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WPA Position Statement: Recommendations for Relationships of Psychiatrists, Health Care Organizations Working in the Psychiatric Field and Psychiatric Associations with the Pharmaceutical Industry

Psychiatrists, health care organizations working in the psychiatric field, and psychiatric associations often have multiple relationships with the pharmaceutical industry in areas including patient care, research, and education. Some of these relationships arise from contact with pharmaceutical representatives who market products, while others derive from industry-sponsored educational activities or research studies. For health care organizations and psychiatric associations, relationships encompass both activities conducted within the organizational framework (e.g., teaching and research), as well as 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, health care organizations working in the psychiatric field and psychiatric associations may negatively affect fidelity to patients, research subjects, and trainees. As has been widely recognized, attention must be given to protecting the role of the physician and the missions of medical organizations from being adversely impacted by these relationships. The following recommendations are offered in that spirit. 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. These recommendations will be reviewed and updated periodically by WPA in response to changing circumstances.

PATIENT CARE

In the delivery of patient care, the interests of patients should take primacy over all other considerations. This is consonant with psychiatrists' duties of beneficence towards their patients and fidelity to patients' interests. Psychiatrists and health care organizations working in the psychiatric field, therefore, should attempt to prevent influences on clinical decision making arising from relationships with industry that may result in decisions (e.g., the choice of medications to be prescribed) based on considerations other than patients' best interests.

Access by Pharmaceutical Representatives

The pharmaceutical industry communicates directly with physicians and other caregivers through its marketing representatives, who routinely visit physicians' offices and other sites of care. A persuasive body of research suggests that visits from representatives are highly effective in changing physicians' prescribing practices and stimulating requests for expansion of hospital formularies. Often these changes are in the direction of newer and more expensive medications, which may not always be used for appropriate indications. Although many physicians rely on pharmaceutical representatives for information about new products, studies indicate that the information provided may be incomplete or misleading. Representatives may frequent public or patient care areas in the hopes of meeting physicians in informal settings.

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. Concerns about influence on their prescribing practices may lead some psychiatrists to choose not to meet with pharmaceutical representatives. Psychiatrists who continue such meetings 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.

Health care organizations working in the psychiatric field should develop policies that discourage their psychiatrists from meeting with pharmaceutical representatives. Some organizations may want to prohibit such meetings, while others will give their psychiatrists discretion in that regard. In the latter case, if psychiatrists desire meetings, representatives should be limited to fixed appointments and should not be permitted in the facility at other times. Pharmaceutical representatives should never be permitted to be involved in patient encounters, or otherwise to be present in patient-care areas.

Meals

Pharmaceutical representatives sometimes offer meals to physicians and their staffs, and to the staffs of clinics and hospital wards. These meals provide opportunities for informal interaction with physicians, distribution of marketing materials, and another way of ingratiating the representative to the organization. As such, they represent a mechanism to further influence physicians' prescribing decisions.

Recommendations

Psychiatrists should forego offers of meals from pharmaceutical companies for themselves and for their staff members.

Health care organizations working in the psychiatric field should develop policies prohibiting acceptance of meals sponsored by pharmaceutical companies on the organization's premises.

Gifts, Including Materials Carrying Logos

Pharmaceutical companies frequently distribute materials with their names and logos and those of the brands that they are promoting. Like all advertising, these items are intended as regular reminders to physicians about the companies' drugs. In general, these are low-value items such as pens, pads of paper, wall clocks and the like, but they are designed to be placed in prominent places in physicians' offices and clinic areas. Beyond the promotional impact, there is reason to believe that these small gifts may induce instincts of reciprocity on the part of recipients, who may desire to reciprocate with a favor to the gift-giver. Both phenomena can result in medication choices being made on other bases than patients' best interests. Presence of these items can also raise doubts in patients' minds as to the grounds on which physicians' treatment decisions are being made.

Recommendations

Psychiatrists should not accept gifts from pharmaceutical companies and should ensure that items carrying companies' logos do not appear in patient care areas.

Health care organizations 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.

Samples

Marketing representatives often distribute medication samples as a technique to encourage adoption of new medications. In some cases, samples may represent the only access that indigent patients have to medications. Sometimes, however, samples may be offered as a mechanism for getting patients started on a medication that will subsequently be paid for by an insurance plan or directly by the patient. Distribution of samples has been shown to have an effect on physicians' prescribing decisions. Physicians whose patients rely on samples may face pressure to maintain positive

relationships with the pharmaceutical representatives who supply them.

Recommendations

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.

Health care organizations working in the psychiatric field 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.

Support for Travel to Professional Meetings

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. However, for many psychiatrists in low-income and middle-income countries, pharmaceutical support may present the only opportunities they have to attend national and international educational meetings.

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. For psychiatrists who will be presenting at meetings, the topic and content of their presentations must remain under their control, regardless of the source of funding for their attendance.

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 on the basis of 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

Health care organizations working in the psychiatric field 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.

