

APA TASK FORCE ON EXTERNAL FUNDING FINAL REPORT

I. EXECUTIVE SUMMARY

INTRODUCTION

A number of sciences and professions have recently become aware of, and concerned about, the extent to which corporate funding has influenced or will influence their activities and directions. For example, the 54th Annual Meeting of the American Institute for Biological Sciences, “Bioethics in a Changing World – Responsible Conduct of Science¹”, included a plenary session on “Public Citizenship and the Duties of Scientists: Avoiding the Best Science Money Can Buy” (Shrader-Freschette, 2003).

Phil Zimbardo, then-President of the American Psychological Association, attended a 2002 American Psychiatric Association meeting and was appalled by the extravagant exhibits sponsored by pharmaceutical companies (as were newspaper reporters – see Seligman, 2003; Vedantam, 2002). Concern that prescription privileges for psychologists will mean increasing pharmaceutical company interest in funding APA activities led to discussions with the Board of Directors and to the appointment of a Presidential Task Force on External Funding to review the experiences of other organizations, sciences and professions receiving corporate funding and to suggest policies and procedures to protect the integrity of the association without unnecessarily restricting APA activities.

Problems may arise, of course, as a consequence of outside funding from any source when the values of the donor and those of the recipient either are in conflict or are incompatible. It has been sobering to note, however, that a broad range of industries, including tobacco (Bero, 2003), lead (Markowitz & Rosner, 2003), agribusiness, real estate development (Ottaway & Stephens, 2003) and pharmaceuticals (Angell, 2004; Mundy, 2001; Rennie, 2003), have employed similar and often hidden strategies to influence a range of sciences and professions. Front organizations—industry-funded grassroots, consumer advocacy (Mundy, 2003; Sterns, 2003), research, and educational organizations whose primary goal is to promote marketing, influence regulations or advance other industry interests—are among the strategies intentionally designed to obscure the actual sources and amounts of funding for activities favoring corporations (Beder, 2002; Center for Science in the Public Interest [CSPI], 2003). In fact, much of the knowledge available to investigators about such industry-funded activities has come through documents only made available in the

¹ The complete title of the meeting was “Bioethics in a Changing World – Responsible Conduct of Science: Collection, Analysis, and Reporting of Data; Public Dissemination of Sensitive Scientific Information; Training the Next Generation

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discovery process of litigation (Castleman, 2003). This is true of the pharmaceutical industry as well as the lead (Needleman, 1993) and tobacco industries.²

The Task Force reviewed the consequences of external funding of a range of activities across several sciences and professions, but chose to focus on pharmaceutical funding as a case example for three reasons. First, the effects of pharmaceutical funding on the science and profession of medicine have been very well documented, and provide a telling example of the distortions and unintended consequences that can occur when academic centers, scientists and practitioners become too dependent on for-profit industries. Second, pharmaceutical companies have expressed interest in funding activities of the American Psychological Association (and, in fact, have already done so to a limited extent), and that interest is expected to increase as more psychologists obtain prescription privileges. Finally, the pharmaceutical industry has been enormously wealthy and politically influential, and is therefore of great interest.

Many readers may find it difficult to understand how the distortions that arose within the field of medicine could happen to such a well-established and powerful profession. That is because they do not fully comprehend the sheer size and scope of the pharmaceutical industry, or the significant role that it has come to play in the cost of medical care, or how it has benefited from a very favorable social and political climate in this country. The result is an enormously powerful industry with virtually unprecedented financial resources to pursue its own agenda. The fact of the matter is that the industry is so profitable and influential that it is not likely that APA or any similar organization, is going to change it or succeed in preventing its influence on the health care system or on psychology as interactions with drug manufacturers increase.³ What we can do is inform ourselves of the nature of the business and make certain that we have adopted appropriate policies and procedures to help avoid the more egregious mistakes of others. It is for that reason that the Task Force strongly encourages the Board of Directors to authorize the development of educational and training modules addressing the range of issues that are associated with external funding identified in this report, in addition to developing policies to protect the integrity of the association.

² The Center for Science in the Public Interest (CSPI) has, since 2003 published a manual listing corporate support for health and environmental professional associations, charities, and industry front groups (Center for Science in the Public Interest, 2003). CSPI has also encouraged reporters to use this information when reporting on the activities of these associations and other organizations.

³ It is encouraging to note that in May of this year an unprecedented settlement of consumer protection claims regarding the “off label” marketing practices of Warner-Lambert in promoting Neurontin was announced by Attorneys General from fifty states. The settlement, which also resolves investigations by the National Association of Medicaid Fraud Units and the U.S. Attorney’s Office for Massachusetts, requires payment of \$430 million dollars to federal and state authorities. Other investigations, settlements, and legal proceedings against pharmaceutical companies have also been announced by state and federal authorities this year.

