

### III. SUBCOMMITTEE REPORTS

#### ASSOCIATION INCOME SUBCOMMITTEE

Dr. Tucker

The Association Income subgroup of the Task Force on External Funding was charged with examining how best to accept, receive, and administer grants and contracts funded by external sources, in order to maintain the operational and mission integrity of APA. As summarized here, we reviewed (1) policies and recommendations adopted by other professional organizations to address issues arising from external funding, with a goal of identifying those with applicability to APA; and (2) existing APA policies and procedures that pertain to external funding, with a goal of identifying areas of adequate and inadequate protection of APA's interests. Based on consideration of these materials, options and recommendations are offered for further development of APA's policies and procedures in ways that protect against risk in the area of association income while capitalizing on the benefits and opportunities afforded by external funding.

#### **External Funding Policies of Other Professional Organizations**

While the Task Force on External Funding represents APA's initial effort in this area, pharmaceutical funding in particular has been a matter of concern for other associations of health professionals for some time. During the late 1980s, the marketing policies of pharmaceutical companies generated significant concern among the health professions about possible conflict of interest. This resulted in several professional organizations adopting ethical guidelines or relevant recommendations in the early 1990s, including the American Medical Association (AMA), the American Nurses Association (ANA) and the American College of Physicians (ACP).

More recently, a resurgence of concern has arisen both about gifts to individual practitioners and about pharmaceutical support of professional organizations and their continuing [medical] education (CME) activities. The AMA, ACP, and the Accreditation Council on Continuing Medical Education (ACCME) have all undertaken policymaking or begun educational activities on the topic. Of particular interest is that, in early 2001, the American Psychiatric Association (ApA) convened a committee to develop guidelines governing the interaction of ApA with the pharmaceutical industry. However, there is no evidence on the ApA website that these guidelines have been developed or approved. Although the formation of the ApA committee was heralded in the *Psychiatric Times*, we could find no subsequent description of any committee work products, despite the fact that this controversial issue continues to be covered in that publication.

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These efforts by professional organizations have primarily addressed the issues of 1) gifts or incentives to individual health professionals—generally physicians—from industry; and 2) industry support for CME. Apart from CME, these professional organizations are generally silent on the issue of relations between the pharmaceutical industry and professional organizations.

It should be noted that in response to the concerns of the health professions--and to the related specter of government regulation--the pharmaceutical industry adopted a new "marketing code," which was approved by the Pharmaceutical Research and Manufacturers Association (PhRMA) in April, 2002. The code describes in detail what are considered to be appropriate and inappropriate interactions of pharmaceutical sales representatives with healthcare professionals. The code appears to be a reasonable set of policies and covers general interactions, entertainment, continuing education, use of consultants, and educational and healthcare practice-related items (i.e., gifts), in parallel to healthcare professional associations' focus on individual practitioners and on CME. We have no evidence that this code has actually been put into practice since then.

### **Need for APA Policies**

The consideration of the types of policies that may best serve and protect APA in managing external funding involves two levels. As discussed next, the first level relates to issues that may be appropriate for policymaking by APA governance, thereby providing a framework for implementation by APA staff. The second level relates to internal administrative functions that fall clearly within the authority and functions of staff.

### **Policies at the Governance Level**

In examining the efforts of other professional organizations, the policies and procedures of the American College of Physicians (ACP) appears to be the most comprehensive and informative with respect to APA's issues. ACP approved a set of Core Principles in 2001 and promulgated an excellent position paper in 2002 that clearly separates the issue of individual physician-industry relations from organizational-industry relations. While many of the policies developed by ACP apply to interactions between the organization and pharmaceutical companies, it is important to note that they are written broadly enough to apply to all external funding sources. This recognition that significant funding from sources such as foundations or even the government may also convey the risk of distorting organizational mission seems important to our task force.

These ACP policies are directly relevant to the task of the Association Income subgroup and appear to be directly applicable to APA. Therefore, APA may wish

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to consider their adoption with minor modifications. Particularly relevant is the following section of the 2002 ACP position paper:

Position 4: Support for Medical Society Activities

*Medical professional societies that accept industry support or other external funding should be aware of potential bias and conflicts of interest and should develop and enforce explicit policies that preserve the independent judgment and professionalism of their members and maintain the ethical standards and credibility of the society.*

**Rationale**

*Medical professional societies share the physician's duty to advocate and act in the best interest of the patient and society, and they are expected to serve as independent and trustworthy sources of health care information and education for members and the public. In developing specific projects or meetings to achieve these goals, many professional associations seek external funding to defray costs. While such arrangements are legitimate, they can result in dual commitments or conflicts of interest. External funding has the potential to alter an organization's agenda, influence its policy positions, or weaken its credibility. To avert potential conflict or bias, which in turn may affect members, professional societies need to adopt specific institutional policies governing their relationships with industry.*

In the view of the Association Income subgroup, the types of institutional policies referred to in the preceding paragraph would generally be policies developed by the CEO, CFO, and other senior staff, which serve to operationalize broader policy statements that reflect the intent and will of APA governance.

The American College of Physicians-American Society of Internal Medicine Core Principles for External Funding and Relationships also contains policy relevant to governance. The following principles, approved by their Board of Regents in July, 2001, appear to be generally appropriate for adoption by APA:

*Commercial, government, foundation, and other funding and relationships can help the College promote its goals and mission of enhancing the quality and effectiveness of health care. However, some financial arrangements might bias, or be seen to bias, the College as an independent, trustworthy, and credible source of health care information, policy, and education.*

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*The following principles should guide financial and other relationships with outside organizations.*

- 1. The College's values, its mission, and its commitment to professionalism and excellence in medicine must drive all external relationships and externally funded activities.*
- 2. Relationships with external organizations and funders should promote the health and welfare of the public or patient care. Member benefits resulting from external arrangements should enhance professionalism and physician practice.*
- 3. In representing the College in external relationships, College leadership and staff must adhere to the values and ethical standards of the organization and should act to promote professionalism and trust in the organization and the medical profession.*
- 4. External funding arrangements and external relationships must be disclosed to relevant parties on a regular basis and with sufficient detail and visibility to allow concerned parties to reach independent conclusions about potential sources of influence and real or perceived conflicts of interest.*
- 5. Specific instances in which a financial arrangement or relationship might have the potential to influence the College's actual or perceived independence, credibility, and trustworthiness should undergo College review to minimize or eliminate such influence.*
- 6. The College should monitor its overall reliance on commercial sources of funding and ensure that its core activities could continue if such support were diminished.*

### **Administrative Policies Internal to APA**

Our second level of review focused on current APA policies and procedures that pertain to applications for external funding and the fiscal management of successful awards. The review generally revealed that APA already has in place many pertinent and protective policies and procedures that govern the solicitation, use, and management of external funds. Although there are select issues identified herein that may require further development, the existing policies and procedures seem well conceived, comprehensive, and appropriately protective of APA. Their functional value is suggested by the fact that APA has been receiving external funds to execute contracts and grants for some time

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without adverse consequences, although the scope of this activity heretofore has been modest. To illustrate this, a list of projects funded in 2002 -- including project title, funding source, amount, Principal Investigator, and period of performance—is presented in Appendix A.

Parallel policies and procedures for the APA Practice Organization (the (c)6 organization) remain to be developed and are beyond the scope of the Task Force's charge. They will likely entail some differences due to the variations in the organizational mission, scope, staffing, and tax status of the (c)3 and (c)6 organizations, but many of the overarching principles will almost certainly be identical.

Appendix B presents relevant sections of the APA Policies and Procedures manual (*G1. Grants and Contracts, G3. Research Projects, G4. Vendor Agreements*), which are summarized here.

Section G1.01 (*Grants and Contracts: Policy*) states that the APA CEO “. . . may apply for or accept sponsored contracts, grants, and donation of funds for special or additional activities of the Association within the following limits”:

- *The project must clearly fall within APA's "special competence."*
- *The project cannot be “. . . more competently conducted by an existing group such as a university department or laboratory, public or private research and consulting organization” (non-competitive clause with Association members).*
- *The project will not “. . . interfere with APA activities already underway nor overtax APA's facilities.”*
- *The project will be “evaluated, in advance of its submission, by the respective executive director in conjunction with the APA board or committee most directly concerned with the substantive matters involved as deemed appropriate, by the CEO (or his/her designee), legal counsel, and the grants/contracts office.”*

“General principles” that govern all work related to grants and contracts are also delineated, as follows:

- *Adherence to the "highest ethical standards" and maintenance of APA's "reputation for integrity.”*
- *No proposal will be pursued for funding:*
- *“. . . on a topic unrelated to APA's mission and objectives, [is] outside APA's special area of competence, or antithetical to APA's positions as an Association.”*
- *“. . . as a conduit for funds for divisions, state associations, members, or any other organizations.”*
- *“. . . has the appearance of or presents a conflict of interest and has not been approved in advanced by the CEO and/or COO or a designee.”*

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The latter directive appropriately precludes APA members who serve on governance groups that make recommendations about funding from serving as consultants or subcontractors on awards that result from those recommendations. However, the CEO and/or COO are given “. . .the authority to modify or take exception to these policies on a case-by-case basis.”

### **Review of proposed projects**

As a condition of accepting Federal awards, APA implicitly agrees to comply with applicable laws, regulations, and the provisions of its contracts and grant agreements, including the requirement to subject the Association to annual independent audit of both its financial records and its major (grant) programs. Recent passage of the Sarbanes-Oxley Act and the post-Enron accounting environment now require that business officers adopt best practices to ensure both the accuracy of the organization’s financial statements and the effectiveness of its system of internal controls, disclosure of instances of known deficiencies in the internal control system or fraud, adoption of an institution-wide compliance program, and education of institutional leaders about financial and other internal control matters.

According to current APA operating policies and procedures, no proposal or application for funding—whether new, follow-on, continuing, or renewal—may be submitted to an external agency without the review and approval of the Executive Management Group (EMG). EMG includes the CEO, COO, CFO, the General Counsel, the Executive Directors of the four Directorates of APA, as well as the Executive Directors of Publications and Communications, Public Affairs, and Governance Affairs.

Appendix C presents the form now used by eligible senior staff members to request review and approval for such initiatives by the EMG. Required information includes the title of the proposal; a description of the initiative, sponsor, amount of funding, period of performance; a justification for APA to pursue the proposed project (rather than an APA member(s) or a university); staffing requirements, including name, role/title on the project, % effort, APA employee or temporary project position; as applicable, planned subcontractors or consultants; and APA in-kind support with approximate value (e.g., staff, support of other offices, space, equipment, printing costs).

