

**ASSOCIATION OF CLINICAL RESEARCHERS AND EDUCATORS
A STATEMENT ON RELATIONSHIPS BETWEEN PHYSICIANS AND INDUSTRY**

Writing Committee of the Association of Clinical Researchers and Educators*

Running Title: Physician and industry relationships

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ABSTRACT

Collaborations between physicians, particularly those in academic medicine, and industries that develop pharmaceutical products, medical devices and diagnostic tests have led to substantial advances in patient care. At the same time, there is a strong awareness that these relationships, however beneficial they may be, should conform to established principles of ethical professional practice. Through a writing committee drawn from diverse disciplines across several institutions, the Association of Clinical Researchers and Educators (ACRE) has written a code of conduct to provide guidance to physicians in observing these principles. Our recommendations are not intended to be prescriptive or inflexible, but rather to be of assistance to physicians in making their own personal decisions on whether, or how, to be involved in research, education or other collaborations with industry.

PURPOSE OF THIS STATEMENT

This statement reviews the major areas of interactions between physicians and health-related industries and makes recommendations to academic and community physicians involved in these activities to assist them in maintaining the highest standards of professional conduct.

Background

The primary goal of physicians and other healthcare professionals is to enhance the quality and length of life of their patients. Beyond their own clinical skills and judgment, clinicians must rely on the availability of the most appropriate medicines, devices and diagnostic procedures.

The active and continuing collaboration of clinicians and industry is vital to patient care. Physicians have the experience and opportunity to identify unmet needs in clinical practice, to design innovative solutions, conduct pivotal clinical trials and, through publications and teaching, to bring this new information to their colleagues and to patients.

Collaborating partners in industry have the resources and expertise to discover new therapies and develop innovative medical procedures, and to take these advances through the painstaking processes of basic research, clinical development and eventual production. The ability to deal with the related scientific, regulatory, legal, financial and manufacturing issues allows industry to complement the skills and contributions of its academic and clinical partners. Many of the major therapeutic advances across the spectrum of medical practice during recent years have been linked to these collaborations.

Why a Code of Conduct?

Collaborations between physicians and industry have added considerably to patient care and overwhelmingly have been conducted with integrity and commitment. Even so, critics of these collaborations have raised concerns which -- while largely theoretical -- have helped create complicated and counterproductive regulations that adversely affect these relationships. As a professional organization, ACRE believes it has a responsibility to help codify the principles governing the interactions between physicians and industry and to provide guidance to academic and community physicians. Our intent is to enhance collaborations that promote innovation and education for the ultimate benefit of patients.

Interactions between Physicians and Industry

The main types of interactions considered in this statement are:

- I. Clinical and scientific research
- II. Consulting and advisory activities
- III. Continuing medical education
- IV. Product-specific education
- V. Publishing
- VI. Expert witness activities
- VII. Travel
- VIII. Professional medical societies

We will briefly explore each of these interactions between physicians and industry and offer recommendations, as relevant, to guide the ethical and effective conduct of these relationships.

I. RESEARCH ACTIVITIES

There are two main types of clinically-based research relevant to physician/industry relationships:

- Sponsored clinical trials research, often multi-center and involving both academic and non-academic center-based investigators, but typically led by academically-based principal investigators and steering committees.
- Investigator-initiated trials, for which individual academic or community physicians solicit financial or other support from industry to facilitate exploration of innovative ideas
- Industry may also support basic research in clinical or non-clinical settings, sometimes linked to the licensing and further development of intellectual property (inventions) owned by individual physicians or institutions

Main Benefits of Research

Physicians in academic institutions or in the community who are considering collaborative research activities with industry should be clear as to the reasons underlying these commitments. The following are examples of expected benefits of research conducted by, or under the guidance of, academic faculty and supported by industry:

- Advances in patient care
- Advances in clinical or basic sciences
- Assistance to industry in credible therapeutic development
- Physician support and career growth: providing younger physicians with experience and knowledge in contemporary research methods, particularly the progressively more sophisticated conduct of clinical trials; in addition, participation as authors in publishing research papers further enhances the academic progress of physicians
- Research experience for fellows and other trainees at academic medical centers, which is often a requirement for satisfying sub-specialty board eligibility

