

**Draft Report of the APA Workgroup on Relationships between Psychiatrists and
the Pharmaceutical and Medical Device Industries
August 24, 2009**

Introduction: Physicians' relationships with pharmaceutical and medical device companies have come under intense scrutiny in recent years. (1,2) These companies develop, distribute, and market the vast majority of the medications and devices on which modern psychiatry depends, and there are several positive reasons for psychiatrists to interact with them (e.g., the development of new treatments, the design and implementation of clinical trials, combating stigma attached to mental disorders). (3,4) However, concerns about the impact on patient care, medical research, medical education, and physicians' professionalism of relationships with pharmaceutical and device companies have been expressed in both professional and public forums, and are reflected in the medical literature (5)—though voices challenging these concerns and emphasizing the positive value of interactions with industry are heard as well. (6,7)

In the current environment in which long-standing patterns of behavior are being called into question and norms of behavior are in flux, the American Psychiatric Association (APA), offers these recommendations to educate its members about the potential for conflicts of interest and to guide their decisions about relationships with industry. The recommendations below are guided by the belief that all physicians, including physicians in training, must always act and be perceived as acting in the best interests of our patients. We seek to balance the positive aspects of relationships with industry with the risks that conflicts of interests may negatively affect patient care, education, research, and public trust in psychiatry.

Finally, these recommendations are intended as a “living document,” subject to amendment as additional issues require attention and as new approaches are developed to the subjects addressed here. They are not intended as definitive rules of behavior; since these general principles cannot anticipate every eventuality, exceptions may be necessary. Rather, it is hoped that they will stimulate reflection and discussion among psychiatrists, and will contribute to heightened awareness of concerns stemming from relationships with industry.

Recommendations Relevant to All Psychiatrists

Gifts: Gifts to individual physicians, even those of token value, have been shown to shape physicians' decisions about prescription of medication (8,9)—though physicians may be unaware of such influence. Gifts have been shown to trigger human impulses toward reciprocity (10,11) and, in addition, keep awareness of particular products in the forefront of physicians' minds. Psychiatrists' decisions about all aspects of their patients' treatment should be determined by patients' needs and not by extraneous variables.

- The APA recommends that psychiatrists and trainees not accept gifts from pharmaceutical, device, and other commercial entities, and that psychiatrists not display products with commercial logos.

Food: Representatives of the pharmaceutical and device industries have often supplied food and refreshments for educational and social functions attended by physicians and other health professionals. Such support is frequently accompanied by the distribution of promotional literature and sometimes by other promotional activities.

- The APA recommends that the same rules that apply to gifts in general should be applied to food: that psychiatrists not permit pharmaceutical, device, and other commercial entities to supply free food and refreshments for educational or social functions or to wards, clinics and offices, and that they not accept food that they are aware is being paid for by pharmaceutical or device companies.

Medication samples: Billions of dollars' worth of samples are distributed to physicians by pharmaceutical companies each year. (12) Samples may make it possible for patients who are unable to afford any medications to obtain treatment for their conditions, and may help psychiatrists engage patients in treatment. However, data also suggest that free samples influence the decisions of physicians and patients regarding which medications to prescribe, and hence are an effective marketing technique (13-15). Distribution of free samples may encourage psychiatrists to start patients on more expensive drugs than would be prescribed if samples were unavailable, and may leave psychiatrists feeling obligated to and dependent on pharmaceutical representatives for continued free medication for their patients. Recognizing both the benefits and risks associated with receipt and use of samples, some health care facilities have established mechanisms for their centralized receipt and distribution, which may be a helpful approach.

- The APA recommends that psychiatrists limit the use of free samples to situations in which their use is clearly in the interests of patient care, and that psychiatrists be alert that the purpose of samples is to increase market share of a particular medication. Samples intended for use by psychiatrists and their families should be considered gifts and should be avoided per the recommendation on gifts above. Psychiatrists in group, clinic, or hospital settings should consider setting up mechanisms for centralized receipt and distribution of samples.