In all applications for external funding, the Principal Investigator must be a senior APA employee. In addition, APA is to “. . . propose and perform 70% or more of any effort . . . and [to] maintain total control of that efforts' performance.” Subcontracts are allowed, as long as APA fulfills its level of required effort and maintains full control of the project performance. Data, text, and publication rights must be addressed in the proposal.

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A detailed project budget must be provided and approved by the APA Grants and Contracts Office (Finance). Per Section G1.02 (*Grants and Contracts: Guidelines and Rules Governing*), the Grants and Contracts Office reviews proposal budgets to ensure that they conform to GAAP (generally accepted accounting principles) and, as applicable, OMB Circular A-122 Cost Principles. This office secures legal review of each proposal and the approval of the CFO, CEO and/or COO as appropriate.

It is required that all project budgets for external funds include indirect cost charges. Indirect cost rates are determined by the federal government through APA's cognizant federal agency, the Department of Health and Human Services. At present, indirect cost rates are 8% of total direct costs or 56% of salary, whichever is applicable to the type of award. These rates must be applied consistently to all externally funded projects regardless of the sponsor.

The APA Research Office (RO) in Central Programs provides a range of relevant support services, including but not limited to assisting with proposal development. The RO does not exercise substantive oversight of projects (per Section G3) other than fulfilling a general directive to:

*“ . . . not undertake/or participate in any project that is offensive or burdensome to APA members or proposed samples that is inconsistent with the mission and goals of the APA or, that is not directly related to the mission of the ‘sponsoring’ office.”*

### **Administration of funds generated by external awards**

Section G1.03 (*Grants and Contracts: Responsibilities Following Approval and Award*) contains principles that direct the internal administration of external funds. In general, external awards are managed in such a way that there is no “co-mingling” of those funds with the APA core budget at any point in the administration of external awards. This approach appropriately minimizes the risk of creating undue dependencies on external funds for core Association activities and promotes their appropriate “value added” function in line with Association policies.

When a proposal is funded, the costs generated by the award are segregated into a separate program budget directed by the eligible APA employee serving as Principal Investigator. The project budget is maintained separately from core APA budgets and from other funded project budgets in order to segregate the sponsored project activity for monitoring and accounting purposes for each project. An entirely separate set of budget codes is created, including salary lines, in order to accomplish this goal. All allowable direct costs are charged to the program.

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APA staff cannot receive salary in excess of normal wages for involvement in an externally funded project, and staff positions funded by external projects are not considered “approved, budgeted, headcount positions.” Grant-funded employees are funded only as specified in the award, and these facts are disclosed to potential employees at the time of a job offer. All consultants or subcontractors on a funded project must sign an agreement that specifies terms and conditions prior to receiving payment from the sponsored project funds.

Finance oversees the accounting of direct, indirect, subcontract, and other fiscal categories associated with external awards. The Grants and Contracts Office is responsible for monitoring and ensuring compliance with “all APA grant and contract policies and procedures and sponsor terms and conditions” (Section G1.02). For example, all project expenditures must be within the scope of work and the parameters outlined in the award notice, and only individuals included in a funded project can incur costs under the award.

### **Avoiding Dependence on External Funding**

Avoiding dependence on any type of external funding—including pharmaceutical funding—for key structural parts of APA is a goal that is both important and simple in concept (see ACP Core Principle 6). With regard to direct support, this goal is essentially achieved by existing financial policies and operations. Actual expenses, including staff time, are generally reported and charged to a separate Contracts and Grants program for each project.

The situation becomes far more complex if one considers indirect support—that is, the reduction of expenditures in operating budgets when costs that would normally be charged to these budgets are covered by external funds. For example, if a portion of an employee’s time is being charged to a grant or a contract—and assuming that no additional employee has to be paid to cover parts of the first employee’s regular duties that he/she is now unable to do because of duties related to the contract or grant—then money is saved in the core APA budget equal to the proportion of salary that is not being paid by APA. Similarly, if after completion of an externally funded project (e.g., a fixed price contract) any unexpended funds revert to the APA general fund then this contract is in an indirect sense supporting core APA activities for the following year.

This type of “indirect support” does not seem to create significant concerns, as long as APA core budgets are not developed based on the assumption of external funding. Managers should not be permitted to increase budgets by the amounts of anticipated offsets unless it is for an additional expense that has directly resulted from the contract or grant, such as having to hire temporary staff to perform some or all of the former duties of grant personnel.

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If the goal of the Association were to completely separate any external funding from APA operating budgets, a specific accounting mechanism for designating or encumbering these funds would need to be created. Such mechanisms already exist for other purposes in APA. In all probability, such funds set aside would have to be accounted for as Board of Directors-approved designations of net worth. Under this model, any “net” remaining funds after completion of the project would have to be placed in a separate designated fund, and appropriate rules would need to be developed for use of this fund. This is referred to as an “allocation of net worth.”

### **Options and Recommendations**

The complex risks associated with accepting external funding must be weighed carefully against the benefits, which can be considerable under the right circumstances. To consider only the risks associated with external funding is to forego opportunities to use these funds in ways that advance psychology and APA’s interests and that would otherwise not be possible. Importantly, it should be recognized that APA is in a unique position to undertake some projects that cannot be done otherwise and that will benefit the Association and psychology. **Therefore, it is recommended that a risk/benefit analysis govern the development of policies and procedures that create a proper context and essential safeguards so that APA can accept and use external funds for appropriate purposes, without incurring undue dependency on them for core association activities.**

A couple of completed projects illustrate this point about the opportunities and benefits afforded by external awards:

The APA Practice Directorate has implemented an Internet-based data collection system known as PracticeNet that surveys licensed psychologists about what transpires during the delivery of services. PracticeNet participants are volunteer APA members who provide clinical services in any setting. PracticeNet uses Real-Time Behavioral Sampling (RTBS) methodology to collect provider reports about a single, specific, recent episode of care at a randomly selected time. RTBS reduces sources of reporting inaccuracy common in conventional survey methods (e.g., mental averaging, subjective inferences). Questions assess provider behavior (e.g., assessment or treatment procedures used), client and setting characteristics, and financial arrangements. Each survey can be completed in fifteen minutes or less. When summed over providers and care episodes, practice trends can be established and monitored. PracticeNet offers a user-friendly, feasible, computerized method to assess provider behavior in specialty and non-specialty settings. It presents opportunities for practice improvement based on established

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communication with front line practitioners and for surveillance of practice patterns over time.

PracticeNet has been built entirely with \$426,000 in external funding over a 3-year period from the Center for Substance Abuse Treatment, based on that agency's interest in information about how problems related to substance use are being encountered and treated by mental health professionals in the private sector. However, PracticeNet is a sophisticated data collection infrastructure that provides a window into psychological practice that will be of lasting value to APA.

Partners for Healthy Growth is an educational initiative designed to assist support personnel in pediatric offices and schools nurses in understanding the physical and psychosocial aspects of growth disorders in children and adolescents. Growth is a major indicator of children's overall health, and growth disorders are conditions that affect physical growth in children. Also referred to as abnormal growth, these physical disorders often affect children psychologically. The APA Practice Directorate agreed to participate in the project because it served as a vehicle for positioning psychology as a key player in health care delivery at the primary care level, in line with the Practice Directorate's strategic objectives. The program was developed in collaboration with the Pediatric Endocrinology Nursing Society (PENS) and Pharmacia Corporation, a large pharmaceutical company. APA retained final editorial approval over all materials and use of its name (a necessary condition for any such collaboration) and in particular took care not to be appearing to endorse pharmacological intervention or pharmaceutical products. The program was implemented through a series of workshops throughout the country that were conducted by a local nurse and a local psychologist. The Practice Directorate received a grant of \$40,000 for its participation in the project, which essentially covered its costs.

**As a general orienting principle, external funding should serve a "value added" function, over and above core association activities made possible using existing revenue streams. Therefore, it is recommended that external funds be sought and used for the following kinds of activities that otherwise are not funded by the core association budget: First and foremost, external funds should be used for research and development (R&D) projects that cannot be accomplished without the funds. Consistent with existing APA policy, such projects should serve and advance the strategic goals of the association and psychology as a whole, and they should not compete with the interests and activities of psychologists. Second, any surplus or recaptured external funds should be used for R&D and for staff development that cannot otherwise be accomplished. Human capital is a precious and fragile resource in an organization, and**

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channeling surplus monies into staff development benefits the association as a whole and is consistent with the "value added" principle that should govern external funding.

Explicit guidance for the use of accumulated external funds will need to be developed if an allocation of net worth mechanism is used to separate external funds from the core APA budget. To develop specific policies governing the use of such a fund, it is recommended that the Board of Directors appoint a combined governance/staff work group to develop specific recommendations for the Board's approval regarding the accumulation and use of external funds. It is further recommended that this work group be asked to give particular consideration in developing these recommendations to issues of 1) research and development, including support for activities within the program generating the revenue; and 2) staff development and work climate. We strongly recommend that such funds not be accessible for governance projects or to compensate for budget shortfalls.

It must be appreciated that, to date, APA has not sought and received large amounts of external funding and that there are issues of "scale" that will have to be considered if APA's external funding grows substantially in the future. First, the supporting infrastructure of the organization will have to grow in size and expertise, and the indirect cost rates currently established to support externally funded projects may prove inadequate. Second, APA does not have an Institutional Review Board (IRB), and some arrangement will need to be made in cases where such review is required (e.g., IRB reviews can be contracted out).

Finally, while APA's internal review process has served APA well to date, if the size and volume of external funding awards increases substantially over time, another level of review may be appropriate or necessary under some conditions, for example due to the sensitivity of the project topic, budget amounts over some predetermined amount (e.g., \$100,000/yr), and/or the characteristics or requirements of the potential funding source. The APA governance structure of standing boards and continuing seems poorly equipped to respond to such opportunities. A small group of credible outside experts (e.g., 3) able to act rapidly might be convened by the CEO on an ad hoc basis to review such proposals. We wish to emphasize our view that this does not make sense for relatively small awards or for topics without some special sensitivity. **Therefore, it is recommended that the CEO and EMG develop criteria that would "trigger" another level of review by appropriate experts and a process for designating such experts that is sufficiently independent of APA to protect APA's interests.**

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APA CONVENTION SUBCOMMITTEE

Dr. Zimbardo

**ISSUES**

The annual convention of APA is one of the organization's most important events, coordinating a remarkable array of psychological talent in a host of academic presentations of research, theory, methodology, and new directions in practice and education. In addition to these intellectual exchanges in invited addresses, symposia, paper and poster sessions, the convention provides unique opportunities for continuing education programs for members, business meetings, honors and awards presentations as well as social exchanges between colleagues.