- Potential financial support for training or fellowship positions and related academic development

Recommendations

1. Be clear why a relationship is being established: Are there true benefits (for example, those listed above)?
2. It is important, right from the beginning of an anticipated project, to establish the role of physicians. Even in research initiated by industry physicians should be involved in such responsibilities as membership of the Executive or Steering Committees, particularly of larger clinical trials. They should participate actively in the design of studies; take part in the analysis and interpretation of data; and have the leading role in writing manuscripts. These considerations should be negotiated and clarified with industry sponsors before reaching final decisions about whether to participate.
3. Be clear about the distribution of funding to be provided by the outside source. Physicians in academic or other large institutions should establish how the funds will be spent within their institution. Will the responsible investigator have adequate authority to ensure the money is used to support the requirements of the study protocol? And, if there are any excess funds, will the investigator have freedom to allocate them to support institutional projects mutually deemed to be worthwhile?
4. Payment of physicians:
 - (i). If physicians are providing meaningful and time-consuming work that is not otherwise compensated, then it is reasonable that the project funding make allowances (either within the research grant or separately) to provide appropriate payment for their professional services. The ways in which industry funding may be used to compensate

physicians should be clearly agreed upon prior to starting the work. Depending on institutional rules, the compensation to physicians may be allocated to the institution and then passed on to the investigator as part of their salary arrangements; or there may be separate arrangements through foundations; or there can be direct payments to the investigator.

(ii). In determining the size of any payments, it is important to make realistic and fair estimates of the value of the work being provided to the project. Excess payments can appear to be inducements designed to encourage favorable outcomes from the physician; payments that are too small can have the effect of undervaluing the importance of the work as well as the stature of the investigator. The key is to ensure that payments are managed in an appropriate and clearly defined fashion. *(Please see more about physician compensation at the end of this statement).*

(iii). As noted above, payment to faculty or community physicians for services during the study that could be described as supervisory, operational or administrative is generally appropriate. But, as the clinical trial reaches its end and the data base is completed (or “locked”), the work of the responsible investigators changes substantively and now focuses on analyzing and interpreting the study results and publically reporting them. At this stage, the appropriateness of receiving compensation from a sponsor should be reconsidered. *(Please see more discussion of this issue in the Publications Section of this statement).*

5. There are instances where physicians engaged in research have made important discoveries and, either alone or in partnership with their institutions, have formed companies to further develop the discovery. Given that these individuals are uniquely

knowledgeable in the subject matter, it is fully appropriate for them to continue participation in this developmental work as long as it is clearly disclosed that they have equity interests in the enterprise. The payment of royalties (calculated according to established principles) to physicians who develop drugs, devices or other useful medical interventions is proper and hopefully stimulates valuable discoveries.

II. CONSULTING AND ADVISORY ACTIVITIES

Some of the most important and creative interactions between industry and academic and community physicians are based on consulting and advisory activities that enable important exchanges of information and ideas. It is from these activities that much of the research and education jointly undertaken by physicians and industry are derived. Consulting activities can generally be described under the following categories:

1. Research and development of new therapies and diagnostic tests, or enhanced use of those already available
2. Resolving regulatory issues e.g. advising companies, or representing them, in interactions with the Food and Drug Administration or with other federal or government authorities
3. The review of safety and efficacy data and advising on further steps when issues arise regarding the safety of approved drug products or devices
4. Education e.g. planning symposia, either freestanding or part of major society meetings; or assisting companies in developing teaching materials such as slide sets
5. Public relations: serving as experts or spokespeople, on behalf of medical institutions or industry or, more likely, joint academic/industry activities, to the media. As well, clinicians may be asked by medical corporations to help explain important medical and scientific concepts to the financial community

6. Corporate advisory boards: these can be long-term consulting activities that may incorporate more than one of the above areas