In addition, NIH announced changes to tighten its conflict of interest policy this year.

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Part One of this report consists of summaries of the problems identified by the various Task Force subcommittees in their assigned domains, along with recommendations that should be included in any solutions that may be adopted by the various governance groups to whom this report is referred for action or implementation. In preparing this report, it was not the intention of the Task Force to develop specific rules and procedures that should be slavishly followed. Instead, we have tried to develop recommendations for the appropriate governance groups (e.g., Continuing Education Committee, CAPP, CEO Office, etc.) to consider and then determine what, if anything, should be done. We want to point to problems that need to be addressed, but it is up to those most familiar with the workings of the organization as a whole to formulate specific actions or changes. The recommendations in Part One were unanimously approved by the Task Force but are not presented in rank order, although it is obvious that some recommendations are of greater consequence than others.

Part Two is a list of references and resources consulted in compiling the report that were not included in the Subcommittee reports.

Part Three contains the full reports of each subcommittee. There is some redundancy in the reports due to the fact that the subject matter of some committees overlapped. These reports were formally “accepted” by the Task Force but they were neither voted on nor approved in detail.

TASK FORCE ON EXTERNAL FUNDING: CHARGE

In view of changing relationships among corporate funding organizations, scientists, and professionals who apply scientific findings, the Task Force on External Funding was created to:

- Review APA policies, procedures and practices regarding the acceptance of funding and material support from private corporations and other organizations for educational and training programs, continuing education offerings, research projects, publications, advertising, scientific and professional meetings and conferences, and consulting, practice and advocacy relationships; and
- Recommend such changes and policies as are deemed necessary to enhance and protect the integrity and ethical standards of psychology.

SUBCOMMITTEE SUMMARIES AND RECOMMENDATIONS

Each section begins with some statements of the problem, using the pharmaceutical industry as an example, followed by recommendations for changes in that specific area.

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ASSOCIATION INCOME

- Enormous financial and political influence has enabled the pharmaceutical industry to assume a significant role in directing medical treatment (Wazawa, 2000), clinical research (Tanner, 2000) and physician education (Antonuccio, McLahanan & Danton, 2002; Coyle, 2002; Relman & Angell, 2002).
- The pharmaceutical industry influences most aspects of the American health care system that are relevant to its business interests: physicians (Choudhry, Stelfox & Detsky, 2002), professional and academic institutions, the US Congress, and the FDA (Antonucci et al. 2002; Relman & Angell, 2002).
- Pharmaceutical industry money is so crucial to the funding of university medical centers that no threats or offers need to be made in order for a company to exert its influence (Elliott, 2001; CSPI, 2003).
- The pharmaceutical industry has the largest lobby force in Washington (n= 625) (Relman & Angell, 2002).
- In 2001, the pharmaceutical industry spent over \$19 billion on marketing (Antonucci et al., 2002). It has been estimated that \$35 billion was spent that year on “marketing masquerading as education” and “marketing masquerading as research.” These costs were then passed on to the public via higher retail prices for the medicines they purchase (Angell, 2004).
- US citizens pay far more for prescription medications than any other country, even though almost 50% of drugs sold in US are manufactured in other countries (Relman & Angell, 2002).
- Pharmaceutical firms spend enormous sums to exploit legal loopholes enabling them to restrain generic manufacturers from bringing less expensive products to the market. For example, the makers of Paxil used such methods to extend its original patent protection by over 5 years. Ironically, a major proportion of the basic research leading to the discovery of Paxil was done at taxpayer expense (Relman & Angell, 2002).

Recommendations:

1. That external funds should never be a part of APA’s operating or core budget, including both direct and indirect costs.
2. It is strongly recommended that external funds never be used to meet budget shortfalls or ongoing, regular governance projects, including both direct and indirect costs.

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3. The Task Force is concerned about the potential consequences of industry funding to the directorates. Given industry marketing strategies, the benefits and consequences of such funding should be examined closely and careful consideration should be given to developing APA policy in this area.
4. 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, if any, of external funds.

ANNUAL CONVENTION

- Observed at a recent ApA convention:

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 logo 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 (Seligman, 2003), 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. These exhibits were so big and so complicated that each 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 to the design coordinator—and was to be used only at one convention of the ApA.

A reporter covering the event for *The Washington Post* also described the scene: "In one part of the convention hall, companies erected 20 foot-high monuments to their medicines and handed out promotional materials, candies and gifts (Vedantam, 2002)." In a further illustration of the industry's influence on the convention the reporter noted, "And in several dozen symposiums during the weeklong meeting, companies paid the ApA about \$50,000 per session to control which scientists and papers were presented and to shape the presentations (Vedantam, 2002)."