Our Task Force on External Funding has identified a number of areas and issues that might compromise the integrity of these conventions if not addressed immediately in reasonable and appropriate ways. Among them are:

- a) Exhibitor Space and Income
- b) Gifts distributed at the convention
- c) Use of Logos and other corporate identification signs on merchandise and giveaways
- d) Industry Sponsored Symposia
- e) Industry Sponsored Hospitality Suites
- f) Industry Sponsored Parties and Receptions
- g) Disclosure and Conflict of Interest
- h) Recommendations to State and Regional Associations
- i) Conferences and Meetings sponsored or approved by APA

(This initial report focuses on only the first three issues, the others are in development.)

**Exhibitor Space and Income**

A unique aspect of our annual convention is the Exhibit Area in which a large number of exhibitors pay standardized fees for the opportunity to rent booth space to promote their products and services. Many members visit this area one of more times during the convention period, and report that it is important to them for exploring new books, tests, and services provided by APA and the vendors exhibiting their wares.

Therefore, it would seem vital to the mission of APA that members perceive the Exhibit Area as an arena in which products and services are exhibited within a dignified atmosphere, free of commercial "glitz, excessive commercial promotion, and where there is a respect for aesthetic values in the design of exhibitor booths that are appropriate to a scientific convention. In addition, it

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would also seem fair to all exhibitors that there not be particular exhibits that are so visually dominant in sheer size and presentational style that they dwarf or minimize other exhibitor booths in their proximity.

The above values guided our task force in proposing the suggested recommendations that follow in order to prevent some exhibitors from developing exhibit spaces that might be judged by many members as offensive and inappropriate for APA, and imbalanced and unfair to “small exhibitors” occupying only single or dual booths.

### **An Exemplar of Task Force Concern**

An example of what we consider inappropriate to the demeanor of a traditional APA convention exhibit display was that witnessed by Phil Zimbardo at the 2002 annual convention of the American Psychiatric Association (ApA) in Philadelphia (where he was an invited speaker).

Dozens of huge exhibits, many occupying at least 250 square feet in area, most of which were at least 20 feet tall, filled the center of the convention arena, on separate “islands” (stand-alone exhibit areas). In addition to their sheer bulk, many displays more prominently featured the name of their primary drug being promoted than the name of the pharmaceutical company. Moreover, they were each staffed by large sales forces (as many as 15 for any one exhibit) wearing colorful logoized shirts or uniforms. In addition to providing information to attendees, they were there to give away a variety of “gifts,” administer “tests,” and engage in other promotional activities. These large booths were also filled with an assortment of unusual features to attract attendees, such as: Zen gardens (10 feet long), aquaria, relaxing music listening areas, maze-like tunnels in which audio and video presentations simulated the psychotic experience, a music shack where attendees had their photo taken playing a musical instrument which was made into the cover of a gift Blues music CD for them, large sculptures, and more. They were so big and so complicated that exhibits required 3 or 4 days to assemble, and several days more to disassemble. One exhibit booth alone cost more than \$450,000 to create, according the design coordinator—and was to be used only at one convention of the ApA.

Dr. Zimbardo took photos that will be appended to this report (Appendix D).

While such exhibits have become commonplace to the Psychiatric meeting, it was felt that any such displays at our APA convention would not be tolerated by many members, certainly all those not connected with private practice where medication might be a relevant treatment option. It was also felt that members who were uncertain or opposed to prescriptive authority for psychologists would complain that the intrusion of such marketing practices at our convention was one of the negatives associated with that policy.

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The Board then authorized the formation of a new task force to research and generate recommendations and guidelines to prevent such unwanted instances of all sources of external funding to APA. The current report deals initially with convention exhibits, it supplements the reports of our other subcommittees.

## **Background**

### **Convention Exhibitor Information**

#### **APA Association Rules (2003) 180-6 Exhibits**

**180-6.1:** *"The Board of Convention Affairs shall approve rules governing the nature of acceptable exhibits. The APA reserves the right to require the immediate withdrawal of an exhibit if the chief staff officer believes it may be injurious to purposes of the Association. Space for commercial exhibits may be provide on uniform terms determined in advance by the Convention Manager."*

#### **Exhibitor Prospectus and Application for Exhibit Space**

A large colorful brochure is distributed to all prospective exhibitors along with a detailed application for sales space (appended to this report).

Of relevance to our Task Force is the statement regarding Exhibit Content, which reads:

*Decisions regarding the acceptability of exhibits will be made in the first instance by the APA Chief Staff Officer, in consultation with the Board of Convention Affairs (BCA) chair. The APA, acting through its Chief Staff Officer, reserves the right and sole discretion to reject any proposed exhibit for any reason. Potential exhibitors are advised that the acceptability of products or services for display at the APA Convention is based on legal, social, professional, and ethical considerations. Exhibits may not be inconsistent with the professional nature of the APA Convention." (P.3, Toronto Exhibitor Prospectus, August 7-10, 2003). This information is repeated on the back of the Application form, the "yellow sheet." \*However, it is in such small font that is virtually unreadable without a visual aid.*

#### **Three kinds of Exhibitor Booths**

1. Standard In-Line Booth: (10 x 10 ft). May be increased by having several standard booths in a row. 8 ft maximum height limit at back wall, 4 ft at sides along the aisles. The price for a single booth is \$850, with the price increasing by about 90% for each additional adjacent booth up to a maximum allowable of four booths.

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In recent times, only a few vendors occupy the four-booth space, among them, Psychology Assessment Resources, National Computer Systems, Psych Corporation. The Psychology Insurance Trust takes from 2 to 4 booths. APA has up to 8 booths.

2. Peninsula Booth: Two or more booths facing a cross aisle, essentially an island exhibit attached to the end of a row of in-line booths. Maximum height extended to 16 feet at back wall but can extend only 4 feet to the left and right from the center backline. However, less clear is the instruction that "The 16 feet in height can extend to the front of the booth as long as it is centered within the back wall limit."

3. Island Booth: A block of booths completely surrounded by aisles with a 16 ft height limit. Instructions make clear that all booths must be constructed to ensure adequate see-through of neighboring exhibits. APA has the prime space in an Island booth.

Convention Registration and Statistical Information, 1971-2003 is a recent document prepared for the Board of Directors retreat (10 9 03). It provides background information about the scope of exhibitor income and extent of exhibiting companies. A general summary of that information for the past decade indicates that:

- a) There have been an average of about 260 booths available for any convention, of which about 250 were sold.
- b) The number of different exhibiting companies varies from about a high of 207 to a low of 116 (Toronto 2003 due to SARS scare), with a figure of 180 as the mean.
- c) The sales revenues of this exhibitor space vary from year to year, with a high of \$455,000, with an average return of about \$400,000.
- d) Booths range in price from \$ 850 for a single booth to \$2,250 for a quad of 4 adjacent booths.

Exhibit Sales Plan Memo (28 Feb. 2003) is another relevant background document from Jodi Ashcroft to Gary VandenBos and Peter Gaviorno. It details the recent steady decline in the percentage of Exhibit Booths reserved from 68% in 2001 to 58% in 2002 and 55% in 2003. Revenue also declined from earlier conventions in each of those years from \$308,000 in 2001, to \$226, 500 in 2003. The memo indicated that one source of this decline was the reduction in booths purchased by Test Publishers. They and other exhibitors are complaining of a decline in the return on their investment following each recent APA convention due to lower convention attendance, less exhibit hall traffic than in past years, thus resulting in lower sales.

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In response, APA has initiated a number of changes to make the exhibit floor more attractive to members and to increase member flow into the exhibit area. The Advertising Sales Department is initiating a series of actions to increase booth sales for coming conventions, as outlined in this memo (Appendix A).

One action item in that memo that is relevant to our External Funding Task Force is "to determine attendee needs and preferences related to exhibit hall vendors." The Task Force also believes that we need to understand better what kinds of exhibits members prefer and want APA to pursue or continue to present in the exhibit area and which kinds they are opposed to and prefer not to include or to place restrictions upon.

Applications for Exhibit Space Space priority is based on the date and time the Application for Exhibit Space is received at the APA Advertising Sales Dept. They are accepted starting at noon EST; Feb. 5. Many previous exhibitors have timed faxes to be received at this initial acceptance point. That priority entitles them to the more desirable floor locations, for example, nearest to the entry way and to more central hall positions. Lots are drawn from this pool of applicants based on time of application, seniority (years exhibiting) and other factors. The Exhibitor Prospectus makes clear that "Convention Management reserves the right to rearrange the floor plan or to relocate booths."

## **Recommendations**

The Task Force seeks to balance the financial interests of APA to optimize sales income from convention exhibits and the desire for exhibitors to increase sales revenues with the membership values of having all such exhibits reflect the professional values of the association and its Convention. [The following recommendations are advanced with the goal of helping to achieve such a working balance. Each of them should be subject to approval, modification and implementation by those in APA central office responsible for such revenue income.]

**The CEO, in consultation with the Board of Directors and the Board of Convention Affairs, as needed, should review current policies governing convention exhibits, gifts and logos to determine the advisability and feasibility of the following new policies:**

- 1. Island Booths. Only APA should occupy such highly visible exhibit space. If there is an exception, it should only be for APA affinity partners and their total space should be no larger than 4 booths.**
- 2. Height Limits. Except for APA, the height limit of any other exhibits should be lowered to 12 feet at their highest projection; only APA should be allowed to have the maximum height limit of 16 feet. (At Toronto, several**

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pharmaceutical companies had exhibits that seemed to exceed even the 16-foot height limit, as shown in the appended photos)

3. **See-Through access to other exhibitors.** Critical for maintaining fairness to all exhibitors, thus this condition must be rigorously monitored by APA sales staff and designs for all large exhibits need to be carefully reviewed and officially approved in advance.

4. **Booth Display Banners.** The primary banner of any exhibitor should be the name of the company and not a specific product that they are promoting. Or the company name should be larger than any product name that they are promoting. (In Toronto, 2003, several pharmaceutical companies had banners prominently displaying their drug, Lilly Co. with Stratter, and McNeil Co. with Concerta. See appended photos of their booth displays.)

5. **Booth staffing.** Limit the number of exhibitor staff present at any one time to a maximum of six to eight.

6. **Gifts, Samples and Giveaways.** Sales staff should be aware in advance of the nature of any exhibitor samples, gifts and giveaways, and make appropriate recommendations to specific exhibitors where they are of questionable nature that might be offensive to members. All such gifts and samples should be related to the product being exhibited and be limited in monetary value in order to minimize competition among exhibitors.

7. **Use of Logos and other corporate identification signs on merchandise and giveaways.** Given the excessive use of such signs at other conventions, some limits should be exercised to keep them more appropriate to our Convention. For example, an Exhibitor who sponsors free coffee should be able to have an appropriate sign indicating that it is the benefactor, but then not be permitted to put its logo on each cup and each napkin, which overly commercializes the gift of the coffee. Again the commercial needs of the exhibitors must be weighed against the concerns of members about becoming targets of excessive commercialization.

