CONFLICT OF INTEREST: ACCP PUBLICATIONS
POLICY AND PROCEDURE

Background
In August 1999, the ACCP Board of Regents approved the policy, “Conflict of Interest: ACCP Publications Policy and Procedure.” At its January 2003 meeting, in response to inquiries from the editorial board of the Pharmacotherapy Self-Assessment Program, Fifth Edition (PSAP-V) and an ACCP member employed by the pharmaceutical industry, the Board of Regents reviewed the policy. The Board discussed (1) a possible revision in ACCP’s current financial threshold for conflict of interest, to reflect income from multiple sources; (2) whether the conflicts disclosed by contributors should be published within the publication; and (3) a need to expand the policy beyond its current focus on potential conflict of interest in drug therapy recommendations.

The Board of Regents directed that staff, with input from selected ACCP committees, provide further structure and clarity to the policy for Board consideration at a future meeting. To address this charge, staff reviewed policies and procedures related to conflict of interest from a variety of sources including: the American Journal of Health-System Pharmacy (AJHP), Annals of Internal Medicine; Food and Drug Administration (FDA); International Committee of Medical Journal Editors; Journal of the American Medical Association (JAMA); Journal of the American Pharmaceutical Association (JAPhA); New England Journal of Medicine (NEJM); and the Public Health Service (PHS), which includes the National Institutes of Health (NIH).

Each of these sources has policies and procedures in place to identify, manage, and disclose conflicts of interest, whether in research or in scholarly publication. Some, like FDA and PHS, specify financial thresholds for disclosure of significant financial conflict of interest. PHS requires individuals and institutions applying for research funding to disclose significant financial interests of investigators (and their spouses and dependent children). PHS defines significant financial interests as interests that would be affected by the research, or interest in entities whose financial interests reasonably appear to be affected by the research. Applicants for PHS funding are required to disclose investigators’ equity interests exceeding $10,000 or 5% ownership in a single entity, as well as salaries and other payments expected to exceed $10,000 over the next year.

The Food and Drug Administration makes similar requirements of applicants who submit marketing applications for human drugs, biological products, or medical devices and submit clinical studies in support of those applications. FDA requires applicants to disclose financial interests and arrangements of the investigator. The agency requires disclosure of: (1) arrangements between the sponsor and investigator (or spouse or dependent child) in which the value of the investigator’s compensation could be influenced by the study outcome; (2) significant payment from the sponsors to the investigator or institution supporting the investigator’s activities that are valued at more than $25,000 beyond the cost of conducting the study; (3) proprietary interests, including patents held by the investigator in the product; or
(4) significant equity interests in the sponsor whose value cannot be determined through public prices or valued at more than $50,000, if the sponsor is publicly traded.

NEJM requires that authors of reviews and editorials not have a significant financial interest in a company (or its competitor) that makes a product discussed in the article. The journal’s definition of significant financial interest, consistent with PHS, is an annual sum of $10,000. NEJM further considers significant any holding in both publicly and privately traded companies in which the potential for profit is not limited, such as stock, stock options, and patents. Though the thresholds vary among these organizations, their disclosure policies are consistent with ACCP’s policy of establishing financial thresholds for the identification and management of conflict of interest.

The discussion of the Board of Regents at its January 2003 meeting addressed disclosure of conflict of interest through publication of disclosure statements within ACCP publications. The International Committee of Medical Journal Editors discusses this issue in its Uniform Requirements for Manuscripts Submitted to Biomedical Journals. The requirements state, “Participants in peer review and publication should disclose their conflicting interests, and the information should be available so that others can judge their effects for themselves.” The *Annals of Internal Medicine*, in its “Information for Authors,” states that the publication will publish conflict of interest disclosures. NEJM also publishes disclosures of authors of research articles, as well as disclosures of authors of reviews and editorials below the thresholds described above. Although these are journal policies, while ACCP’s policy governs its book and audiovisual publishing program, there are sufficient similarities to support publication of disclosure statements in ACCP publications.

The Board of Regents discussed a broader focus for ACCP’s conflict of interest disclosure beyond pharmaceuticals to include, for example, medical device manufacturers, computer hardware and software vendors, medical education and communication companies, and biotechnology companies. Both NEJM and *Annals* provide broad direction to prospective authors regarding disclosure of conflict of interest. NEJM’s disclosure statement explains, “The editors’ interest extends to those areas relevant to the article that, broadly viewed, could be construed as constituting a conflict of interest or the appearance thereof.” For some activities, such as consulting fees and paid advisory boards, the journal requires disclosure for the past two years, while lecture fees are to be disclosed for the past two years or the known future. *Annals* asks authors to indicate whether or not they have any of several listed relationships “with an entity that has a financial interest in the subject matter discussed in the manuscript,” and to provide details of the relationship. The disclosure period is the past five years through the present. These policies support ACCP’s interest in broadening the focus of its conflict of interest disclosure. The policies also point out a need to identify a disclosure period for ACCP’s policy.

Based upon the above review of conflict of interest policies and procedures, and subsequent to discussion by the Board of Regents, the following policy, procedure, and disclosure form were approved by the Board of Regents January 22, 2004.
POLICY AND PROCEDURE

Purpose
The purpose of the conflict of interest policy is to identify and address the opportunity for excessive, real or perceived, conflict of interest among contributors to ACCP publications.

It is recognized that prospective contributors to ACCP publications also may be asked to participate in a variety of projects from a wide variety of sources. Their participation in these projects may enhance the standing of the individual and the individual’s contribution to ACCP projects.

