

Organizational Guidance: Accepting Commercial Support¹

American College of Clinical Pharmacy, Inc. (ACCP)
ACCP Research Institute, Inc. (ACCP RI)
Pharmacotherapy Publications, Inc. (PPI)

Introduction

Relationships between a professional organization and commercial entities involved in health care² can be appropriate and beneficial to the organization's members. However, the challenge for ACCP, ACCP RI, and PPI (hereafter referred to collectively as "the College"), is to ensure that relationships with commercial entities remain within acceptable professional boundaries and avoid real or perceived conflicts of interest. Therefore, the College has set forth guiding principles and developed policies to govern its interactions with these commercial entities.

One of the College's organizational assets is its reputation for independence and integrity regarding clinical pharmacy practice, research, and the promotion of rational pharmacotherapy. The College believes that relationships between professional health care provider organizations and commercial entities should be carefully structured to avoid compromising the organization's decisions, policies, and reputation for objectivity. Historically, external support from commercial entities has contributed to the College's mission in a variety of ways:

- sponsorship of meetings, publications, and projects
- grants to support continuing pharmacy education (CPE)
- support of awards and awards programming
- support of the exhibitor hall during ACCP's Annual Meeting
- support of research awards, fellowships, and traineeships
- advertising in *Pharmacotherapy*

The policies outlined in this document signal a new approach to acceptance of commercial support and become effective on January 1, 2013. This effective date provides the organization and its members a transition period of nearly 3 years for implementation of the policies in order to minimize disruption to existing programs and practices. However, by declaring its commitment now, the College makes clear its intent to accomplish this transition such that all of the policies will be fully implemented by 2013. Finally, the policies set forth in this document will be revisited regularly to ensure that they remain consistent with the changing regulatory and professional environment surrounding associations' commercial relationships.

¹ Released April 9, 2010, as approved by the ACCP Board of Regents, ACCP RI Board of Trustees, and the Pharmacotherapy Board of Directors.

² Defined for the purposes of this document as pharmaceutical, biotechnology, and medical device companies.

Guiding Principles for Accepting Commercial Support

The following principles guide financial interactions between the College and commercial entities. These principles are designed to reduce or eliminate organizational conflicts of interest and serve as a foundation for the policies set forth in this document.

1. Commercial entities make important contributions to health care. Although positive outcomes can result from financial interactions with commercial entities, avoiding conflicts of interest and preventing undue influence on the College are of paramount importance when these interactions occur. Achieving this goal should not require elimination of all of the College's relationships with a given industry or distancing from ACCP members associated with that industry.
2. Gifts and/or financial support can bias health care professionals' judgment and decision-making.
3. Continuing education and other forms of professional development must be clearly differentiated from commercial marketing practices or programs.
4. The potential financial benefits of commercial support should not affect the College's determination of its activities or strategic/operational agenda.
5. The relationships of leaders of the College (e.g., officers, board members, senior staff) with commercial entities, as well as any organizational ties to industry, can influence the College's direction and priorities. These relationships are addressed in a separate board policy document, "Managing Conflicts of Interest," to guard against undue commercial influence on the College.
6. Although ACCP, ACCP RI, and PPI are separately governed not-for-profit entities, they share a common mission and possess the same core values. Hence, they should be held to the same conflict of interest standards and commercial support policies.

Policies for Acceptance of Commercial Support

Note: The statements below take effect January 1, 2013. Until that time, the College will adhere to its existing continuing pharmacy education (CPE) policies, which comply with guidelines of the Accreditation Council for Pharmacy Education (ACPE), to coordinate all requests for commercial support and documentation of the use of funds for CPE activity. Other aspects of commercial support will be guided in the interim by specific Board of Regents action, if needed.