8. **Booth video displays.** Exhibitors intending to have video displays should make clear their content along with the booth application. APA should reserve the right to review such displays and make recommendations regarding the appropriateness of the content to attendees. The volume of such displays or of music and lighting displays should also be regulated so as not to intrude on neighboring exhibits or be loud enough to be offensive to members.

9. **Glitz factor.** Given the professional, scientific and educational nature of APA's Convention, all such exhibits should be appropriate to those basic

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values by not being excessively flashy, or whose overall design is likely to be offensive to a substantial number of member attendees -- as determined by the Convention Manager. This constraint should be included in instructions to potential exhibitors (in terms agreed upon by the Sales Advertising staff and the Convention Manager).

**10. Exhibit Clustering.** Where possible, exhibitors with a similar product or service should be clustered in proximity. This allows easier access for attendees interested in their products and to avoid them for those not interested in what they are selling.

**11. Pharmaceutical Company Exhibits.** Since these products and their promotion are more likely than others to be offensive to some member attendees, they should be clustered in adjacent areas for the above reasons. That would also enable them to compete more directly for attendee attention by being able to provide informational materials and discussions with their sales representatives about the comparative merits of their products.

**12. Revising the Application form Yellow Sheet.** Make critical sections on the back of the Application Form more readable by increasing font size or some other way of notifying exhibitors of our regulations so that they do not complain afterwards of being unaware of their existence.

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RESEARCH AND JOURNALS SUBCOMMITTEE

Drs. Antonuccio, Stitzer & Schuster

**Issue**

We have been charged with developing options for APA to consider in order to manage conflicts of interest in research and journal advertising. Although the scientific literature bearing on this issue primarily applies to the pharmaceutical industry, the relevant principles may apply to any industry.

**Current APA policies**

APA has developed a conflict of interest form (<http://www.apa.org/journals/acorner.html#pubforms>) that is designed to be completed by authors and presenters. There are some gaps in its use but these are beginning to close. As far as we can tell, there are not any specific guidelines for recusal (e.g. by journal reviewers) or divestiture when the conflicts are large and unresolvable. Professionals are generally expected to self-identify these conflicts and act in accordance with ethical guidelines. There are also guidelines for advertising in APA journals (<http://www.apa.org/ads/guide.html>) but they don't specifically address conflicts of interest of the journal if the advertised products are also the subject of scientific scrutiny in the journal. The APA has separated the business aspects of the organization from the editorial decision making process and this is apparently documented in the APA Editors handbook. An inspection of the Editors Handbook may be necessary to determine whether this APA policy needs to be modified to ensure against erosion in the future. Among other issues, the APA ethical guidelines relating to research (<http://www.apa.org/ethics/code2002.html#8>) address informed consent, deception in research, use of animals, human subjects protection, reporting of results, plagiarism, publication credit, and sharing of data **but do not specifically address conflicts of interest**. Although APA does not appear to address research conflict of interest issues directly, there are government agencies, like the Office of Research Integrity (<http://ohrp.osophs.dhhs.gov/humansubjects/finreltn/finguid.htm>) that have drafted interim guidelines possibly worthy of emulation.

**Background**

Industry ties to Research. There are widely acknowledged publication biases (e.g., Blumenthal et al., 1997; Callaham et al., 1998; Chalmers, 2000; Gilbody & Song, 2000; Misakian & Bero, 1998; Rennie, 1999; The Lancet, 2001; Wise & Drury, 1996), often related to conflicts of interest (Campbell et al., 1998; Cech & Leonard, 2001; DeAngelis et al., 2001; Fava, 2001; Lo, Wolf, & Berkeley, 2000), that favor pharmaceutical industry products (Bekelman et al., 2003). In fact, these biases have so eroded the credibility of the medical literature (Quick, 2001), including the psychiatry literature (e.g., Torrey, 2002), new proposals call

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for stringent accountability guidelines (e.g., Moses & Martin, 2001; Davidoff et al., 2001) that attempt to ensure researcher independence in study design, access to data, and right to publish. So far there has been minimal adherence by American medical schools to the standards embodied by these guidelines (Schulman et al. 2002).

An indirect estimate of publication bias is possible in the antidepressant literature. by examining the FDA antidepressant database for medications in the initial approval process when all data from every study must be submitted, whether the study is ultimately published or not. Several independent analyses of the FDA antidepressant database have shown that study medication had a significant advantage over inert placebo in as few as 43% of randomized controlled trials (Khan, Khan, & Brown, 2002; Kirsch et al., 2002; Laughren, 2001). In the published literature, antidepressants are significantly more effective than inert placebos in about 2/3 of studies (Thase, 1999). Such a pattern would be consistent with a failure to publish results from as many as 35% of antidepressant trials (presumably those showing no advantage to the antidepressant), which is somewhat higher than previous estimates of up to 20% (Gram, 1994). The discrepancy between the FDA database and the published literature may also reflect duplicate publication, selective publication, or selective reporting as has recently been found in SSRI studies submitted to the Swedish drug regulatory authority (Melander, Ahlqvist-Rastad, Jeijer, & Beermann, 2003).

Roughly one quarter of biomedical investigators have industry affiliations, and roughly two thirds of academic institutions hold equity in start-up companies that sponsor research at the same institutions (Bekelman et al., 2003). One study (Krimsky et al., 1998) examined research conducted by 1000 Massachusetts scientists who were lead authors on articles published in major scientific and medical journals during 1992. The report concluded that more than a third of the articles had lead authors with a financial interest in the research, even without considering honoraria and consultancies. Another study found that the vast majority of authors of Clinical Practice Guidelines had financial relationships (mostly undisclosed in the guidelines) with companies whose drugs were considered in the guidelines (Choudhry, Stelfox, & Detsky, 2002). Even leading bioethicists, whose objectivity is crucial to their role as ethical watchdogs, have developed financial conflicts in the form of consulting fees, contracts, honoraria, and salaries from the drug industry (Elliot, 2001). Conflicts of interest can occur at the level of the individual scientist or at the level of the academic institution itself, resulting in a call for divestiture and oversight by an independent review panel (e.g., Johns, Barnes, & Florencio, 2003).

Some journals require disclosure of financial conflicts of interest. For example, the *New England Journal of Medicine* revealed that 11 of the 12 authors of an article about the efficacy of nefazadone and behavior analytic therapy (Keller et al., 2000), were paid by Bristol Myers Squibb, the drug's

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manufacturer. In fact, the authors' ties with companies that make antidepressant medications were so extensive that it was decided to summarize them on the New England Journal of Medicine website rather than take up journal space to detail them fully (Angell, 2000). The journal even had trouble finding psychiatric researchers who met their standard of independence from manufacturers of antidepressants, to write an accompanying editorial (Angell, 2000). In fact, because the editors of the New England Journal of Medicine concluded that they cannot find enough experts without financial ties to the drug industry, the journal recently relaxed its strict policy against financial conflicts of interest by editorial and review authors (Drazen & Curfman, 2002), bringing it in line with most top medical journals. This example gives a clear indication of just how pervasive the industry ties are. This is a challenging and important issue, because it has been established that public relations firms for major drug companies are even willing to pay professionals to write articles such as editorials designed to favor their clients' products (Brennan, 1994).

Industry support is shifting from academic medical centers to private research companies called contract research organizations (CROs) and site-management organizations (SMOs), both of which have grown tremendously in recent years (Bodenheimer, 2000). In 1991, 80% of industry money for clinical trials went to academic medical centers; in 1998, only 40% went to academia (Bodenheimer, 2000). The following subtle biases may influence the kind of research that is produced (Bodenheimer, 2000). Drug company marketing departments may rule out funding studies that might reduce sales of their products. The companies may design studies likely to favor their products. A new medication may be tested on a healthier population than the population that will actually receive the drug. A new medication may be compared with an insufficient dose of an older one. Clinical trials may use surrogate end points or "markers" instead of clinical end points (e.g., measuring blood pressure as a surrogate for heart attacks or measuring suicidal ideation as a surrogate for suicidal behavior) or certain data analysis strategies (e.g., last observation carried forward instead of observed cases; Kirsch et al., 2002) to get the most favorable outcome. In drug company studies, investigators may receive only portions of the data. In fact, industry sponsorship has been associated with restrictions on publication and data sharing (Bekelman et al., 2003). Drug companies have even been hiring advertising companies that are buying or investing in other companies that perform clinical trials of experimental drugs in an attempt to get "closer to the test tube" (Petersen, 2002).

There are several other questionable practices that can bias the scientific literature in favor of products favored by the marketing departments of such companies (Bodenheimer, 2000). Professional medical writers ("ghostwriters") are often paid by a drug company to write an article but not be named as an author. Sometimes a clinical investigator ("guest author") will appear as an author on a paper on which they did not contribute or analyze the original data. In

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one study, 19% of articles had guest authors who did not sufficiently contribute (i.e., did not help conceive the study, analyze the data, or contribute to the writing) and 11% had ghostwriters who were not named as authors (Flanagin et al., 1998). Healy (2001) has estimated that up to 50% of review articles about new drugs appearing in respectable Medline journals appear as supplements (i.e., are not peer reviewed), are ghost written, or are written by company personnel. Such supplements and reprints of actual articles can be a rich source of revenue for scientific journals. Sometimes an apparently independent journal can have strong undisclosed editorial ties to industry that can influence content and emphasis of articles that appear in the journal (Letter to Academic Press, 2002). Another study found that in journals with policies calling for disclosure of conflicts of interest, only 0.5% of authors made such disclosure (Krimsky & Rothenberg, 2001), most likely reflecting poor compliance with such policies. As yet, there are not enough data to evaluate the impact of ghost writing on the literature. However, since the “ghost writers” generally work for the marketing departments of the drug companies themselves, it is probable that the articles will favor the manufacturer’s medication.

Potential Methodological Biases. Recent methodological analyses of randomized controlled trials (RCTs) suggest that design flaws and reporting omissions are associated with biased estimates of treatment outcome (Moher, Schultz, & Altman, 2001). This has led to the publication of the CONSORT (Consolidated Standards of Reporting Trials) statement, developed by an international group of clinical trial specialists, statisticians, epidemiologists, and biomedical editors (Moher et al., 2001). The CONSORT statement, adopted by many leading medical journals, specifies design and reporting standards for selection criteria, intervention details, randomization, blinding procedures, and intent-to-treat analyses in RCTs.

