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Recommendations for Relationships of Psychiatrists, Health Care Organizations Working in the Psychiatric Field and Psychiatric Associations with the Pharmaceutical Industry GA23.10.11

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FOREWORD

The WPA recognizes the potential benefits that can derive from the relationships of psychiatrists, health care organizations, and psychiatric associations with the pharmaceutical industry, but also acknowledges the risk of harm that can result from the sometimes divergent interests of these groups. To maximize the benefits and reduce the risk of harms, the WPA offers this set of recommendations to guide these relationships.

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INTRODUCTION

Psychiatrists, health care organizations (HCOs) working in the psychiatric field, and psychiatric associations (PAs) often have relationships with the pharmaceutical industry in areas including patient care, research, and education. Some of these relationships arise from contacts with pharmaceutical representatives who market products, while others derive from industry-sponsored educational or research activities. For HCOs and PAs, relationships encompass activities conducted within the organizational framework (e.g., teaching and research), and those based on the financial relationships of organizational leadership or the organization itself with industry (e.g., stock ownership, licensure of patents). Many benefits can flow from such relationships, including the opportunity for psychiatrists to have input into product development and organizational access to increased resources that can be devoted to the entity's primary missions. However, there is also the possibility that financial and other benefits for psychiatrists, HCOs and PAs may negatively affect fidelity to patients, research subjects, and trainees.

WHAT THE POSITION STATEMENT AIMS TO ACHIEVE

The WPA Position Statement on the Relationships of Psychiatrists, Health Care Organizations Working in the Psychiatric Field and Psychiatric Associations with the Pharmaceutical Industry provides a set of recommendations aimed to: a) protect the role of the physician and the missions of medical organizations

from being adversely impacted by relationships with the pharmaceutical industry; and b) encourage national PAs to develop and update guidelines for relationships with the pharmaceutical industry based on these recommendations and provide ongoing education for their members on these issues. These recommendations will be reviewed and updated periodically by WPA in response to changing circumstances.

MAIN TEXT

The main text of the document is organized in 6 sections: Patient Care, Psychiatrists' Participation in Professional Meetings, Formularies, Research, Education and Issues Specific to Psychiatric Associations. Each section contains a summary of the main issues and relevant recommendations

1. Patient Care

In the delivery of patient care, the interests of patients should take primacy over all other considerations. A persuasive body of research suggests that visits from representatives and the acceptance of gifts, including items with industry/brand names and logos, or of medication samples influence physicians' prescribing practices.

Recommendations

Psychiatrists should be aware that the primary role of pharmaceutical representatives is to market medications and other products, and that the information received from such sources may not be completely objective. Psychiatrists should be aware of the data indicating the likelihood of subtle influences on their behavior and should never rely on pharmaceutical representatives as a primary source of information about treatments. Pharmaceutical representatives should be required to make appointments to see psychiatrists and should never be involved in patient encounters. *HCOs* should develop policies that regulate contacts between psychiatrists and pharmaceutical representatives, in particular by limiting encounters to fixed appointments that should never take place in patient-care areas or otherwise involve the presence of patients

Psychiatrists should not accept gifts, including meals for themselves and their staffs, from pharmaceutical companies and should ensure that items carrying companies' logos do not appear in patient care areas; *HCOs* working in the psychiatric field should adopt policies that preclude psychiatrists and other staff from accepting gifts from pharmaceutical companies. Items carrying logos of pharmaceutical companies should never appear in patient care areas.

Psychiatrists should be aware of the reasons why pharmaceutical companies may distribute samples and should generally not accept them. If they continue to accept medication samples, they should do so only for patients who would otherwise be unable to afford medications. *HCOs* that desire to continue accepting samples should develop mechanisms for central receipt and distribution (e.g., in a hospital or clinic pharmacy) to ensure that individual psychiatrists do not feel pressured by the receipt of samples for their patients to prescribe medications recommended by pharmaceutical representatives.

2. <u>Support for Travel to Professional Meetings</u>

Pharmaceutical companies may offer to provide support for psychiatrists to attend professional meetings, including registration, travel costs, hotel rooms, and meals. By offering such support, the

companies may hope to induce feelings of gratitude that will result in greater receptivity by the psychiatrists to promotional materials and a greater likelihood of prescribing the companies' products.