1. ACCP will neither solicit nor accept any commercial support for CPE activities at its national meetings, whether such support is provided directly or indirectly through subsidiary agencies.
2. ACCP and its chapters can seek commercial support for their meetings (not tied to any specific programming, business meeting, or networking event) to expand or enhance meeting content or quality, or to reduce the cost of the meeting for all attendees.
3. ACCP and its chapters will neither solicit nor accept funds from commercial entities for the provision of social functions during their meetings (including PRN business and networking forums).
4. ACCP and its chapters can offer exhibit programs, and solicit funds to support such programs, with the provision that exhibitors may only provide professional information, books, reprints of articles, and other informational materials, provided that they are of nominal monetary value.
5. ACCP and its chapters can solicit and accept grants to conduct non-CPE activities that foster the advancement of clinical pharmacy and that are consistent with the College's mission.
6. ACCP RI can solicit and accept funding for non-CPE training programs from commercial entities, not-for-profit organizations, and individuals, provided that the evaluation and selection of recipients for participation in such programs are the sole responsibilities of the Research Institute.
7. The ACCP PBRN may seek and accept philanthropy and support from commercial entities, not-for-profit organizations, and individuals for general operational support and the conduct of individual research projects only if the analysis and publication of findings are under the direction of the ACCP PBRN.
8. ACCP may solicit and accept funds for the production and distribution of non-pharmacotherapy, non-CPE publications relevant to clinical pharmacy. ACCP will

not accept commercial support for publications that address drug therapy or for any activity related to governance, strategic planning, policy development, or advocacy.

9. PPI may solicit and accept funds from commercial entities for advertising that is in compliance with FDA standards, for the production of reprints of journal articles or entire issues, and for the support of peer-reviewed CPE supplements that conform to the policies of the PPI Board of Directors.
10. The College does not endorse commercial entities or the products they produce. While ACCP, ACCP RI, and PPI always will disclose financial support from these entities, that disclosure does not imply endorsement.
11. The statements above do not apply to joint initiatives with other professional societies where those societies may have policies governing commercial support that differ from those of the College. In such cases, the Board of Regents will make a determination as to whether the College should enter into such joint initiatives.

Policies for Acceptance of Commercial Support

Frequently Asked Questions

1. Q: When do the policies take effect? If they are to be enforced later, why are they being released now?

A: Strictly speaking, the policies take effect on January 1, 2013. However, it is expected that some policies will be voluntarily followed even before the enforcement date. The College's leadership is releasing the policies now in order to allow its members, PRNs, chapters, staff, and other stakeholders enough time to plan alternate approaches to managing their respective operations; and to begin the process of identifying alternate sources of financial support. In the case of ACCP staff, planning for new products, services, and budgeting strategies is already underway in order to assure that members don't suffer a reduction in services or a sharp increase in expenses (e.g., for dues, meetings, products, or services) in 2013.

2. Q: When the document refers to "the College," to what organization(s) is it referring?

A: In this document, "the College" refers to all 3 entities (ACCP, the ACCP Research Institute, and *Pharmacotherapy*).

3. Q: When the document refers to "ACCP, Inc.," to what is it referring?

A: ACCP, Inc. refers to the parent organization (ACCP) and includes its regional chapters, PRNs, committees/task forces, officers, and Regents; and the products and services delivered by ACCP.

4. Q: When the document refers to "ACCP RI," to what organization(s) is it referring?

A: ACCP RI refers to the ACCP Research Institute and includes its programs and services (such as the Practice-based Research Network and the Focused Investigator Training Program), Web site, and elected and appointed trustees.

5. Q: When the document refers to "PPI, Inc.," to what organization(s) is it referring?

A: PPI, Inc. or Pharmacotherapy Publications, Inc., includes ACCP's official journal, *Pharmacotherapy*, and its supplements and Web site; the journal's Scientific Editors; and the Board of Directors.

6. Q: Policy statement #1 indicates that ACCP will not solicit or accept any commercial support for CPE activities at its national meetings. Does this apply to PRNs?

A: Yes. PRNs coordinate fundraising through ACCP staff and hence cannot directly solicit or accept commercial support. All formal solicitation and acceptance of funds, according to the ACCP PRN Handbook, are only conducted by ACCP staff. Therefore, when this policy takes effect, commercial support for CPE will no longer be sought or accepted for PRN focus sessions during ACCP's national meetings.