Recommendations

1. These consulting activities potentially are valuable, not only for corporate sponsors but more broadly in enhancing research, new technologies, education and drug safety that could contribute to the public benefit as well as to the knowledge of participating physicians. In deciding whether to serve as consultants, physicians should consider these issues and be clear as to the relevance of their involvement in these activities.
2. When consulting activities do not directly provide benefit to the physician's institution, care should be taken by physicians to clear time for this work. Some academic institutions may put time and compensation limits on faculty involvement in consulting.
3. When asked by industry to serve as public spokespeople, it is generally appropriate for faculty experts to explain scientific and clinical data arising from collaborative work in which they took part. It may also be acceptable for faculty physicians to explain scientific facts, even when they were not involved in the underlying research, if doing so helps clarify important issues. However, faculty experts should be very careful to avoid giving the impression that they are primarily defending industry interests. A medical company should have its own well qualified internal people capable of explaining the company's position.
4. Payment must be fair. These consulting activities represent valuable professional services and should be compensated at a level commensurate with the work done, even for salaried physicians who share this income with their academic or other institutions. *(Please see more about faculty compensation at the end of this document).*

III. CONTINUING MEDICAL EDUCATION

Some critics have expressed concern over CME activities and have suggested that financial support by industry could influence the teaching and so compromise the objectivity of these events. These assertions are primarily hypothetical, however, and not substantiated by available evidence. Currently, several safeguards are in place as part of the approval process for CME activities designed to eliminate bias and enhance true value of the educational experience.

Broadly, there are two types of CME activity.

1. Non-industry supported CME events: many professional educational activities, including lectures or other forms of teaching in medical schools or hospitals, or during sessions at scientific programs of medical societies, do not receive corporate support and thus do not encompass physician/industry relationships. (But see Recommendation #2 below).
2. Industry Supported CME programs: these events may be held in different ways, including live activities in public places or as on-line programs. They can be sponsored (and thus provide participants with official CME credits) by medical schools, medical societies and commercial CME providers. Often these programs are first planned by external medical education companies which, jointly with the CME sponsors, seek financial support from pharmaceutical or device companies or other health-related industries. The rules of the Accreditation Council for Continuing Medical Education (ACCME) for such educational events, which usually comprise presentations by multiple faculty members, are stringent. They require that presentations carefully avoid explicit commercial interests or specific products and observe strict balance when products are discussed. External reviewers are enlisted to ensure that proposed programs follow these rules.

Recommendations

1. Faculty members are strongly encouraged to participate in the planning of CME events, and in particular to ensure that they have control over the content of their presentations and are comfortable with their educational and scientific value.
2. Even for CME events that do not have corporate support, individual presenters or teachers might have research, consulting or other relationships with industry. Standard acknowledgement-of-support procedures should be applied when relevant to the subject matter being discussed.
3. Ensure that the primary goal of CME is met: to empower practitioners who participate to provide improved care for their patients. This is the ultimate test of the value of CME, and faculty members should be willing to assist in post-CME surveys that examine whether, in fact, attendees have changed practice strategies in response to what they learned at the event.
4. Faculty members should insist on creating their own talks, preferably in collaboration with the other speakers (typically facilitated by one or more telephone conferences). Sometimes it is useful to get assistance from an external medical education company, but final responsibility for the content, scientific integrity and objectivity of the presentation rests with the speaker
5. Honoraria: the amount of the speaker's honorarium for such an event is usually pre-set by the CME provider and the commercial supporter, and usually reflects their policies (based on the judgment of their legal and regulatory officers) regarding the fair value of faculty services. However, the fee should reflect the often considerable amount of work required to prepare a presentation, travel and time away from family or work, giving the actual talk,

participating in panel discussions and helping to write syllabi and other printed materials.

Contracts for this work should be negotiated between presenters and the CME sponsors. (*See further comments about faculty fees at the end of this statement*).

IV. PRODUCT-SPECIFIC (PEER-TO-PEER) EDUCATION

These types of industry-initiated educational events -- sometimes labeled as “promotional” -- have become strictly controlled such that a physician-speaker is asked to present, on behalf of a pharmaceutical or device company, FDA-approved information restricted tightly to a product’s approved indications and labeled data on efficacy and adverse effects. Ideally, such education can still represent an opportunity for physicians to share valuable knowledge with practicing colleagues. In some cases this sharing of new or interesting medical information can be built into the official presentation. Alternatively, the informal period following the presentation can provide an opportunity for collegial interaction between the presenter and the audience. Skilled speakers may also stimulate spontaneous questions from their audiences during their presentations, thus enhancing the educational experience. The attendees at these sessions usually know in advance of their limited scope, but they still should have a reasonable expectation of asking questions and getting useful information from an expert speaker. However, if questions get into “off-label” attributes of drugs, speakers are sometimes constrained by the sponsors from fully dealing with them in the public setting, perhaps necessitating later private conversations.