Attendance at industry-supported educational programs: Pharmaceutical and device companies spend large amounts of money each year in support of educational activities. (16,17) Their involvement ranges from support of funding Accreditation Council for Continuing Medical Education (ACCME) accredited and peer-reviewed presentations to frankly promotional presentations. Although suggestions have been made for the elimination of industry support for continuing education programs, pharmaceutical companies currently provide the majority of funding for these educational activities. (18) The ACCME has developed standards intended to minimize the risk that industry-funded presentations will be biased toward the products manufactured by the sponsor (e.g., requiring that selection of presenters and content be free from control by commercial interests). (19)

- The APA recommends that psychiatrists participate in educational sessions sponsored by pharmaceutical, device, and other commercial entities, only if they are ACCME-accredited or otherwise have in place procedures to ensure that speakers are fully responsible for the content of their presentations. Payment for travel and lodging to attend CME programs should be considered gifts, and should be declined in compliance with the recommendation for gifts above.

Planning and presenting at industry-supported educational programs: Physicians may be offered the opportunity to plan or make educational presentations that are funded by pharmaceutical and device companies, whether in person, via teleconference, recorded, or on-line. Again, these opportunities vary from planning or speaking at ACCME-accredited programs to joining speakers' bureaus organized by those companies. Speakers' bureaus provide training, slide sets, and other materials to potential speakers who are then paid to present promotional talks on behalf of the companies and their products; typically, presenters are not in complete control of the content of their presentations. When program planners are subjected to undue influence in selecting educational presentations, or when speakers are not allowed to control the information and materials that they present, there is an inherent risk of bias in presentations.

- The APA recommends that involvement as program planners or speakers for industry-supported presentations should be limited to programs that are ACCME-accredited or otherwise have in place procedures to ensure that speakers are fully responsible for the content of their presentations. Payment for such activities should be proportional to the actual time and effort expended. Whenever possible, to insulate speakers from pressures from industry representatives, such payments should be made to the academic entity sponsoring the program, which would then pay the speakers.

Consulting arrangements: Pharmaceutical and device companies contract with physicians for consultation on a variety of issues, many of them important and legitimate (e.g., patients' needs for more effective treatments, drug development, study design, novel uses of existing drugs, concerns about side effects). However, consulting arrangements in which no substantive contributions are made in exchange for payment have been reported, and are largely designed as marketing techniques. Attendance at sessions that meet this description is not sufficient justification for payment.

- The APA recommends that psychiatrists avoid participation in consulting arrangements in which they are unlikely to make substantive contributions. Payment for legitimate consultation activities should be proportional to the actual time and effort expended.

Contact with pharmaceutical and device representatives: Pharmaceutical and device companies employ marketing representatives to "detail" physicians, establishing personal relationships, offering gifts and samples, and providing information intended to promote their companies' products. Many healthcare facilities now limit the activity of these representatives, requiring advance appointments, avoidance of patient care areas, and

distinct badges, and some facilities bar access altogether. Even if gifts are not accepted and samples are limited in accord with the recommendations above, there is risk that biased information will be provided and that physicians' prescribing practices may be influenced by innate tendencies toward reciprocity. (8) The result of such contacts may be decisions to prescribe medications that are based on something other than patients' best interests.

- The APA recommends that psychiatrists be aware that the role of pharmaceutical and device representatives is to market their company's products, and seriously consider the issues described above and the implications for patient care before deciding whether to interact with them. Institutional policies may also limit psychiatrists' interactions with industry representatives. In any case, psychiatrists should avoid reliance on pharmaceutical and device representatives as primary sources of treatment-related information.

Disclosure of relationships with pharmaceutical and device companies: Patients, students, and colleagues may have legitimate interests in knowing whether a physician has received money and gifts from pharmaceutical and device companies. (20) Moreover, awareness that such relationships need to be disclosed will sensitize physicians to the possible conflicts that may result and practical means of avoiding or managing them. Among the initiatives now under way are state legislation mandating industry disclosure of payment to physicians and web-based posting of payments by a number of academic medical centers. (21) However, disclosure is likely to be an imperfect remedy at best, as the persons receiving the information may neither understand the disclosure nor appreciate its implications. (22)

- The APA acknowledges the strong desire among the public for greater transparency of the relationships between physicians and pharmaceutical and device companies, and endorses the concept of physician disclosure of these relationships on an annual basis. To maximize the likelihood that such information will be understood and used appropriately, the APA encourages the development and adoption of uniform and accessible formats and content for disclosures required by academic institutions, funding agencies, journals and other entities, and experimentation with the best means of communicating this information to its target audience in a meaningful manner.