Recommendations

Psychiatrists, especially from low-income and middle-income countries, who would not otherwise be able to attend professional educational meetings may accept support from pharmaceutical companies to do so. Support should be limited to psychiatrists themselves, not extended to family members or friends. Since the primary goal of accepting such support is to enhance psychiatrists' professional knowledge, recipients should be diligent about attending educational sessions. Psychiatrists who accept such funding should be aware of the possible influence on their treatment decision making and should be vigilant in ensuring that all subsequent decisions regarding selection of treatments are based on patients' interests. Psychiatrists should not accept support to attend meetings that is contingent on the use of a company's products. If questions arise about the appropriateness of accepting such support, psychiatrists should consult with their national psychiatric association's ethics committee.

3. Formularies

Many national health systems, hospitals, and clinics maintain formularies, i.e., lists of medications that will be kept in institutional pharmacies and that can be ordered for patients. Decisions about which medications should be listed in formularies should be made based on their utility for patient care, taking into account limitations on resources. These choices can have significant financial implications for pharmaceutical companies, which may try to influence the decisions.

Recommendation

HCOs should develop policies prohibiting persons with current, recent or prospective financial relationships with pharmaceutical companies, or whose first-degree relatives have such relationships, from serving on national or institutional formulary committees.

4. <u>Research</u>

In many parts of the world, a substantial proportion of funding for clinical research comes from industry, which has an interest in demonstrating the efficacy of its products. Industry-funded research can yield valid and important results, so long as its integrity is protected from adverse influence. Preservation of public trust in the integrity of the research process is critical to maintaining public support and funding for the research enterprise. Psychiatrists, HCOs working in the psychiatric field, and PAs may have financial relationships with industry that call into question the objectivity with which they and their employees conduct research on products in which the pharmaceutical industry has an interest. For PAs, this concern extends to development of practice guidelines and similar documents based on existing research. Insulating the research enterprise from possible negative effects of industry relationships with investigators begins with transparency about those relationships. In addition, the pharmaceutical industry may fund research projects by entering into contracts either with medical organizations where the research will be performed, or directly with individual physicians. At times, provisions in these contracts have restricted the ability of investigators to publish the data they collect, allowing companies to control the presentation of results. Suppression of unfavorable findings has led to significant distortions in the medical literature, resulting in the risk of less-than-optimal treatments being chosen for patients.

Recommendations

Psychiatrists with more than a minimal financial relationship with a pharmaceutical company (excluding grant or contract support for the research itself), or whose first-degree relatives have such relationships, in general should not engage in research involving that company's products. In those uncommon instances in which an exception may be appropriate, organizationally based investigators should seek review by their institution's conflict of interests committee. Investigators who are not organizationally based should identify an appropriate conflict of interests committee that would be willing to review their situation or seek advice from their national psychiatric association's ethics committee.

HCOs that conduct research should establish an institutional conflict of interests committee to review potential studies for which an organizational relationship with industry exists and develop and implement appropriate management strategies to protect the integrity of the research from organizational pressures. Organizations should also develop policies requiring disclosure of investigators' financial relationships with industry. An individual conflict of interests committee (which could be the same committee that reviews institutional conflicts) should be established to review and manage investigators' financial relationships.

PAs that conduct research should follow the recommendations for health care organizations. In addition, associations that produce practice guidelines and similar documents should apply these approaches to the relationships with industry of members and consultants who serve on the committees that develop these resources. *Psychiatrists* engaged in research should affirmatively disclose the existence and nature of their relationships with industry, and the relationships with industry of their first-degree relatives, to potential research participants.

HCOs and PAs should develop policies requiring investigators to disclose the existence and nature of organizational and investigator relationships with industry to potential research participants.

Psychiatrists and *HCOs* should avoid entering into research contracts with industry that contain provisions allowing the company to restrict publication of research findings, limit investigators' access to the original research data, or give the company the right to control how the findings are analyzed and presented. PAs should develop policies that preclude organizational involvement in industry-funded research in which investigators do not have access to data analysis and cannot control decisions about publication of findings.