A vexing problem

Because of alleged off-label marketing of drugs by a small number of pharmaceutical companies which in recent years has resulted in actions by the US Department of Justice, the pharmaceutical industry has become very restrictive in its conduct of product-specific education. In essence, to prevent potential violations, speakers are now expected to utilize company-

provided slide sets, often without options to add or alter the content. This applies even to those parts of the talk that do not deal with sponsors' products but simply discuss broad clinical aspects of the relevant disease or condition.

Response by Some Institutions

Some academic and community medical institutions, quite understandably, have identified an ethical dilemma: How can their faculty members, when introduced as speakers at such events, in good conscience give a presentation in which they have had no creative input? Some institutions have advised their faculty members not to participate in these programs (although research, consulting and other types of relationships with industry are treated differently), thereby limiting potentially useful teaching opportunities in their communities.

Clearly, in the interests of academic independence it would be most desirable for speakers, while being guided by the rules (chiefly, conformity with product labeling) that govern sponsored peer-to-peer education, to have the freedom to put together their own presentations. One of ACRE's goals is to work with industry, which we believe has become overly restrictive in its conduct of these peer-to-peer programs, and also with federal and other regulatory agencies, to devise ways in which the full clinical value of product-related educational events can be achieved for all concerned.

Recommendations

1. In deciding whether to join in product-specific education programs, the same overarching principle applies as for all forms of interactions with industry: Will participation by faculty members provide teaching that ultimately contributes to improved patient care? And, even though the product being discussed might represent a useful addition to patient

care, it remains critical that faculty lecturers assert their independence and avoid the appearance of selling the product.

2. Be aware that critics of academia/industry relationships attempt to disparage product-specific or peer-to-peer educational programs by claiming that increased information about newer products could increase their use and potentially, though not necessarily, drive up costs. This argument is at least partly correct: after all, while these educational programs by industry primarily represent a legitimate activity, in reality an obligation, to provide well balanced and FDA-approved information to practitioners about newer products, utilization of these products may indeed increase if they are shown to provide new benefits. However, issues of cost and cost-effectiveness may not be within the expertise of clinical faculty who should be focused on optimal outcomes for patients. But, it is worth emphasizing again that while credibility for this important process is best fulfilled by experienced teacher-physicians, presenters still retain a primary obligation to serve the broad interests of patient care. ACRE believes that the key test of these presentations is being able to demonstrate that they are accurate and will enhance the clinical reach of the audience.
3. Potential presenters should carefully study the flexibility of each speaker program – which can vary from company to company - to determine whether there is an acceptable degree of intellectual freedom. Can a speaker create sufficient interchange with the audience to give them a valuable and personal learning experience despite the prevailing legal and regulatory constraints of the program?

4. Is it possible for the faculty member to work with the industry sponsor in compiling the presentation, thus having at least some measure of personal input into its content? Many faculty people feel that without this option they would find their participation difficult to justify.
5. It can be valuable for faculty members to be associated with multiple sponsors of product specific educational activities. This overcomes the concern that faculty members might favor one particular company and thus have their objectivity brought into question. However the primary responsibility of presenters, even if affiliated with only one sponsor, is to be accurate and objective in disseminating information.
6. A variation on the traditional peer-to-peer speakers' programs, which usually are held in restaurants or other public places, are programs held in medical offices, typically of larger group practices. The same issues and rules apply as for the standard programs, although there is an extra burden on the speaker to avoid, at all costs, the appearance of providing commercial support for the sponsor's product. These in-office programs can provide highly valuable information to clinicians, but speakers must be especially rigorous in being objective and fair-balanced.
7. If none of the recommendations listed above is tenable for a sponsor's peer-to-peer educational program, and if it doesn't appear to offer reasonable flexibility and independence for the speaker, then the faculty member should decline invitations to participate.