Ethics Education: With the advance of medical knowledge and the evolution of ethical understandings, it is important for all psychiatrists to remain up-to-date on ethical challenges in psychiatric practice and research, and on approaches to their resolution.

- The APA recommends that psychiatrists and trainees engage in on-going education on ethics issues, including relationships with industry, and stay current with their institutional policies regarding conflicts of interest.

Recommendations Relevant to Psychiatrists Who Conduct Research on Pharmaceuticals and Devices – Although the recommendations above are relevant to all

psychiatrists, whether in private or group practice or in academia, an additional set of considerations come into play for psychiatrists who conduct research on products of pharmaceutical and device companies.

Participation in Research by Psychiatrists with Financial Relationships with Pharmaceutical and Device Companies: When psychiatrists participate in research that may affect the financial interests of a company, regardless of the source of funding, researchers' financial relationships with the company raise understandable concerns about the objectivity of research findings. (2) Such relationships may include, but not be limited to: equity ownership in the company, receipt of royalty payments from the company, membership on company advisory boards, consultation to the company, and participation in speaking engagements funded by the company.

- The APA endorses the recommendation of the Association of American Medical Colleges and the American Association of Universities (23) that researchers generally should not be involved in research that may affect the interests of a company with which they, their spouses, or their dependent children have financial relationships apart from the funding of the study itself. Exceptions to this general rule should occur only under compelling circumstances (e.g., initial clinical testing of a device invented by the researcher that is unlikely to be pursued by other investigators), and only when an acceptable plan for management of the conflict created by the relationship has been developed and implemented.

Disclosure of Researchers' Financial Relationships: Prior to enrolling in a research study, prospective subjects have the right to know when researchers have financial relationships with pharmaceutical and device companies whose financial interests may be affected by the study, along with the source of funding for the study.

- The APA recommends, in addition to the routine disclosure of financial relationships recommended above, that prospective research subjects be told in a clear fashion that such relationships exist before being asked for their consent to participate. In addition, psychiatric researchers should be in compliance with the applicable disclosure requirements of their institutions (24) and funding agencies.

Payment for the Conduct of Research Studies: Funding from pharmaceutical or device companies for research should cover the actual costs of performing the research, including salaries of researchers and research staff; costs of tests, procedures, and medications; data analysis costs; and appropriate overhead. Such payment may be structured on a flat rate or a per subject basis. However, payments unrelated to actual costs and appropriate compensation for time expended may unduly influence psychiatrists' decisions about enrollment of prospective subjects, leading to inappropriate pressure on subjects to participate.

- The APA recommends strongly that psychiatrists not participate in research that involves payment unrelated to actual costs and appropriate compensation for time expended.

Control Over Publication of Research Findings: Suppression of findings unfavorable to companies that have funded research studies threatens the integrity of medical research and the validity of data on which clinicians make decisions that affect patient care and researchers design future investigations. (25-27) From the perspective of increasing the medical evidence base, publication of negative findings is extremely important.

- APA believes that it is critical that mechanisms be created in every clinical trial to ensure publication of clinically significant findings, including negative ones. Psychiatrists should not participate as authors without full access to the relevant data and the ability to report negative results and adverse events.

Authorship of Reports of Research Findings: “Ghost-writing” of research reports—i.e., employees of pharmaceutical or device companies drafting and/or revising such reports without acknowledgement of their role—makes it difficult for editors, reviewers, and readers to ascertain the reliability and validity of the data and interpretations being presented. (28) Ghost-writing may also involve listing authors who have not played a meaningful role in writing or reviewing the paper on which their names appear.

- The APA recommends that all authors be acknowledged, that their roles in the research and preparation of the manuscript be accurately described, and that they strictly abide by the requirements of the International Committee of Medical Journal Editors (29), including that “Authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published.” Every coauthor is equally responsible for the content of the entire paper, and each must seek to ensure that data presentation and interpretation meet the highest scientific standards. Financial support, if any, for the preparation of the manuscript should be disclosed.

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