Some of the methodological biases are subtle and woven into the fabric of study design. For example in antidepressant research, it is common to use a “placebo washout” procedure prior to randomization (Antonuccio et al., 1999). This procedure typically involves a 1 to 2 week single blind trial during which all prospective subjects are placed on placebo. Any patients who improve during this washout period are excluded from the study before randomization. Such a procedure may subtly favor the drug condition by, among other things, eliminating placebo responders before the study even starts (Antonuccio et al., 2002).

The double blind in antidepressant studies is likely to be unintentionally penetrated due to the pattern of side effects in the active and inactive drug conditions (Greenberg & Fisher, 1997; White, Kando, Park, Wateraux, & Brown, 1992). Research clinicians routinely educate themselves and patients about potential side effects as part of the standard informed consent process. Further, these studies tend to rely on measures by clinicians who often have a major

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allegiance or stake in the outcome, resulting in larger differences than with patient rated measures (Greenberg, Bornstein, Greenberg, & Fisher, 1992; Moncrieff, 2001). Efforts to ensure the integrity of the blind tend to diminish estimates of drug efficacy. For example, a review of the Cochrane database of antidepressant studies using “active” placebos (i.e., placebos with side effects, making side effect differences more difficult to detect) found very small or nonsignificant outcome differences, suggesting that trials using inert placebos may overestimate drug effects (Moncrieff, Wessely, & Hardy, 2001).

Also, antidepressant studies do not adequately evaluate the efficacy of medication alone because most of these studies allow the prescription of a sedative (Kirsch et al., 2002; Walsh, Seidman, Sysko, & Gould, 2002). If patients in the drug condition are more likely to take sedatives or antidepressants with sedative properties, this could distort results because there are at least 6 points on the Hamilton Depression Rating Scale that favor medications with sedative properties (Moncrieff, 2001). Many of these studies provide concurrent supportive psychotherapy, giving a distorted picture of the effectiveness of these medications in a typical managed primary care environment where mental health support may be offered on a more limited basis or even not at all (Antonuccio et al., 2002).

Klein (2000) and Quitkin (1999) have argued that since antidepressants have been established as effective in the treatment of depression, trials that do not find a statistical advantage of antidepressants over placebo lack “assay sensitivity” (i.e., the ability to detect specific treatment effects). In other words, they argue that something is wrong with the sampling or methodology of such trials and the results should be discounted or discarded. If that logic had been applied to the recent meta-analysis of the FDA antidepressant database (Kirsch et al., 2002), more than half of the studies would have been discarded, a strategy that would have seriously distorted the overall results (Antonuccio et al., 2002; Otto & Nierenberg, 2002).

Advertising to Professional Organizations. In 2000, the American Psychiatric Association received over \$13 million dollars from the pharmaceutical industry, more than the roughly \$10 million generated by dues paying members (Vedantam, 2002), and representing about 30% of its budget (Pfeiffer, 2001). The April and May 2002 issues of the American Journal of Psychiatry, the flagship journal of the American Psychiatric Association, had more than 25% of the pages devoted to appendices, primarily advertising for psychotropic medications or drug company sponsored continuing education. Such journals typically generate considerable profits for their parent organizations and risk losing advertising revenue if they publish articles critical of their advertiser’s products (Abassi & Smith, 2003; Pellegrino & Relman, 1999). For example, in 1992, the Annals of Internal Medicine published a study (Wilkes, Doblin, & Shapiro, 1992) showing that new drug advertisements in journals were often

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misleading regarding safety and effectiveness. The journal editor ultimately resigned under pressure at least in part because the journal lost up to \$1.5 million in advertising revenue when the drug companies stopped advertising as a result of the published article (Altman, 1999). While such advertising may serve an educative function, many ads lack adequate quantitative information and can indeed be misleading (e.g., Loke, Koh, & Ward, 2002; Villanueva, Peiro, Librero, & Pereiro, 2003).

Professional meetings also provide opportunities for advertising efforts. At the 1999 Fall meeting of the American Psychiatric Association, about 17% of all presenters listed affiliations with the pharmaceutical industry in the conference brochure, though such disclosure policies may underestimate conflicts of interest (e.g., Krinsky & Rothenberg, 2001). To its credit, organized psychiatry has a long established mechanism for disclosing to the public these potential conflicts whereas organized psychology is only beginning such efforts. The American Psychological Association (APA) Council of Representatives approved a motion in 1997 to have APA send disclosure forms to authors and presenters. APA began using such forms (<http://www.apa.org/journals/acorner.html#pubforms>) in 2001, though there are still some gaps in their use and in public acknowledgement of disclosed conflicts. Drug company support for the APA is currently less than 0.4% of the operating budget (Graves, 2003), though the potential for greater interest and support from the industry is likely as psychologists continue to achieve prescriptive authority. Also, there is at least some industry support for APA divisions (e.g., the brochure project at <http://www.brochureproject.org/>), something the organization does not track.

## Recommendations

**At a minimum, reports of all drug treatment RCTs, should conform to the CONSORT statement (Moher et al., 2001). The following requirements are designed to complement those standards.**

- (1) All studies claiming double blind status could test and report whether the blind was penetrated in order to pass peer review for a psychology journal (Piasecki et al., 2002). Even if the blind is penetrated, such studies can be published if the effect of blind penetration is analyzed.**

Advantages: Psychology journals would offer a more stringent methodological standard than psychiatry journals. As a result, our journals could become a more respected source of information on true drug efficacy. Additionally, the prevalence and influence of blind penetration would become known.

Disadvantages: It would require extra effort on the part of researchers who would be expected to ask subjects and clinician raters to guess the actual treatment condition.

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Practicality: This could very easily be done without modifying existing designs or adding significant cost. A few studies are starting to report blind penetration in mainstream journals.

**(2) Scientists could consider omitting placebo washout procedures or randomly assigning patients who improve during placebo washout (see Antonuccio et al., 2002)**

Advantages: Placebo washout procedures potentially exaggerate the drug-placebo difference by eliminating subjects who improve after placebo. Including patients who improve would enhance external validity of studies. If a placebo washout phase is included, this may permit separate analyses with and without “placebo responders” (assuming adequate statistical power) and help solve the mystery about how placebo washout procedures actually affect the outcome of these studies.

Disadvantages: Increased variability in placebo group would likely result in need for increased sample size and related costs. The extra analysis would take a little bit of extra time. It might be argued that including patients in an antidepressant study when they are no longer depressed after the washout procedure doesn’t make sense or is unethical. Clearly such patients did meet criteria at the beginning of the study and are at least at risk for relapse. In the real world, there is no placebo washout and these patients would likely get antidepressants. It is important to understand what happens to them if they do receive antidepressants.

Practicality: This could be done fairly easily.

**(3) All studies could be required to include patient rated self-report measures in addition to clinician rated measures (Antonuccio et al., 2002). For example, depression studies should include and report on a self-report measure like the Beck Depression Inventory in addition to the commonly used Hamilton Scale for Depression, a clinician rated measure.**

Advantages: This requirement could reduce the possibility of clinician bias affecting estimates of treatment effects. From our perspective, it would fulfill an ethical obligation to give patients an opportunity to directly self-report their outcome experiences. Self-report measures would contribute an additional perspective at relatively low cost.

Disadvantages: Patients are not always the best sources of information about their conditions. This guideline would also result in a slight increase in assessment costs.

Practicality: This could be implemented fairly easily. Data from both clinicians and patients could provide a database that will allow researchers the opportunity to compare and contrast these sources of data.

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**(4) Use of any concurrent medication and concurrent treatment of any kind could be well specified in the analysis and abstract of all RCTs.**

Advantages: Consumers will be informed about the possible contribution of concurrent treatments.

Disadvantages: Minimal.

Practicality: This suggestion could be implemented fairly easily just by reporting data that have already been collected.

**(5) All raw data for any study published in a psychology journal could be submitted to the journal and made available to any qualified scientist, allowing for independent review of the data and data analysis (Klein et al., 2002; Bekelman et al., 2003). The data would be stripped of any identifying information.**

Advantages: Although psychologists already agree to share their data with other researchers as a condition of publication at some journals, this policy would permit independent verification of prior data analyses by any qualified scientist. This could also reduce the file drawer phenomenon because researchers without vested interests could have access to all of the data. This could also give reviewers the same kind of direct access to data that the FDA scientists now enjoy, improving the quality of peer review.

Disadvantages: Issues of confidentiality would have to be addressed.

Extra effort would have to be made to ensure that no identifying information inadvertently became public. Professional rivals might use this as an opportunity to discredit each others' research.

Practicality: This would be difficult to implement. Some scientists would be reluctant to make their data accessible out of concern that others might steal their ideas. The potential benefits would seem to outweigh the potential risks, especially since most top journals already require access to data if requested.

**(6) Scientists considering participation in pharmaceutical company sponsored research should ideally have input during the study design phase of the project. Whether or not they have design input, they should be satisfied with the design and measurement integrity of the study in which they plan to participate. All authors could offer signed assurance that they had independent access to all of the raw data (not just summaries of the data) and contributed to the writing of any manuscript for any study published in a psychology journal. Research contracts between psychologists and industry could ensure the right to publish findings independently of the sponsor (Schulman et al., 2002) in order to be published in a psychology journal.**

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**Advantages:** This policy would reduce (but not eliminate) the risk of unfavorable outcome data being placed in a file drawer, a practice that may violate the Belmont principle of beneficence, and ensure that the public will benefit from research involving human subjects.

**Disadvantages:** This would be difficult to independently verify. Many drug companies may decline to include psychologists in conducting their research if other professionals are willing to sign a contract without such limitation.

**Practicality:** Assuring independent access would be as easy as having authors sign a declaration of some sort. This is already being done at some top medical journals. More difficult would be requiring the submission of a copy of a research contract, something many would be reluctant to do. An agreement among university administrators for a standardized contract would probably have to be developed at a national level for this to work.

**(7) Full public disclosure of all financial conflicts of interest could be required in any psychology-sponsored presentation (including all publicity and handouts), publication, computer listserve, interaction with a research human subject (as recommended by AAMC), or policy making public meeting (similar to AMA requirement). All journal reviewers could also be required to disclose such conflicts and should be excluded from the peer review of any article that evaluates products related to any stated financial conflicts. There may be other situations where disclosure would not be sufficient and exclusion or divestiture might be more appropriate (e.g., a financial conflict of interest involving an APA officer).**

**Advantages:** Full disclosure would enhance the creditability of the information provided and allow consumers of any information on any topic the opportunity to consider the source. Another advantage of such a strategy would be that it could apply universally to any financial conflict of interest, not just drug industry conflicts. The policy could enhance the credibility of the peer review process.

**Disadvantages:** Some will certainly see this as unwieldy. It would take up extra journal space to publish the information. Additional training will be required to educate psychologists about when and where such disclosures are required.