V. PUBLISHING

There are five broad types of articles in which academic physicians and industry may have common publishing interests.

1. Manuscript arising from major clinical outcomes trials conducted by physicians and supported by industry
2. Manuscripts arising from smaller investigator-initiated trials (typically at one location) supported by industry.
3. Manuscripts that are based on clinical trials conducted by industry as part of registration or post-approval programs, in which academic faculty may have played an advisory role and possibly acted as researchers but not taken primary responsibility.
4. Derivative articles arising from a sponsor's completed studies (e.g. analysis of pooled data) or review article summarizing an area of interest and where a sponsor's primary interest is in seeking the writing expertise of physician experts.
5. Collaborative projects concerning basic research, observational studies, epidemiology and other areas not directly related to products

Recommendations

1. For the first two types of research articles listed above, studies for which academic or community physicians have exercised the primary responsibility, the decision to publish the articles must be made by the physicians, who (as discussed earlier in this Statement) should also take overall responsibility for planning the analysis of the data, the interpretation of the findings, the actual writing of the manuscript and its submission to a journal. This is a critical issue that must be dealt with before the study begins since there must be no perception that a sponsor could prevent or delay publication of results that may appear to be unfavorable. The sponsor is often (but not always) responsible for managing the database and performing statistical analysis as requested by the independent investigators. For reporting clinical trials that have been managed primarily

by the sponsor (typically registration studies), it is reasonable for authors – after appropriate scrutiny -- to accept the analyses and data provided by the sponsor. Sponsors should be granted the right to review manuscripts to confirm data accuracy and -- where appropriate – regulatory compliance.

2. **Editorial Assistance:** The use of external writing agencies, or “editorial assistance” – sometimes referred to as “ghost writing” – should, in general, be declined.. Many academic physicians, in fact, already refuse the use of such services. The production of medical articles attributed to academic authors but actually written by professional writers engaged by industry has become a public issue. Despite the best of intentions by the physician authors to provide oversight of this process, such articles often do not truly represent the work and ideas of the authors. Inevitably, the greatest concern is for papers that report original research and where the authors thus carry a particularly high level of professional responsibility. Still, it may be reasonable to consider accepting editorial assistance for those parts of research papers dealing with certain complex or detailed items: - for example, advanced methodological, design or statistical issues that fall in the domain of professional writers with specific technical expertise.
3. For derivative or review articles it can be acceptable for busy physicians to utilize editorial assistance, but it is important to establish in detail how the authors will actually contribute to the article and take full responsibility for its content. This oversight should begin before the outlines of an article are suggested by the professional medical writers and certainly before drafts are written; be especially cautious about accepting authorship of a paper that is already in progress because exerting genuine input and making necessary changes at that point may be very difficult. In the view of many academic

physicians, it is difficult to justify being designated as an author of an article that in reality has been written by professional writers hired by an industry sponsor. Again, this type of support should generally be declined.

4. **Authorships**: For physicians, authorship of articles rightly can enhance reputations and be helpful in advancing careers. It is important, however, to be comfortable that this recognition has been justly earned. For instance, a sponsor may sometimes suggest inclusion of authors as a reward for perceived services other than contributions to writing the manuscript. There is a growing scrutiny by medical journals of the appropriateness of authorships.
5. **Compensation of Authors**: This is an area without fixed rules and where careful personal judgment is needed. Since writing major research papers can consume days or even weeks of effort, it could be argued that this valuable time should be fairly compensated. But the currently prevailing convention is that the authors of research papers are not paid for this work, presumably to protect their independence. In fact, this activity is regarded as part of the fundamental commitment of academic investigators to research and that the prestige and recognition accorded authors of major papers should serve as the rewards for this work. As well, when reporting results in the peer-reviewed literature, there is an understandable concern when authors receive payments from the same industry source that sponsored the study and has a commercial interest in its outcome. At the present time, this point has become moot since almost all sponsors have adopted policies that preclude payment to academic authors.