7. Q: Policy statement #2 indicates that ACCP and its chapters can seek commercial support for their meetings (not tied to any specific programming, business meeting, or networking event) to expand or enhance meeting content or quality, or to reduce the cost of the meeting for all attendees. Will PRNs still be able to obtain support for their business meetings and networking forums under this policy?

A: No. When this policy takes effect, ACCP will no longer be able to accept commercial support for any specific program, business meeting, or networking function. This includes the PRN business and networking forums held during ACCP's national meetings. ACCP will be able to accept "general support" from a commercial entity not tied to any specific programming or event. For example, a company can support an ACCP national meeting as a "silver" or "gold" sponsor if that support is used to support expenses of the meeting, in general. In such situations, the sponsoring company would receive from ACCP acknowledgements in the meeting promotional materials and other considerations (such as a number of complimentary meeting registrations, priority exhibit space in the exhibit hall, and so forth).

8. Q: If the College is trying to limit commercial influence, why is it permissible to accept "general support" from commercial entities as is described in the answer to question 7 above?

A: The College is trying to establish a balance between commercial support and commercial influence. In the case of specific therapeutic CPE presentations and PRN business/networking sessions, the potential for gaining influence through provision of financial support is apparent. However, the College recognizes that the clinical pharmacy discipline shares a number of interests with its commercial partners, including quality patient care outcomes. It also recognizes that many of its members have previously worked in industry, are currently employed by industry, or will in the future work for an industry employer. Therefore, the

College and industry enjoy an often complex, but potentially symbiotic, relationship. Hence, if a commercial entity values clinical pharmacy and wishes to lend financial support to the discipline, provision of this “general support” provides an acceptable mechanism by which a company can contribute to the College’s members without generating undue influence on therapeutic decisions or professional judgment.

9. Q: Policy statement #1 indicates that ACCP will neither solicit nor accept any commercial support for CPE activities at its national meetings, whether such support is provided directly or indirectly through subsidiary agencies. What does the underscored language above mean?

A: The statement is intended to cover not only support provided directly to ACCP by a pharmaceutical company or other commercial entity, but also funding provided indirectly through a “third party,” such as a medical education/communications company. In this latter case, the third party offers an educational program with financial support it receives from a pharmaceutical company or other commercial organization.

10. Q: Statement #3 indicates that ACCP and its chapters will neither solicit nor accept funds from commercial entities for the provision of social functions during their meetings (including PRN business and networking forums). Does this mean that receptions and other networking events, at both ACCP national meetings and regional chapter meetings, will no longer be eligible for commercial support?

A: Yes. Receptions at ACCP meetings, dinners at Chapter meetings, refreshments during PRN business meetings and networking forums, and other social activities will no longer be eligible to receive commercial support when this policy takes effect.

11. Q: Statement #4 indicates that ACCP and its chapters can offer exhibit programs, and solicit funds to support such programs, with the provision that exhibitors may only provide professional information, books, reprints of articles, and other informational materials, provided that they are of nominal monetary value. What constitutes “nominal monetary value?”

A: No specific monetary amount has been assigned to this policy. In this statement, “nominal” means an amount that would not be considered of particular value to most ACCP members or meeting attendees. That is, something of educational/professional use that is not associated with a substantial retail cost, such as an article reprint or set of reprints; a chart, guide, or model that could be useful for teaching purposes but that no student would object to purchasing themselves; perhaps a small book, if it is not deemed expensive. Note that

“nominal,” as used here, is not equivalent to the modest value items referred to in the 2009 PhRMA guidelines (stipulated to be \$100 or less in value). In the case of ACCP’s policy, nominal is meant to apply to a value much less than \$100.

12. Q: Statement #5 indicates that ACCP and its chapters can solicit and accept grants to conduct non-CPE activities that foster the advancement of clinical pharmacy and that are consistent with the College’s mission. What are some examples of such “non-CPE activities?”

A: Examples that would be characterized here as appropriate non-CPE activities would include a forum or panel discussion on postgraduate training; a non-CPE discussion of “how to study for the board certification exams;” or a poster session, provided no CPE credit is provided, no food/refreshments are provided, and the objective is to disseminate research findings not focused on a single drug or therapeutic area.

