects that they or their members conduct. Research is essential to medical progress and PMAs must be responsible for determining research priorities and which teams to support. Industry should not be allowed to provide a grant for a project of its choosing or be associated with a specific project. Research funds from industry, like educational support from industry, should go to a PMA's central repository or committee as described above. The research awards should be peer reviewed without any involvement from industry. In addition, the PMA and the investigators, not industry, should control the data, determining when and where findings should be presented and published. Although these standards are more stringent for PMAs than for academic medical centers, PMAs have a more immediate and direct influence on setting standards for the medical profession, and for the specialties and subspecialties.

4. Industry Funds for Fellowships and Training Programs. It appears to be common for industry to offer funding to PMAs to support fellowships and training programs for resident physicians and fellows. Providing these physicians with the opportunity to undertake intensive study, training, travel to educational meetings, and research is

crucial for building a cohort of skilled clinicians and investigators. But as in the case of funding for research, decision making about which residents or fellows are chosen and the specific disciplines from which they are selected must be determined by the PMAs alone.

Fellowships should not be named after the pharmaceutical or medical device company sponsors. No conditions may be attached to the gift such as compelling the appointee to meet with company representatives or acknowledge the company by name in a publication or curriculum vitae. Appointees should not know which company's funds underwrote their fellowship or travel so they are not under a sense of obligation to a particular company during the course of their careers. Small specialty societies that primarily relate to a single company should consider avoiding all such support. As with gifts more generally, PMAs should not allow industry payment for such items as journal subscriptions or books.

5. Committees That Formulate Practice Guidelines or Outcome Measures. One of the most significant activities of many PMAs is to formulate practice guidelines and devise performance and outcome measures. These activities guide physician diagnostic and treatment decisions and set evidence-based standards for decision making. By so doing, PMAs also influence reimbursement policies by third-party payers and carry weight in malpractice litigation. Clearly, pharmaceutical and medical device companies have a stake in all of these activities.

For these reasons, the establishment of guidelines and registries must be independent of all industry influence, actual or perceived. Under no circumstances should PMAs accept funding from industry to develop practice guidelines or outcome measures. As Sniderman and Furberg²² recently urged, PMAs must hold the individuals who write guidelines and outcome measures to the most stringent conflict-of-interest standards. Disclosure of industry relationships by committee members is not sufficient protection.

Professional medical associations should be encouraged to appoint to these committees only individuals who have no ties to industry. At a minimum, PMAs must exclude from such committees persons with any conflict of interest (\$0 threshold) involving direct salary support, research support, or additional income from a company whose product sales could be affected by the guidelines.

One concern might be that such restrictions will exclude the most qualified individuals from guideline committees. However, there is a tendency to confuse the most qualified with the most visible. Moreover, any difficulties can be easily circumvented by circulating drafts of guidelines widely for comment, but leaving the drafting of the final document to a group of knowledgeable professionals, who are free of conflict of interest insofar as a particular class of drugs or devices is concerned.

6. Industry Support of PMAs' Publications. Given the importance of the findings and recommendations of PMAs, both the creation and distribution of guidelines and other advisory materials should be independent of industry funding. No PMA publication should bear the logo of a drug or device company. The PMAs should not accept industry funding for journal supplements. Companies are free to purchase the materials, distribute them, and refer to them in their promotional materials. However, PMA documents should always stand alone, and not be associated with a commercial brand.

Just as it can be acceptable for PMAs to derive revenue from industry for exhibit hall displays at scientific meetings, revenue from industry advertising in PMA journals can be acceptable when the advertising is clearly identified as such. Some journals separate advertisements from the scientific and editorial content (both in print and online publications) so that readers can choose to ignore the advertisements or can remove the print advertisements from the journal. However, PMA journals must have policies governing journal-based

advertising to ensure that scientific and editorial integrity is maintained, for instance, by prohibiting editorial decisions to be based on the likelihood of generating advertising revenue and by prohibiting advertising placement to be based on upcoming journal content. As with PMA guideline publications, companies should be permitted to purchase reprints of articles published in PMA journals, but these documents should stand alone, and should not bear the name or logo of the industry purchaser.