Not all research publications report major results. Papers can be written before or during a clinical trial to document such information as the study's rationale and design or the characteristics of the patient cohort. Receiving compensation from a sponsor for this type of writing could possibly be justified, but by contemporary standards such arrangements are regarded as problematic and most medical companies have stopped paying faculty people for this type of writing activity. This restraint is understandable and we agree with it.

Authorship of derivative or review articles is also a time-consuming and demanding task. If the primary purpose of writing such a paper is to provide service to a sponsor, then again this could justify compensation. All the same, the same sensitivities that were discussed earlier come into play and payment for this type of work should also be declined. Overall, for all the types of papers we have considered, it is appropriate to take the position that physicians should not accept money from industry for authorship.

We should point out that these recommendations against accepting payment for writing research and review articles do not necessarily apply to major works such as monographs or textbooks where fees or royalties are paid through a publisher.

VI. EXPERT WITNESS WORK

Legal work of this type performed on behalf of healthcare companies is often related to liability cases and patent issues. (Malpractice cases are usually not related to corporate sponsors and are not discussed in this statement). The financial and other arrangements for these activities

are usually determined in discussions with attorneys acting on behalf of the companies rather than directly with the companies themselves.

Recommendation

These activities provide interesting and instructive professional experiences. Although the physician experts, apart from acting as advisors, appropriately are expected to serve as advocates for their clients, it is important to remember that the details of legal proceedings often finish in the public domain (including newspapers). Care should be taken to avoid positions that cannot be scientifically validated or supported.

VII. TRAVEL EXPENSES

Travel expenses paid by industry to physicians have come under increasing scrutiny. There has been an unfortunate past history, seized upon by critics of the academia/industry relationship, of healthcare companies supporting non-professional trips or paying for extravagant professional trips. The implication was that these payments served as rewards for prescribing particular products. Even though these practices are now firmly in the past, memories still linger.

There are clearly legitimate reasons for industry to fund physician travel:

- To attend scientific meetings at which the traveling physician or scientist will present a research paper arising from work done collaboratively by the presenter and the sponsor
- To provide travel grants to medical societies that, in turn, can be used to support or subsidize the attendance at important scholarly meetings of younger faculty members or trainees.
- To pay the travel expenses of faculty members who have been engaged to make formal presentations at continuing medical education meetings (though these expenses are

generally handled by an independent party, most often the medical societies, medical schools, hospitals or other organizers of these events).

- To enable physicians to attend investigator meetings for sponsored research projects
- To cover expenses for physicians serving as advisors or consultants, or who work with the company on legal or regulatory affairs at locations that involve travel by the physician.

Recommendations

1. Ensure that travel support is used for the legitimate reasons listed above. Most industry sponsors are now keenly aware of the need for compliance with this principle, and if anything tend to be rather parsimonious in their support of expenses. Travel support to attend a meeting as a member of the audience, as opposed to being a speaker, should not be accepted; the value of the educational experience should serve as full compensation for any out-of-pocket expenses that might have been incurred.
2. Acceptance of travel support by physicians must not be linked in any way to their prescribing performance or other perceived endorsement of a sponsor's product.

VIII. MEDICAL SOCIETIES

For many years medical societies, both general medicine and specialties, have depended on corporate support to maintain their missions. The high costs of running professional organizations cannot usually be met by membership subscriptions and by the registration fees for their scientific meetings. Some of the ways in which companies contribute to medical societies are through corporate memberships, educational grants, sponsorship of symposia, exhibitor fees at major meetings, travel grants, advertizing in society journals and underwriting printed meeting programs and other society publications. As a further benefit, relationships between industry and

medical leaders can facilitate their joint involvement in research and education. Despite the obvious value of these relationships, concern has been expressed – both by elected officials and the media – that physician organizations may appear to favor particular companies or their products.

Recommendation

Corporate support of medical societies is of clear value to scientists and clinicians – and ultimately to their patients – and should be encouraged. There is a strong obligation for the leaders of these societies to create internal operational procedures, perhaps best labeled as professional compliance, to ensure that their much-needed corporate support does not create inappropriate endorsements of industry products, or give the appearance of doing so. Societies should be proactive in protecting themselves and their corporate supporters from such unwanted outcomes.