Recommendation:

5. In order to balance the financial interests of APA and exhibitors with membership values and exhibits that reflect the professional values of the association, twelve specific recommendations are made on such items as

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height limits, banners, staffing, gifts and so forth (see Convention Subcommittee Report, Section III, p. 43-45).

RESEARCH AND JOURNALS

- Increasingly, medical research is funded by drug companies and others in private industry with a vested interest in the outcome of the research (Albee, 2002; Gorner, 2000; Mundy & Marcus, 2000; Tanner 2000; Vedantam, 2001).
- Over 50% of the scientific experts employed by the FDA to evaluate new drugs have a conflict of interest because of pharmaceutical industry ties (Elliott, 2001).
- The major source of pharmaceutical innovations comes from publicly funded medical research, not from the industry itself [e.g. eight of the 10 most popular drugs produced by one of America's largest pharmaceutical companies and most of today's anti-cancer drugs were developed at the National Institutes of Health] (Reich, R., 2003; Relman & Angell, 2002).
- Over one half of clinical trials have been shifted to private practice settings where the industry has more control over critical elements of the research. In an effort to regain or hold on to the lost income from manufacturers, many large medical centers have made significant changes in policies and procedures to cater more to the industry they are supposed to evaluate impartially (Relman & Angell, 2002).
- 70% of the money for clinical trials in the US comes from the industry rather than from NIH (Bodenheimer, 2000).
- The FDA, which is supposed to regulate the industry, is dependent on that very industry. Approximately one half of the FDA budget for drug evaluations comes from pharmaceutical firms (Relman & Angell, 2002).
- There is overwhelming data to show that researchers funded by pharmaceutical companies that sell the drug they are evaluating tend to produce results favorable to that drug (Bodenheimer, 2000; Coyle, 2002; Lexchin, 2003; Wazana, 2000). For example, 96 percent of researchers writing favorably about a drug for hypertension were funded by the manufacturer that produced and sold that drug; but only 37% of those not funded by the company reported favorable results (Gorner, 2000).
- In search of easier profit, the thrust of industry-supported research has shifted from trying to find causes and mechanisms of disease to certifying "me-too"

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drugs (copycats of negligible improvement or added value) (Angell, 2004; Gorner, 2000).

- A study of 89 major universities found that less than 19% had specific limits or prohibitions on relationships with industry (Gorner, 2000).
- The pharmaceutical industry is biasing our evidence base by increasing their control of investigators, research designs, and when or whether results are published (Bodenheimer, 2000; Bodenheimer & Collins, 2001; Lexchin, 2003; Melander, 2003; Vedantam, 2001).

Recommendations:

6. That all raw data for any study published in a psychology journal should be made available to any qualified scientist, allowing for independent review of data and data analysis.
7. That scientists participating in industry sponsored research have input into the study design, be satisfied with the design and measurement integrity of the study, offer signed assurance that they had independent access to all raw data and contributed to the writing of any manuscript submitted to a psychology journal.
8. That full public disclosure be required of all financial conflicts of interest for any psychology-sponsored presentation, publication, computer listserve, interaction with a research human subject or policy making public meeting. Further, that all journal reviewers be required to disclose such conflicts and be excluded from peer review of articles evaluating products related to any stated financial conflicts.
9. That, at a minimum, journals should have a disclaimer about the accuracy of claims made in advertisements. A significant portion (perhaps 25%) of selected industry advertising revenue should be set aside to support data based perspectives (possibly through scheduled debate or other continuing education) that might otherwise be stifled in those areas in which one industry dominates the advertising agenda.
10. That all initiated clinical trials be registered in a public registry such as <http://www.clinicaltrials.gov> prior to trial implementation in order to qualify for publication in any APA journal. APA should consider starting its own clinical trial registry.

CONTINUING EDUCATION

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- The pharmaceutical industry spends billions of dollars on Continuing Medical Education (CME) because they have learned it is a powerful tool for a company to deliver its message to key audiences and get those audiences to take actions that benefit their products (Goldfinger, 1990; Hensley, 2002; McCarthy, 2000; Relman, 2001; Wazana, 2000).
- Most companies pay for CME from their marketing budgets; a fact that speaks for itself (Relman & Angell, 2002).
- The industry is assuming a role in CME that is inappropriate for an industry with a vested interest in selling prescription drugs (Goldfinger, 1990; Pear, 2002; Relman, 2001).
- The professional bodies traditionally responsible for CME have been co-opted by the industry (Hensley, 2002; Relman & Angell, 2002).
- Given the well documented priority of marketing concerns over scientific goals in continuing education offerings (Angell, 2004), as well as the fact that disclosure alone is sometimes not sufficient to allow for correction of bias (Bero, 1999; 2003), APA should explore the option of not offering continuing education credits for industry-funded courses.