7. Product Endorsements. Although some PMAs have endorsed commercial products, ranging from food and toothpaste to sunscreen products, the propriety of doing so is now highly suspect. Nevertheless, the American Academy of Dermatology is prepared to give its seal of approval to certain sunscreen products, charging a sizeable fee for the endorsement.³¹⁻³³ A contract with one or another company sullies the reputation of the PMA, implying that the PMA's name apparently is purchasable by the highest bidder. Accordingly, PMAs should never solicit or accept any offer that would attach its name or logo to a commercial product, service, or activity.

8. Affiliated Foundations. Many PMAs have established affiliated research and education foundations that share their name and their mission. Although separate from a governance and taxation standpoint, these organizations are generally closely aligned with and indistinguishable from the parent PMA. Accordingly, the affiliated foundation must be held to the same standards on conflict of interest as the parent PMA. Gifts and grants from industry should be governed by the policies in effect at the parent PMA. Moreover, in accepting funding directly from its affiliated foundation, the parent PMA is not absolved of the need to avoid or minimize conflict of interest.

9. Conflict of Interest Among PMA Presidents, Officers, and Board Members. The reputation of a PMA is often based on the quality and integrity of its leaders. They speak for the organiza-

tion and are most visible to the public and the profession. The PMA's leaders also exert the greatest influence on policy, deciding which issues are to be addressed and the composition of the committees that will conduct the evaluations and issue the findings. Therefore, it is essential that the president of the PMA, its officers, and its board of trustees be held to the highest standards in avoiding conflict of interest.

At a minimum, the president and officers (eg, president-elect, immediate past president, vice president, secretary, and treasurer) of a PMA should be conflict-free (\$0 threshold) during their tenure. For these individuals, no personal income and no research support should be derived from industry. Because their election or selection typically occurs 2 or more years before they take office, they should be conflict-free from that starting point. This may require would-be office holders to delay assuming the leadership position until an already existing and multi-year grant expires. They should make every effort to maintain that standard in the period immediately following their service.

A PMA should be governed by a board of trustees that is free of conflict of interest. Board members should be asked to sever all financial ties to industry during their term of service; ideally appointments could be made far enough in advance so that board members would be conflict-free for a 2-year period before assuming the position. If this is not yet feasible—it may take a few years to change the culture of an organization—a PMA should require its board members to disclose all conflicts of interest and not to participate when any activity bearing on their conflicts arises.

The PMA's executive and operational staff should have no financial ties with industry and should be prohibited from accepting gifts or other favors. So too, industry should not be permitted to fund any board activity. All travel and meeting costs, including food, are the financial responsibility of the PMA.

Each PMA should have a formal mechanism for reviewing disclosures of conflict of interest. In many organizations it would be most efficient and effective for some combination of president, CEO, general counsel, and compliance officer to have this responsibility. Questions about an individual's conflict of interest might be raised with the PMA's ethics committee chair and members. Disclosure forms should be detailed and explicit, including providing descriptions of activities and the sums received so that appropriate decisions can be made about recusal or removal for an individual.

10. Guidance for PMA Members. As PMAs strengthen their organizational conflict-of-interest policies, they should use the principles and standards developed by the organization to influence and lead their members in adopting similar standards. Each PMA should make explicit that the principles underlying ethical organizational behavior apply to physician behavior.^{16,34} Thus, both physicians and medical societies should avoid marketing industry products. Just as industry gifts influence a physician's decision making, they also can bias a PMA's decision making. A number of academic medical centers and the Association of American Medical Colleges have recently adopted conflict-of-interest policies for faculty that can serve as useful models.³⁵

Conclusion

Enacting these recommendations will require PMAs to transform their mode of operation and perhaps even give up activities of considerable value. The proposals are rigorous: PMAs should work toward a goal of \$0 contributions from industry; they should not collaborate in or profit from industry marketing activities; PMA leaders and executive staff should be free of conflict of interest and, in time, so should the entirety of the board and the members of the practice guideline committees. To maintain integrity will require sacrifice. Nevertheless, these changes are in the best interest of the medical profession, of

PMAs and their members, and of the larger society.

These proposals are likely to generate controversy and claims that they are too restrictive. However, PMAs, like academic medical centers, are at a turning point. Many physician leaders and government officials are calling for fundamental reforms, certain that past practices have undercut scientific integrity and patients' best interests. Professional medical associations have such an important role to play in speaking for medicine, defining best practices, and promoting evidence-based decision making that they cannot allow relationships with industry to diminish the public's trust.

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