FINAL NOTES

An Additional Comment on Payments

As already discussed, it is appropriate for academic or community physicians to receive fair compensation for their professional work performed in collaboration with industry. It is not always clear, however, how these fees or honoraria are calculated. It is becoming more common for industry sponsors to calculate these payments on an hourly or daily basis using a concept that is referred to as “fair value.”

This “fair value” often appears to be arbitrarily announced by legal or regulatory officials within sponsoring companies and may not accurately reflect the amount and quality of the work being provided by the faculty person. Physicians should not be reluctant to negotiate with sponsors to establish what they believe their payments should be. In obtaining guidance for

calculating reasonable levels of compensation, particularly as these might vary according to a physician's specialty, geographic location or the type of effort involved, it is helpful to find benchmarks that can provide a reasonable basis for measuring the worth of the work being done. Among such benchmarks are estimates of the income levels of physicians in the same specialty in that geographic area. For academic physicians, the incomes of fully-salaried medical school officials such as department chairs or deans or even hospital executives can be used for guidance. For physicians in private practice (or academic faculty practices) the loss of practice income for physician involvement in industry work should be considered.

Likewise, for salaried faculty members who must relinquish vacation days to engage in industry-supported activities, the cost of these lost days to the faculty members should also be incorporated into the fee calculations. In addition, fees paid to physicians for consulting or education activities should include allowance for time spent in preparing for the assignments as well as the time involved in travel. And when publications (also known as "enduring materials") or on-line programs are anticipated as part of educational activities, especially where multiple uses of these products are planned over a prolonged time period, there should be consideration of the value of this continued "exposure" of the faculty member.

A special case applies to faculty physicians (probably a small minority) who receive comprehensive income packages from their institutions that allow them freedom to perform external research or consulting tasks on a *pro bono* basis or, alternatively, to direct the fees for such services to their institutions. The livelihoods of other physicians, however, will often depend on direct compensation for time-consuming external professional activities. Whichever system may exist, responsible tasks performed by faculty physicians as part of collaborative efforts with outside organizations should be assigned an appropriate value.

Areas of Greater Scrutiny

There are some important physician activities that tend to be scrutinized by external observers and critics of academic medicine. Faculty members who participate in such activities should be aware of a heightened need to ensure that any connections with industry are fully disclosed and acknowledged in the context of such activities. Among these areas of sensitivity are:

- Formulary committees serving hospitals or other entities
- Institutional review boards (IRBs) for proposed human research projects
- Specialists employing high cost drugs or interventions that draw the attention of payers or other observers

Remember: Be cautious about accepting fees or honoraria that could appear to be a reward beyond the justifiable value of the service provided

Disclosures

We now accept that relationships between academic physicians and industry should be disclosed *when relevant*. This is now standard practice for publication and research activities. So, in educational activities or published articles there is usually an indication of the presenter's or author's relevant relationships with corporate entities that might have an interest in the subject matter of the activities. For instance, this includes indicating that the faculty member is, or recently has been, an investigator, consultant or speaker for a related commercial entity, or owns stock or other equity in the company. More detailed information, however, such as actual amounts of payments, appears to be superfluous in the context of community standards that apply to such professions as law, financial services, accounting or other domains of academic

activity. It is important in the medical field that disclosures not be used to create implications of impropriety in what are perfectly legitimate interactions.

There has been a disturbing trend, when describing relationships between physicians and industry, to use such terms as “conflict of interest” or “competing interests”. These terms are largely pejorative, because the words “conflict” or “competing” make the inference that the person making such a disclosure has accepted financial or other rewards in return for statements or advocacy that are not in the best interests of patient care or scientific integrity. For this reason, ACRE strongly believes that the term “acknowledgements of support” is more appropriate and should be used in lieu of “conflicts of interest” when making disclosures.

Preparation of this Statement

This statement on relationships between physicians and industry was written by the members of the ACRE Writing Committee listed below. Opinions on earlier drafts of the statement were sought from external senior academic physicians from a variety of disciplines, but full responsibility for the final content of the statement has remained with the Committee. On issues where personal judgment is required, the recommendations offer what we believe are sufficient alternatives to allow readers to make their own responsible decisions on whether, or how, to become engaged in collaborative endeavors between physicians and industry.