**Practicality:** This is already being done at the top journals. Authors need only fill out a single page form. This policy can and should be extended to reviewers as well. It is likely that requiring disclosure of conflicts of interest for participation on computer listerves or public meetings would be seen as too intrusive, yet the same single page disclosure form could easily be used for this purpose. The information

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could be displayed on a publicly accessible web page and serve as one disclosure source for all purposes.

**(8) The task force is divided on the issue of industry advertising. Dr. Antonuccio feels strongly that no industry advertising should be permitted in psychology journals that publish scientific articles scrutinizing their products due to the inherent conflict of interest for the journal. Stitzer feels that we should permit advertising relevant to journal content. Dr. Shuster tends to agree with Stitzer on this issue but wonders about whether we should exert some control over advertising content, though he acknowledges that this is probably not practical. At a minimum Dr. Shuster feels we should have a disclaimer about the accuracy of any claims made in advertisements. We have run out of time to achieve a consensus on this item.**

Advantages: A policy restricting advertising in scientific journals could free editors from the concern that publishing or not publishing certain articles will impact advertising revenue. It would enhance the credibility of our journals as independent unbiased arbiters of the studies they publish.

Disadvantages: This practice would be costly in terms of lost potential advertising revenue. In some cases, it may be difficult to specify when and where such restrictions would apply. Some may argue that such a policy would represent an inappropriate restraint of trade.

Practicality: Restricting advertising in some way could be accomplished more easily now but once journals start accepting industry advertising, it will likely be very difficult to step backward. Legal counsel would probably have to sort out the restraint of trade issues.

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CONTINUING EDUCATION SUBCOMMITTEE

Dr. Sammons

Part I: Formulate policy regarding industry sponsored CE: Is disclosure sufficient or are limits on funding necessary? Can industry ever fund an APA accredited CE program?

Response – disclosure of conflict of interest:

APA should adopt a policy on disclosure of funding sources and potential conflicts of interest for all individuals and entities seeking APA approval for CE presentations. Regarding the identification of potential conflicts of interest, the following should be considered:

Conflicts of interest are common in academic and clinical psychology, to the point that they may reasonably be considered to be universal. All academics have an inherent conflict of interest when submitting a manuscript for publication, for their career depends on a successful record of publication in the area of their expertise. Clinicians who specialize in the treatment of a specific disorder or patient population have similar conflicts of interest: without preserving their reputation as a specialist in the disorder or population in question, they are likely to lose a significant portion of their income.

Conflicts of interest are not inherently negative. Publications, grants and lectures are the vehicles enabling researchers and clinicians to develop and communicate particular expertise in specific areas of the discipline, and by so doing, advance our understanding of mechanisms and treatments of numerous psychological disorders.

Undisclosed conflicts of interest, however, are universally negative, because even if they do not bring any particular financial or professional benefit, they cast doubt of the integrity of the scientific process and the profession as a whole.

Conflicts of interest, then, should always be disclosed. The disclosure of conflict of interest does not impute wrongdoing or bias, but alerts the recipient to potential sources of bias and engenders an appropriate level of critical thinking regarding the information being presented.

The following policy is recommended for consideration:

**Any entity or individual that provides, or is applying to provide, APA approved continuing education units from which that entity or individual may gain, either directly or indirectly, some benefit, either financial via the increased sales of educational materials, books, test devices, or drugs, or economic via the awarding of grants, continuation of awarded grants, or**

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**clinical service provision, is deemed to have a conflict of interest and is required to disclose such conflicts of interest, whether or not they result in actual gain to the presenter or sponsoring agency.**

- 1. All entities applying to offer APA approved CEUs must clearly state the source of funding for presenters.**
- 2. All persons or entities offering APA approved CEUs must clearly state sponsorship of those activities by any agency that could reasonably be construed to have a conflict of interest relating to the material being presented.**

Examples of this include, but are not limited to:

- A. A pharmaceutical company sponsors an unrestricted educational grant for a lecture on treatments for attention deficit hyperactivity disorder.
  - B. An educational or philanthropic foundation, the goal of which is to enhance awareness of the effects of ADHD, sponsors a lecture on treatment of ADHD.
  - C. A publisher of an assessment tool for ADHD in adults underwrites the publication of a booklet regarding the differential diagnosis of ADHD in children.
  - d. A university-based researcher, who has received numerous grants from private and public sources to study drug abuse in adolescents with ADHD, presents a CEU on her findings.
  - E. A clinician who has devised a novel, nonpharmacological treatment for ADHD in children, offers instructional CEUs teaching clinicians about this new treatment.
- 3. All recipients of grants must disclose any sources of funding that are related to the topic being presented, even if such funds were not directly used in the development of the material being presented.**
  - 4. The period of disclosure of conflict of interest or potential conflict of interest for entities or individuals offering APA sanctioned CEUs will be for 5 years prior to the date of the presentation.**
  - 5. The following guidelines are recommended for APA divisional program chairs and CEU coordinators:**

#### **Disclosure guidelines for evaluators of CEU presentations**

- 1. All APA-sponsored CE will require that presenters disclose any potential source of conflict of interest. All sources of funding that are related to the subject being presented during the past 5 years, whether or not such funding directly sponsored the current**

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- presentation, must be disclosed.
2. **Presenters who are officials of foundations, non-profit agencies, or members of public or private boards that sponsor work or have interest in the subject being presented must disclose such affiliation at the time the program is submitted for consideration.**
  3. **Presenters will clearly state their current employment, and any employment in the past 5 years that pertains directly to the subject being presented. Affiliations with foundations, public or private institutions, pharmaceutical firms, managed care entities, insurers, publishers, and other agencies having interest in the subject must be disclosed.**
  4. **Participation in speaker's bureaus, consulting contracts with pharmaceutical firms, makers or distributors of psychological tests or scientific instruments will be disclosed for a period of 5 years prior to the submission of a proposal for a presentation.**
  5. **The above material will be provided to all participants enrolling in the CEU program in question.**

Part II: Are limits on funding necessary?

Response: No. As long as full disclosure is made, arbitrary limits on funding by any external agency are unnecessary. No distinction, however, should be made between funding from "industry" and funding from other external sources. The funding of a presentation via a NIDA grant is as subject to full disclosure as is the funding of a presentation via an "unrestricted educational grant" from a pharmaceutical manufacturer.

Part III: Can industry ever fund an APA accredited CE program?

Response: "Industry" can, and indeed commonly does, fund APA accredited CE programs. Two issues must be addressed here. First, as in the above responses, the issue is less one of sources of funding and more so one of disclosure. Per the previous responses, all sources of funding should be fully disclosed. Second, "industry" requires definition. Obvious examples of "industry" are pharmaceutical firms, test publishers, book publishers, clinics, hospitals, and managed care entities, manufacturers of scientific equipment, and agencies offering malpractice and other insurance to psychologists. Less obvious examples of entities having an interest in the material being presented are governmental and private grant making institutions, research institutes associated with public or private educational entities, foundations, and coalitions of lay and professional people with an interest in a particular disorder or field of study. To reiterate,

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it is not the source of funding that must be addressed, but accurate disclosure of potential or real conflicts of interest.

#### Part IV: Guidelines for consumers of CEUs.

Accurate disclosure of sources of funding and potential conflicts of interest will help consumers of CEUs appropriately interpret the material being presented. It is the opinion of this work group that in addition to these safeguards, psychologists and other consumers of APA approved CEUs will benefit from a reminder of how to interpret material being presented. We therefore recommend that a brief outline be published along with any announcement of an APA approved CEU offering that outlines, in general, common threats to internal and external validity of a study, to better assist participants in carefully evaluating the material at hand. What follows is an incomplete version of such an outline. While entitled "how to read a drug study" it could in general easily apply to any area of the discipline.

##### How to read a drug study

##### Threats to external validity

##### Sources of funding:

Is the study funded in whole or in part by a drug manufacturer?

Are authors consultants to drug manufacturers, or do they receive honoraria or other forms of remuneration from drug manufacturers?

External sources of bias have emerged as a compelling issue in the past several years, and, in the aftermath of several scandals, major medical journals are requiring complete disclosure of possible conflicts of interest. Nevertheless, the problem is endemic in modern science, and most researchers have such close ties to industry that at least one major journal has complained that the absence of sufficient numbers of unbiased reviewers is a severe impediment to the editorial process.

But disclosure of financial or employment conflicts of interest is more common than in the past, and in any event is one of the more transparent forms of bias influencing outcomes of studies.

Internal sources of bias can be more difficult to detect.

##### Threats to internal validity

##### Statistics

Is the power of the study sufficient to enable conclusions to be drawn? Often outcomes are measured in terms of relatively small differences in raters' perceptions or patient completed scales.

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Power

Design

Characteristics of the subjects:

Are the subjects appropriately matched for age, sex, diagnosis, and characteristics of the disorder? Here it is important to determine if the severity and duration of the disorder is the same in all groups under investigation.

Are co-morbid conditions or diagnoses excluded or controlled? Studies that exclude diagnoses that are often co-morbid with the disorder in question are open to criticisms of lack of generalizability. Anxiety and depression co-occur extremely commonly in clinical settings, and to limit a study to patients with only one of these conditions

On the other hand, certain conditions that have been demonstrated to respond positively to the drug being investigated should be excluded. SRIs are for example, far more effective in managing obsessive-compulsive disorder than the tricyclic antidepressants. Thus, in any study of SRIs for depression, it is clear that including patients with OCD would introduce a potentially fatal confound to the analysis.

Are "rescue drugs" permitted? Read carefully to determine what other agents may be used by participants in the study. A study of antidepressants for anxiety disorders should not, obviously, allow participants to utilize benzodiazepines or other drugs that are known to be effective anxiolytics.

Examine the strength of the blind. Most patients can detect when they are taking an active compound versus an inert placebo. While they may not be able to judge the therapeutic efficacy of the drug, non-therapeutic effects are likely present that are not associated with inert placebos.

SRIs very commonly cause detectable side effects long before their therapeutic effects are seen. Symptoms such as nausea or insomnia are extremely common and would not be expected to occur with the administration of an inert drug. The difference between active antidepressants and placebos tends to be small in most studies, and some authors have found that this difference becomes significantly smaller when an active placebo - one that possesses the adverse effects but not the therapeutic effects of the drug in question - is compared with the antidepressant.

## CHARACTERISTICS OF THE PATIENTS

The placebo wash-out debate.