13. Q: Statement #6 indicates that ACCP RI can solicit and accept funding for non-CPE training programs from commercial entities, not-for-profit organizations, and individuals, provided that the evaluation and selection of recipients for participation in such programs are the sole responsibilities of the Research Institute. What kind of non-CPE training programs is this referring to?

A: ACCP RI non-CPE programs would include the Focused Investigator Training (FIT) Program, a PBRN member online training module or live session, a grantwriting course, or other possible non-CPE programs that similarly address the mission of the Research Institute.

14. Q: Statement #8 indicates that ACCP may solicit and accept funds for the production and distribution of non-pharmacotherapy, non-CPE publications relevant to clinical pharmacy. ACCP will not accept commercial support for publications that address drug therapy or for any activity related to governance, strategic planning, policy development, or advocacy. What are some possible examples of “non-pharmacotherapy, non-CPE publications relevant to clinical pharmacy?”

A: At present, ACCP’s print and online *Directory of Residencies, Fellowships, and Graduate Programs* would be examples. A booklet or online module on clinical pharmacy careers, clinical teaching, or other non-therapeutic subjects would also be eligible for commercial support under this policy.

15. Q: Statement #9 indicates that PPI may solicit and accept funds from commercial entities for advertising that is in compliance with FDA standards, for the production of reprints of journal articles or entire issues, and for the support of

peer-reviewed CPE supplements that conform to the policies of the PPI Board of Directors. Why are CPE supplements eligible for commercial support while commercially-sponsored “satellite symposia” cannot be delivered at ACCP’s meetings?

A: Articles that appear in *Pharmacotherapy* supplements are subject to the same peer review and conflict of interest disclosure processes that are applied to any manuscript submitted to the journal. Hence, they undergo a level of prospective peer and editor review prior to publication that is not possible to replicate for a live symposium delivered during a national or regional meeting.

16. Q: Statement #11 indicates that the policies don’t apply to joint initiatives with other professional societies where those societies may have policies governing commercial support that differ from those of the College. In such cases, the Board of Regents will make a determination as to whether the College should enter into such joint initiatives. Why is this provision included in this document?

A: In developing this guidance document on commercial support, the respective boards were sensitive to the fact that organizational policies in this area are in a state of flux among virtually all health care professional societies. Because ACCP and its PRNs frequently seek to collaborate with professional societies from other disciplines (including medical specialty organizations like the Heart Failure Society of America and the Society of Critical Care Medicine) and from other parts of the world (including the European Society of Clinical Pharmacy), there was concern that ACCP should not necessarily impose its policies on a collaborating professional society. Hence, it will be left to the Board of Regents to determine if a given collaborative activity should be pursued in situations where another organization’s policies are at odds with one or more ACCP policies regarding acceptance of commercial support.

17. Q: What are the likely financial implications of this policy for the College? Is the organization likely to find itself in an unstable financial situation? Should members expect dues, meeting registration fees, and prices of products and services to increase substantially in order to compensate for lost commercial revenue in the future?

A: The implementation of these policies is expected to have little or no impact on the College or its members. ACCP is fortunate in that it has never been heavily dependent on commercial support to meet its mission. The ACCP leadership has considered carefully the potential outcomes of these policies and has concluded that they will strengthen the College by creating enhanced levels of independence and credibility. No price tag can be assigned to such

organizational integrity. Importantly, identification of new sources of revenue to compensate for the forthcoming decline in commercial support has already begun and ACCP doesn't foresee the need to substantially increase dues or prices of its products and services in the future (beyond the normal adjustments that already occur in response to inflation). In addition, the College continues to seek ways to reduce the cost of its activities through the use of technology, elimination of redundancy, and implementation of more efficient practices in a variety of its operations. Finally, ACCP leadership and staff will be working to provide PRNs and chapters with ideas to help advance their respective agendas in new ways, including different approaches to educational program delivery, business meetings, and networking.