Recommendation:

11. That APA adopt a policy on disclosure of funding sources and potential conflicts of interest for all individuals and entities seeking APA approval for CE presentations.

[Cf following section on Education for further CE recommendations]

EDUCATION

- Numerous experts have documented ways in which university scientific work has been extensively contaminated by corporate money, arguing for a complete separation of academic research and researchers from corporate money (Bok, 2003; Greenberg, 2003; Needleman, 1992; Relman, 2001).
- Aggregated results of several studies show a statistically significant association between industry sponsorship and pro-industry conclusions of investigators (Bekelman, Li & Gross, 2003; Needleman, 1992, Wazana, 2000).
- Some corporations have pilloried and intimidated academicians who publish research antithetical to the corporation's interests. Several pharmaceutical

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firms have threatened researchers (Bodenheimer & Collins, 2001; Morin & Deane, 2003), interrupted trials, and blocked publication of unfavorable results (Bok, 2003; Greenberg, 2003).

- A survey of academic institutions reveals that they rarely insure that their investigators have full participation in the design of clinical trial research, unimpeded access to trial data, and the right to publish their findings (Schulman, 2002).

Recommendations

12. That APA members should be advised of the potential biases inherent in accepting inducements that might affect the selection of texts, the use of particular tests, and/or sponsorship of CE courses.
13. That APA seminars, lectures or CE courses presenting commercial products should discuss competing products and provide information on how to access that information.
14. That 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.
15. That CE seminar participants should be asked to evaluate the perceived promotional or commercial bias in presentations and, when applicable, describe the manner in which they felt the bias was shown.
16. That all externally sponsored CE programs should be reviewed by the appropriate oversight group(s), which should also consider developing procedures for evaluating outcomes, notifying violators of rules along with sanctions against further participation or sponsorship.
17. That the Board of Directors should authorize funding to develop educational and training modules addressing the range of issues associated with external funding.

PRACTICE

- Gifts from pharmaceutical firms to providers significantly increase the cost of medical care and the expenditures on prescription drugs (Appleby, 2001; Brubaker, 2002; Coyle, 2002; Dana & Lowenstein, 2003; Dember, 2001; Maguire, 2001; Pear, 2002; Siegel, 2002; Shapiro, 2004; Torassa, 2002).
- Pharmaceutical companies are well aware of the research literature showing that even small gifts influence or bias the recipient physicians; that is why

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many of them restrict their own employees from accepting gifts of any size (Dana & Loewenstein, 2003).

- Numerous studies have shown that limiting the size of gift, or educating providers, or requiring mandatory disclosure do not eliminate biases favoring the industry that provides the gift (Dana & Lowenstein, 2003; Dember, 2001; Hall, 2001).
- Meeting with pharmaceutical representatives (Shapiro, 2004; Watkins, 2003), attending industry sponsored CE, accepting travel or lodging funds and attending presentations by pharmaceutical representatives all lead to non-rational prescribing practices (Appleby, 2001; Coyle, 2002; Dember, 2001; Hall, 2001; Torassa, 2002; Wazana, 2000).
- The largest segment of the pharmaceutical industry's marketing budget is spent on direct promotion of products to doctors (Dana & Lowenstein, 2003; Japsen, 2001).
- The penetration by the pharmaceutical industry into the medical culture is so pervasive that when the AMA prepared to roll out an educational campaign reminding doctors to be wary of the effect of acceptance of gifts, they turned to pharmaceutical companies to underwrite the project and only gave up on the request when there was a public outcry (Appleby, 2001).

Recommendations:

18. That psychologists be aware that advertising represents a likely source of unrecognized influence on decision-making regarding pharmaceutical recommendations. Advertising materials such as pens, mugs, and notepads are visible not only to psychologists but to their patients. Presence of 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 recommended that psychologists do not display drug-related advertising material in their place of work.
19. That psychologists understand the effects of personal relationships with industry representatives on their decisions regarding patient care.
20. That psychologists should be discouraged from accepting gifts, perquisites, or other benefits from pharmaceutical representatives, even when such gifts are of modest value. 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

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for travel, tickets to entertainment events and similar events is not considered appropriate.

CONFLICTS OF INTEREST/ETHICS

N.B. - This report was completed too late for key points and recommendations to be reviewed and voted on by the task force as a whole, our criterion for inclusion in section one. The co-chairs request that the full Conflicts of Interest/Ethics report be submitted to the Ethics Committee for consideration and that the Board identify other governance groups and staff who should review the report for consideration and action on the issues and options presented.

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