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Should patients who respond to placebos, or who have not responded to drugs similar to the investigatory drug, be excluded from clinical trials? In a study of sertraline in children and adolescents (Wagner, et al, 2003), subjects who had not previously responded to an antidepressant were excluded from the study. Thus, a far better title for the study would have been "Efficacy of sertraline in the treatment of children and adolescents with medication responsive to major depressive disorder". If patients who had not previously responded to an antidepressant were also enrolled in the study, one would expect the rather small difference between antidepressant and placebo to be even smaller still.

Is the study of adequate duration?

Most psychological disorders are chronic and relapsing. We also know that for antidepressants to exert a true therapeutic effect, at least 3-4 weeks of treatment are required. Yet most studies of antidepressants are quite short - often averaging 8 weeks. This is an insufficient period to determine if the antidepressant will work in patients who are expected to take it for months, if not longer, to control a chronic, often relapsing, condition.

A recent review examining the relationship between funding source and outcome of drug studies found that experimental drugs were found to be superior over conventional agents in 51% of studies funded by for profit agencies. This number declined to 35% for studies funded by both for profit and non-profit agencies. In studies not reporting funding source, experimental drugs were found to be superior in 30% of trials. Where non-profit agencies investigated experimental drugs, however, the experimental treatment emerged as the treatment of choice in only 16% of studies (Als-Nielsen, et al., 2003).

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PRACTICE SUBCOMMITTEE

Drs. Sammons, Stitzer and Fox

**Background**

Until passage of successive versions of the Pure Food and Drug Acts in the first portions of the 20<sup>th</sup> century, drugs were marketed to consumers without the intermediary step of a physician's prescription. Homeopathic remedies and potent pharmaceuticals such as morphine and cocaine containing compounds were marketed freely and directly to the public at large. With the ascendance of the medical profession in the early decades of the 20<sup>th</sup> century, physicians were increasingly recognized by the pharmaceutical industry as well regarded authorities who could serve as highly credible representatives of the agents they manufactured. This, combined with restrictions on the sale or promotion of supposedly therapeutic substances that were either toxic or of no utility in treating disease, led to physicians establishing a virtual monopoly on the prescription pad, and it was essentially unheard of to have direct marketing of prescription-only drugs to the public.

In the past decade, this situation has been rapidly reversed, and pharmaceutical manufacturers are increasingly bypassing physicians in favor of promoting their products to consumers. We thus find ourselves in a curious historical moment where trends in drug marketing common a century ago have now become commonplace again. Nevertheless, marketing of pharmaceuticals to health care providers remains a mainstay of the drug industry, and estimates of dollar expenditures on marketing to physicians range from 12-15 billion dollars annually. Also of note is that, while previously detailers had confined their attentions largely to physician providers, visits by drug detailers to nonphysician healthcare providers have increased dramatically in the past decade. Thus, as psychologists move towards the acquisition of prescriptive authority, it is clear that the influence of drug detailing on prescription choices by psychologists is an issue the profession must address.

**Current attempts by the medical profession to limit the influence of pharmaceutical detailing**

Concern regarding the influence of pharmaceutical representatives on prescribing patterns is not new, and references in the literature on this subject date back at least 30 years<sup>1</sup>. In the early 1990s, the American Medical

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<sup>1</sup> It is interesting to note, however, that in spite of a long history of concern by the AMA regarding the effects of drug detailing, most physicians do not regard it as a significant ethical issue. In a recent study, physicians and residents were asked to report their level of ethical concern in response to a series of common drug detailing scenarios. Most scenarios, even those involving the acceptance of expensive gifts, were not rated by the majority as being of particular ethical concern. Even the most questionable scenario, **This report has been received by the APA Board of Directors and provided to the APA Council of Representatives as information. It has not been adopted as APA policy by the APA Council and therefore does not commit APA to the activities or opinions described.**

Association undertook an effort to limit the influence of pharmaceutical manufacturers by publishing guidelines for physicians regarding receipt of gifts from pharmaceutical manufacturers. These guidelines were again revisited in 2002, and the AMA, in concert with the Pharmaceutical Research and Manufacturers Association (PhRMA) launched a campaign to educate physicians about these republished guidelines. Although this campaign received some criticism because it was underwritten by large pharmaceutical firms, the guidelines did seek to rein in inappropriate detailing practices. In general, under the new standards, gifts must be of modest value, must be associated with some educational purpose, and must serve the interests of a patient. Under these rules, then, gifts of pens, cups, and notepads would be acceptable, as would a staff lunch accompanied by a presentation from a drug representative. Elaborate dinners, theatre or sporting event tickets, or other entertainment not connected with an information program would be prohibited, as would be funding physicians to attend conferences or seminars (though the latter may still be underwritten by pharmaceutical firms; American Medical Association, 2002; Croasdale, 2002; Robeznieks, 2002).

In addition to industry and professional association initiatives, the state of Vermont has enacted regulations requiring physicians to report any gift of over \$25 value to the state Attorney General. The US Department of Health and Human Services Office of the Inspector General has also published draft guidance on voluntary guidelines for pharmaceutical firms that are based on anti-kickback statutes (HHS OIG Notice of Draft Compliance Program Guidance for Pharmaceutical Manufacturers, 2003, as cited in Robeznieks, 2003).

### **Implications for psychologists**

Although most psychologists do not currently prescribe, they may influence the decision of prescribers in regards to a choice of medication, and thus may be of interest to drug manufacturers. Practicing psychologists may be influenced in three main ways by pharmaceutical manufacturing. Most directly, they may be influenced by the efforts of drug detailers, who either visit them in their office or sponsor an educational event, such as a lunch accompanied by a drug lecture, under the aegis of a clinic or healthcare facility.

The principal issue in such a scenario is the ability of the detailer to influence the prescribing patterns or recommendations of the psychologist by the provision of gifts or perquisites. There are, however, two secondary issues worthy of mention. First, pharmaceutical detailers provide gifts, information packets, and patient oriented material in the context of an ongoing interpersonal relationship. While the provision of gifts may influence a practitioner, it is equally likely that the

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involving an all expenses paid weekend at a resort in return for attending a short drug seminar, was rated as moderately or significantly problematic by only 60% of respondents (Brett, Burr, & Moloo, 2003).

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quality of an interpersonal relationship may have a more profound influence. This potential source of undue influence has received little attention to date.

Second, there has been little examination to date of the effects of detailing on the patients of professionals visited by drug representatives. Pharmaceutical company advertising is ubiquitous in many practice settings. Drug names and company logos are emblazoned on pens, coffee cups, clipboards, posters, self-report questionnaires, and notepads. It is commonplace for a patient to be handed a self-report questionnaire, containing the name of a drug company, on a similarly inscribed clipboard, along with a pen advertising a particular medication. While the effects of detailing on providers are well known, the effects of such advertising on patient preferences regarding a choice of medication are unstudied, but can be presumed to be of significance in patient choice or acceptance of a drug.

Psychologists may also be influenced more indirectly by drug detailers, via attendance at conferences and continuing education opportunities that are sponsored by drug firms. Industry support of continuing education is a contentious and ongoing issue that is addressed elsewhere by members of the current task force.

Finally, psychologists may be indirectly influenced by drug manufacturers through their patients. Patients are subject to an increasingly sophisticated array of direct marketing techniques, appearing on television, the internet, magazines, and newspapers. Advertisements frequently offer enrollment in programs pertaining to a health problem of interest to patients. These patients may then regularly receive literature, videotapes, and e-mailings regarding a company's services and products, and may subsequently exert pressure on a practitioner to prescribe or recommend for prescription the product so advertised.

### **Summary and recommendations**

Drug detailing is ubiquitous in modern medicine, and psychologists are not immune to the effects of concerted marketing campaigns by pharmaceutical firms. While much drug company influence on psychologists is more often indirect at present, direct marketing to psychologists will likely grow. Accordingly, it is recommended that the Association consider the promulgation of guidance for psychologists receiving direct marketing from drug detailers, as follows.

#### **Recommendation 1**

**Psychologists should be aware that drug detailing represents a likely source of unrecognized influence on decision-making regarding pharmaceuticals. Advertising materials such as pens, mugs, and notepads are visible not only to psychologists but to their patients. Presence of**

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such materials in the clinician's office is likely to be interpreted by patients as tacit endorsement by the psychologist of the product being advertised. Accordingly, it is not recommended that psychologists display drug related advertising material in their place of work.

**Recommendation 2**

Provision of advertising materials, gifts, and other perquisites by pharmaceutical representatives is almost always done in the context of an ongoing personal relationship between the psychologist and the drug detailer. Psychologists should be aware of the effects of that relationship on their decisions regarding patient care.

**Recommendation 3**

Psychologists should accept gifts, perquisites, or other benefits from pharmaceutical representatives only when such gifts are of modest value and have a direct educational purpose that is likely to enhance patient care. Examples of such gifts might be a noontime lunch accompanied by a lecture, or educational material regarding general management of a disorder. Acceptance of reimbursement for attendance at conferences or seminars, reimbursement for travel, tickets to entertainment events and similar events is not considered appropriate.

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EDUCATION SUBCOMMITTEE

Drs. Shuster & Zimbardo

Education of psychologists is one of the major missions of APA, which is achieved across many domains, from undergraduate, graduate, post-graduate and continuing education. Central to any educational enterprise are the principles of: objective, unbiased transmission of knowledge by qualified experts; flexible openness to change one's ideas, attitudes and values based on the best available information, and reliance on credible sources of data for forming conclusions.

A potential exists for this ideal to become distorted or corrupted by the introduction of external funding from commercial corporations whose primary mission is to sell products or services that make profits for their businesses. In the realm of education, the three major sources of influence come from publishers of texts, publishers of psychological tests and assessment devices, and pharmaceutical companies. The APA's Education Directorate has had considerable experience dealing with text and test publishers, but relatively little with sources of pharmaceutical influence.

**Textbook** selection influence from text publishers is most likely to be in the form of "seduction pressures" on individual teachers and committees responsible for adopting their texts. Sales representatives and editors may bias that decision by offering inducements in addition to the quality of the their text and supplements, such as meals, gifts, money for equipment, remuneration for AV supplies and products.

APA can inform its members about the need to recognize such potential biases on the decisions of these teachers, not to accept them, and report them as unacceptable to the publisher and Department Chair.

**Testing and assessment** has become a multi-billion dollar business and thus such publishers can wield considerable influence on those in charge of decisions to use particular tests. In this area, it is incumbent upon test adopters to insist on the best available information about each test's psychometric properties, including adequate current, normative data for the populations being tested.

APA can inform its members about the need to be aware of alternative tests for the same domain of assessment with preferable psychometrics, to insist on updating of major scales and assessment instruments to reflect current demographics in normative sampling, and to provide opportunities for challenges and sponsor public debates by APA experts in this area of any and all such instruments.