RESEARCH

Physicians and health care organizations working in the psychiatric field, and less commonly professional associations, that conduct research play critical roles in advancing medical knowledge. 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. When investigators, organizations or associations have relationships with industry, concerns can arise about the independence and objectivity of the research they pursue. Given that research findings constitute the evidence-base on which clinical decisions are made, ensuring that those decisions are made in patients' best interests requires protecting the integrity of psychiatric research from outside interests.

Disclosure, Review, and Management of Relationships with Industry in the Research Setting

Psychiatrists, health care organizations working in the psychiatric field, and psychiatric associations 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 psychiatric associations, this concern extends to development of practice guidelines and similar documents based on existing research. Psychiatrists' relationships may include lecture fees, consultantships, service on advisory boards, and equity interests in companies, or similar relationships of their first-degree relatives. Organizational relationships may include industry gifts to the organization, licensure of patents, and industry funding for clinical, research, or educational endeavors. A subcategory of organizational relationships involves financial interests that the organization's leaders may have in

pharmaceutical companies, e.g., stock ownership, receipt of honoraria, etc. Insulating the research enterprise from possible negative effects of industry relationships with investigators begins with transparency about those relationships. Investigators should bear the burden of disclosing their financial relationships with the pharmaceutical industry to their institutions, while the organizations and associations themselves are responsible for developing and implementing plans to avoid and manage potential conflicts. In general, the more closely a psychiatrist's or an organization's research activity relates to its financial interest (e.g., research on a compound licensed to industry for which the psychiatrist is a consultant or the organization owns the patent), the stronger the need for management of potential conflicts. Management approaches can include avoiding relationships with industry during the conduct of a research study, creating buffers between those responsible for an organization's finances and those conducting the research, and external review of research findings to insure their validity.

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.

Health care organizations working in the psychiatric field that conduct research should establish an institutional conflict of interests committee to review potential studies for which an organizational relationship with industry exists. The committee should have the authority to 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.

Psychiatric associations 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.

Disclosure of Institutional- and Investigator-Industry Relationships to Research Participants

Potential research participants may find an institution's or investigator's relationships with the pharmaceutical industry to be material to their decisions as to whether to participate in a research study. Studies suggest that research subjects desire to receive this information about investigators in particular. At least in some cases, this information will affect their participation decisions. Moreover, transparency of this sort may play an important role in preserving public trust in the conduct of research.

Recommendations

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.

Health care organizations working in the psychiatric field and psychiatric associations should develop policies requiring investigators to disclose the existence and nature of organizational and investigator relationships with industry to potential research participants.

The written informed consent form is a useful vehicle for these disclosures.

Contracts with Industry to Fund Research

As noted above, the pharmaceutical industry provides a substantial proportion of funding for clinical research in many parts of the world today. Typically, this funding comes in the form of contracts with medical organizations where the research will be performed, but industry may contract 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 and *health care organizations* working in the psychiatric field 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. *Psychiatric associations* should develop policies that preclude organizational involvement in research in which investigators do not have full control of data analysis and publication.

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 undergraduate and graduate medical and other health professional education, 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.

Industry-Controlled Educational Presentations

Pharmaceutical companies may have direct control over presentations to medical audiences when those presentations are made by their employees or when they provide the content and funding for a presentation by a non-employee. Given companies' interests in selling their products, such presentations are not likely to meet medical standards for objective and valid information.

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.

Health care organizations working in the psychiatric field and *psychiatric associations* 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.

Industry-Funded Educational Presentations

Pharmaceutical companies may offer funding to physicians, medical organizations, and professional associations to produce educational programs on particular topics, involving identified speakers, and with specified target audiences. Acceptance of these terms presents a significant risk that such presentations will not meet generally accepted standards for objectivity.

Recommendations

Psychiatrists should not accept funding from the pharmaceutical industry for educational presentations unless they have control over the topic and content of their presentations.

Health care organizations working in the psychiatric field and *psychiatric associations* 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 complete control of topics, speakers, and audiences. Funding for such programs should be provided to the organization or association or to one of its administrative divisions, not directly to a member of its staff. Pharmaceutical marketing materials should not be distributed at educational presentations.

Education on Relationships with Industry

Physicians should be aware of the positive and negative aspects of relationships with industry, and medical organizations and professional associations can play an important role in educating trainees and physician staff members on these issues. Such education can permit trainees and physicians to determine their own conduct in relation to industry in an informed manner.

Recommendation

Psychiatrists should seek out and *health care organizations* working in the psychiatric field and *psychiatric associations* 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.

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

Psychiatric associations 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. Psychiatric associations should not participate in marketing activities on behalf of pharmaceutical companies, including endorsement of commercial products. Finally, psychiatric associations have a responsibility to develop guidelines for their members regarding members' relationships with industry.

When organizing national or international conferences or congresses, *psychiatric associations* 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. Psychiatric associations 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. Psychiatric associations should place limits on exhibits and exhibitor conduct to ensure that the tone of the exhibit area is professional in nature.

Health care organizations working in the psychiatric field and *psychiatric associations* 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.