5. Education

Physicians, medical organizations, and professional associations are often involved in the education of students in medical, nursing, and other health professional programs, the training of house officers and other staff, and the provision of continuing education for physicians, nurses and other professions. Pharmaceutical companies may provide support for educational activities, and are often heavily involved in supporting continuing education programs for physicians. This involvement has raised concerns about the objectivity of information presented with industry funding, which may be designed to shed a favorable light on the funder's products. Exposure to industry-controlled continuing education programs has been shown to have a direct effect on the prescription practices of trainees and practicing physicians.

Psychiatrists' primary obligations to patients' interests require that steps be taken to minimize the impact of pharmaceutical companies on medical education.

Recommendations

Psychiatrists should avoid participating – as speakers or attendees – in educational presentations in which the speaker does not directly control the content of the presentation, and should not accept funding from the pharmaceutical industry for educational presentations unless they have control over the topic and content of their presentations.

HCOs and *PAs* should develop policies that preclude educational presentations on their premises, at their meetings, or with their sponsorship in which the speaker does not directly control the content of the presentation. *HCOs* and *PAs* should develop policies that prohibit receipt of funds from industry for educational programs conditioned on industry designation of topics, speakers, or target audiences. Industry funding for education should come in the form of unrestricted grants, with the stipulation that the organization or association shall have control of topics, speakers, and audiences. Pharmaceutical marketing materials should not be distributed at educational presentations.

Psychiatrists should seek out and *HCOs* and *PAs* should develop educational programs on how to avoid or manage problems that can arise from relationships with the pharmaceutical industry. Such programs should emphasize data on the nature and positive and negative effects of relationships with industry.

6. Issues Specific to Psychiatric Associations

In addition to the recommendations above, the unique role of professional associations in formulating standards – including ethical standards – and providing education to members raise additional issues that should be considered.

Recommendations

PAs should seek to minimize reliance on industry support of their activities. Public disclosure should be made of all industry support, and association leaders should disclose their relationships with industry on at least an annual basis. Institutional conflict of interest committees should consider strategies for managing or eliminating conflicts that may arise from organizational or individual relationships with industry. PAs should not participate in marketing activities on behalf of pharmaceutical companies, including endorsement of commercial products. Finally, PAs have a responsibility to develop guidelines for their members regarding members' relationships with industry.

When organizing national or international conferences or congresses, *PAs* can accept support from industry, but should make reasonable efforts to seek sponsorship from multiple sources. All commercial support should be openly disclosed to attendees. PAs should identify the topics, content, and presenters at their meetings independent of influence from pharmaceutical and other companies, and ensure that they meet appropriate guidelines for continuing medical education. Satellite symposia should be held to identical standards as presentations that are part of the official program. PAs should place limits on exhibits and exhibitor conduct to ensure that the tone of the exhibit area is professional in nature.

HCOs working in the psychiatric field and *PAs* should establish a process to develop and implement guidelines regulating organizational relationships with industry, including the creation of conflict-of-interest committees, consistent with the recommendations above.

SUMMARY AND CONCLUSIONS

Relationships of Psychiatrists, Health Care Organizations Working in the Psychiatric Field and Psychiatric Associations with the Pharmaceutical Industry may be beneficial for the advancement of research, care and knowledge. However, when these relationships are not guided by the principle that the interests of patients should take primacy over all other considerations, they may negatively affect patient care, research and education.

In this document we have highlighted the main areas in which we envisage a risk of putting the interests of the pharmaceutical industry, individual psychiatrists, HCOs or PA above patient interest, and have provided relevant recommendations. The collaboration between medical doctors and pharmaceutical industry is an important resource and should not be jeopardized by misbehaviors of individuals, HCOs, or associations. It should be characterized by mutual respect for the different roles and interests involved, fruitful exchanges of scientific and clinical knowledge, a shared goal to advance treatment outcomes, and by transparent disclosure of potential conflicts of interest arising from the collaboration itself.

RECOMMENDATIONS FOR ACTION

WPA encourages national psychiatric associations to develop and update guidelines for relationships with the pharmaceutical industry based on these recommendations and to provide ongoing education for their members on these issues.