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APA can also sponsor CE courses and seminars by experts on particular assessment instruments to keep members up to date on best practices with various tests. In doing so, conflict of interest considerations must be transparent and evident to all concerned (as described more fully below).

**Pharmaceutical company** influences on education within APA, and among psychologists, is likely to become considerable in the future as an increasing number of states qualify psychologists with prescriptive authority. Our Task Force has documented the extent and range of the biasing impact that such enormous funding sources are having in medicine and on the practice of psychiatry. That distortion comes at all levels: from biasing drug trial research, deceptive marketing, conflicts of interest in seminar leaders, CE experts, journal research reviewers, grants, fellowships, awards, contributions to operating budgets, expensive journal ads, and excessive presences at national convention exhibitor halls. Some of these issues and our recommendations are presented in other committee reports.

The major sources of such biasing on education of psychologists is likely to come in the form of potentially conflicted information presented at seminars, invited lectures, CE workshops, and on-line courses sponsored by APA. The Education Directorate has been sensitive to ways of minimizing these biases in their educational offerings to members. Some of their procedures will be outlined next, along with our recommendations for going further in making such procedures more effective and valid. Finally, we will propose a new set of recommendations about developing education and training modules on “External Funding.”

One “firewall” imposed by the Education Directorate between all external funding and its educational programs is to separate financial sponsors from the development of the *content* of any programming. We applaud that action.

We recommend further that all APA Directorates be pro-active in first determining the nature and content of programs they believe are of educational value to members and then seeking external funding to support them.

The four key aspects of minimizing unwanted biasing of educational information in the education of our members are: Educational Content Fairness, Presentation Balance, Disclosure, and Feedback Evaluation.

**Educational Content Fairness:** If a specific commercial product is presented in a seminar, lecture, or CE course, it is necessary also to discuss competing products and give the audience information about how to access that information on their own. This requirement should be made explicit in prior instructions given by the relevant Directorate staff to presenters.

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**Presentation Balance:** All APA educational programs should strive to offer members information that is accurate, current, credible and as unbiased as possible. To this end, programs should be initiated, selected or organized by APA staff, or its expert members, that seek to have their presentations offer balanced perspectives on the issues, products being discussed.

This recommendation is in the spirit of the Education Directorates' mandate that: "Programs must be tailored to psychologists and should strive to provide attendees with a fair balance of information presented so that attendees can form professional opinions and become valuable informational resources." Highlighted is the strong statement that: "Programs appearing commercial or biased in nature will not be considered for presentation."

**To follow upon this rule, our task force adds the following specific recommendation:**

**Each APA educational presentation must be authorized and duly noted by a specific staff member who is then responsible for following-up on compliance with this rule when the presentation is actually made.**

**Disclosure:** Critical for minimizing the appearance of objectivity of presenters is the audience's awareness of sources of conflict of interest that might introduce undesirable biases.

APA staff and attendees at APA-sponsored functions must be apprised of any potential sources of conflict of interest in presenters or external funding sources of the event.

The Education Directorate's Rule is:

"All Satellite Symposia must include information on the funding sources for the presentation, if any. In addition, all speakers are required to include information on any open grants or funding from the sponsor at the time of the presentation, and any funding the speaker received for the materials presented, (e.g., grants for research the results of which are presented), as well as any future financial benefit (beyond honoraria's received) by the sale of any product or publication as a result of this presentation (e.g., royalties). Said Disclosure must be made orally at the start of the presentation, or in writing as part of any distributed handouts."

**Feedback Evaluation:** All such rules work only when there is institutional review, follow-up, and systematic feedback in the form of evaluation by attendees and APA monitors. Too often good intentions and rules are not enough to prevent abuses if there is not systematic and regular feedback evaluation built into the oversight procedures.

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Attendees at all CE seminars and workshops should be asked to complete program evaluation forms indicating the degree to which they believed the information provided exhibited a promotional or commercial bias—on standardized forms. Where they indicate “strong bias,” participants should briefly describe in what manner they felt this bias was shown.

**The CPEC should review all sponsored programs for CE applicability (they are the most expert body to render such determinations). In addition, perhaps they should be involved in the post-presentation evaluations of collected data from various CE and other APA educational presentations. It is also essential to create procedures for notifying violators of these rules and procedures, along with sanctions against their further participation or sponsorship.**

**Education and Training Module Development:** The Education Directorate can play a central role in helping to develop a set of materials around all the issues studied by our Task Force on External Funding that would be available to all graduate programs, directorates, the field of psychology in general, and other institutions and agencies concerned about minimizing undesirable external financial influences on the integrity, fairness, and objectivity of their enterprise.

**We recommend that the APA Board of Directors and Executive Management authorize funding for the Education Directorate to develop a set of educational and training modules that address the range of issues associated with External Funding.**

The ED is expected to work with other directorates and staff of the Task Force on External Funding in developing these materials. These resources could be created in DVD formats that included all essential background information, the issues raised, relevant references and summaries of key articles, training exercises, as well as discussion and role-playing exercises. They should be made into CE programs, as well as into a course on the APA Online Academy. Such a unique resource could prove invaluable for all of our State Psychological Associations as well as for many other national associations in psychology, medicine, psychiatry and social sciences.

We assume that the issues outlined here are but the start in opening a broader discussion of the ways in which APA and all psychologists can be more vigilant about preventing and minimizing undesirable sources of biasing influences on the science and practice of the profession of psychology.

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CONFLICTS OF INTEREST: ISSUES, ETHICS AND OPTIONS

Dr. Pachter

A number of practices have been identified across professions, sciences and industries that have the potential to seriously interfere with the integrity of professional work or the scientific enterprise. The 2002 APA Ethics Code addresses a number of the problems directly and well, for example those involving ghostwriting and publication credit, duplicate publication of research results, and responsibility for publications. There are, however, several issues raised by the literature on conflicts of interest that warrant further consideration by the Ethics Committee or others within APA.

**1. Problem: Due Diligence and Responsibility of Psychologists**

How much due diligence should be required of a psychologist interested in being a consultant or receiving a grant? For example, what is reasonable for a psychologist to do in order to learn who is truly funding a project if a corporation is using one or more front groups to develop an educational program, contract for research, or find therapists to lead groups? And if a psychologist does find out that there is an industry funding the activity and that conflicts with the independence of the psychologist are likely or inevitable, what is the psychologist's responsibility?

**Ethical Code:**

Ethical Standard 1.01 Misuse of Psychologists' Work requires psychologists to take "reasonable steps" to correct or minimize the misuse or misrepresentation of their work if they learn about such misuse or misrepresentation. What steps are required of a psychologist to find out about misuse or misrepresentation of their work?

Conflicts of interest between a psychologist and an organization such as a corporation are dealt with in two places in the Ethical Code and these provisions are not comparable in what they require from the psychologist. Ethical Standard 3.06 Conflict of Interest states that "psychologists refrain from taking on a professional role when personal, scientific, professional, legal, financial, or other interests or relationships could reasonably be expected to (1) impair their objectivity, competence or effectiveness in performing their functions as psychologists or (2) expose the person or organization with whom the professional relationship exists to harm or exploitation." While this standard does not clarify what standard of diligence is required, it is clear that a psychologist should not take on the role if it could "reasonably" be expected to cause a conflict.

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On the other hand, Ethical Standard 1.03 Conflicts Between Ethics and Organizational Demands states that “if the demands of an organization with which psychologists are affiliated or for whom they are working conflict with this Ethics Code, psychologists clarify the nature of the conflict, make known their commitment to the Ethics Code, and to the extent feasible, resolve the conflict in a way that permits adherence to the Ethics Code.” Again, this standard does not indicate what a psychologist must do to determine whether there is a conflict. In addition, this standard does not require psychologists to resolve the conflict in a way that permits adherence to the code.

The two provisions taken together provide no guidance on what a psychologist should do to determine whether a conflict exists, but indicate that a psychologist is not required to resolve the conflict in a way that adheres to the Code if he or she is affiliated with, or employed by a corporation, but should avoid taking on such a role if he or she has not already done so. This discrepancy does not seem helpful to psychologists looking for guidance about ethical behavior when working in the complex context of corporate consulting or contracting, particularly if a psychologist finds out about a problem in the course of employment or consulting with a corporation. Having such a soft standard for those already employed by corporate entities does not give them the support they may need to be whistleblowers or to try to change the situations in which they may find themselves.

**Options:**

- Guidelines or educational materials should be developed by APA to assist psychologists in understanding and knowing how to identify possible front organizations and to assist with the ethical issues in negotiating contracts with corporations.
- A consistent and meaningful conflict of interest standard could be developed in the next Ethics Code revision that assists both contractors and employees in confronting the ethical dilemmas they may encounter.

**2. Problem: Disclosure of Conflicts of Interest or Bias**

Disclosure of financial or other conflicts of interest is often seen as a remedy for publications, conference presentations, and continuing education. While disclosure is a good idea, it is sometimes not sufficient for correction of bias (Bero, 1999; 2003). Problems include:

- Accuracy of disclosure
- Disclosure may not make clear who is accountable

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**Conflicts of Interest: Ethics & Options**

- Bias may not be a deliberate, intentional, choice (Dana & Lowenstein, 2003), so disclosure of information may not be sufficient to override the effects of a biased presentation.

**Options:**

- Encourage research on the effects of disclosure of various types of bias on outcomes of CME, evaluation of published information and oral presentations.
- Assess the extent to which disclosure is sufficient in those activities and the circumstances under which it cannot be sufficient.
- Develop policies for those instances in which disclosure is not sufficient to overcome bias (e.g., do not allow CE credit, require biased journal articles be published with others with opposing views).

**3. Problem: Corporate Use of Scientists for Harassment or Developing Biased Science**

Various industries have used paid scientists to harass opponents with scientific misconduct charges and/or to muddy the waters about what is known (aiding industry by creating “scientific” support for their positions or attacking existing science where there really is no scientific controversy). Examples from the lead and tobacco industries may have already involved psychologists. This is unlikely to be a frequent problem, but can be very difficult for individuals as well as psychological science on those occasions on which it does occur.

**Ethical Code:**

Ethical Standard 1.01 Misuse of Psychologists’ Work and Ethical Standard 1.07 Improper Complaints seem relevant for scientists targeted by industry. However, “improper complaints” seems to anticipate only ethics complaints, not those complaints made in bad faith to other bodies. The assumption may be that other bodies will have mechanisms to detect and deal with frivolous complaints affecting psychologist.

**Options:**

- APA could continue to deal with this as an ethical issue.
- Consider whether the Science Directorate should have a role and mechanism for clarifying current knowledge in psychology and supporting psychologists who are protecting the science (even if

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that is against another psychologist paid by industry) or others who are targeted by a psychologist with a conflict of interest.

### **References**

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