This policy is designed to provide flexibility for professional participation, while avoiding real or perceived conflict of interest that may adversely affect the quality of ACCP publications.

Works published by ACCP often provide recommendations for drug therapy that directly impact patient care. Drug therapy recommendations should be based on the best interests of the patient and sound principles of pharmacology and pharmacoeconomics. Conflict of interest may influence the thinking of the contributor, leading to sub-optimal drug therapy recommendations. Further, because pharmacists frequently influence the purchase of nonpharmaceutical products, services, and devices, ACCP publications may periodically discuss these products, services, or devices. Conflict of interest may again influence the thinking of the contributor, presenting an opportunity for bias.

Scope
This policy applies to all publications where ACCP holds the copyright or ACCP is the primary publisher, other than Pharmaco therapy, which maintains its own policies on conflict of interest unique to the needs of a scientific journal.

Definition
Conflict of interest is defined as a direct or indirect interest or relationship that is inconsistent or conflicts with the responsibilities, duties, loyalty, or the exercise of independent judgement. This conflict of interest may be with the participating individual, with an immediate family member, or significant other. Conflicts of interest are often, but not always, financial.

Real conflict of interest exists when an individual has professional or personal interests that are obviously and directly inconsistent with the goals of the ACCP publication.

Perceived conflict of interest exists when the individual has professional or personal interests that might suggest an inconsistency in the reasonable judgement of a person outside of the project.

Direct income is defined, for the purposes of this policy, to be any income paid directly to the individual.
Policy
Any potential author, reviewer, editor, or contributor to an ACCP publication will be evaluated to determine if the potential for excessive real or perceived conflict of interest exists. If this evaluation determines that conflict of interest does exist, that individual will be excused from duty or participation in that ACCP publication.

Procedure
1. At the time they are asked to participate in an ACCP publication project, but before any substantial work has been completed, each author, reviewer, editor, or other contributor will be asked to submit a curriculum vitae and complete the Conflict of Interest Disclosure Statement. The disclosure period will extend from the past two years through the known future.

2. The documentation returned will be evaluated by staff and a relevant member of the appropriate editorial board (e.g., the editorial board member responsible for the chapter that the author is to write) to determine the types and extent of conflicts of interest that exist. Those with a real or potential conflict of interest (see 4 and 5, below) will be reviewed by the entire editorial board of the publication involved.

3. Categories of potential conflict of interest that should be disclosed include, but are not limited to:
   - salary, royalties, and licensing fees
   - receipt of grants, research support, scholarships, awards, gifts, consulting fees, or honoraria
   - substantial equity interests (equity ownership, stock options, partnerships, or other equity, exclusive of mutual funds, in publicly or privately traded firms)
   - membership on boards, advisory panels, committees, or other regulatory body
   - participation in other publications
   - patents, copyrights, or other intellectual property

4. Individuals who receive more than 10% of their annual direct income from a single pharmaceutical manufacturer, or its agents, may be considered to have excessive potential for real or perceived conflict of interest and may not be eligible to participate in chapters or sections of publications that make drug therapy recommendations. Individuals who receive more than 25% of their annual direct income from multiple pharmaceutical manufacturers, or their agents, may be considered to have excessive potential for real or perceived conflict of interest and may not be eligible to participate in chapters or sections of publications that make drug therapy recommendations. However, these individuals may be eligible to participate in chapters that focus on non-drug therapy issues (pharmacoeconomics, computer systems, drug information, etc.).

5. Individuals who receive more than 10% of their annual direct income from a single commercial interest, or its agents, whose products, services, or devices, or those of competitor companies, are to be discussed in a chapter or section may be considered to have excessive potential for real or perceived conflict of interest and may not be eligible
to participate in the chapter or section. Individuals who receive more than 25% of their annual direct income from multiple commercial interests, or their agents, whose products, services, or devices, or those of competitor companies, are to be discussed in a chapter or section may be considered to have excessive potential for real or perceived conflict of interest and may not be eligible to participate in the chapter or section. However, these individuals may be eligible to participate in chapters that focus on issues other than products, services, or devices.

6. The Editorial Board of each project will be responsible for determining if an individual author, reviewer, or other contributor should participate in a project based upon their conflict of interest disclosure.

7. The Board of Regents will be responsible for determining the composition of Editorial Boards for ACCP publications, based upon their conflict of interest disclosure. If an Editorial Board is not seated for a project, then ACCP staff will approve the authors, reviewers, and other contributors, in consultation with the BOR as needed.

8. Conflict of interest that may prevent participation in one publication may not influence the eligibility of that contributor for participation in another publication.

9. Disclosures from Editorial Board members, editors, authors, reviewers, and other contributors to ACCP publications will be published in the respective publication.

10. Conflict of interest disclosures will appear at the end of the relevant chapter or section of the publication. Published disclosures will include at least the type (e.g., stock, royalty, patent, etc.) and source of the financial interest. Disclosures will conform generally to the sample format below. The Editorial Board for a publication will determine whether additional information should be disclosed, or whether the format of the published disclosure should be modified. If an Editorial Board is not seated for a project, ACCP staff will make these determinations, in consultation with the Board of Regents as needed.

SAMPLE Disclosure of Potential Conflicts of Interest: Consultancies: John Doe (XYZ Corporation); Stock ownership: Jane Smith (ABC Corporation); Royalties: Jane Doe (ABC Corporation, royalties to spouse); Honoraria: John Smith (speaker’s bureau, XYZ Corporation); Grants: John Doe (ABC Corporation).