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## ACRE Model Guidelines on Physician and Pharmaceutical Industry Interactions

The Association of Clinical Researchers and Educators (“ACRE”)<sup>1</sup> recently distributed model guidelines on physician and pharmaceutical industry interactions (Statement).<sup>2</sup> ACRE plans to educate physicians employed by academic medical centers, medical schools, and professional medical associations about the Statement. This Bulletin highlights the provisions of the Statement that are most relevant to pharmaceutical companies.

### 1. Research Funding

A pharmaceutical company often supports research by physicians, whether by directly sponsoring clinical studies conducted by physicians or by supporting research initiated and conducted by physicians. At the outset of these studies, ACRE recommends that the company and investigators determine how the company’s funding will be allocated and earmarked. ACRE also suggests that the company and the investigators clarify the protocol to be followed if any excess funds become available, and whether the investigators may allocate these funds to support other projects.

### 2. Payments to Physicians during Industry-Sponsored Studies

When a pharmaceutical company decides to sponsor a study conducted by physicians, the Statement indicates that the company should compensate these physicians for any professional services they provide which are “meaningful and time-consuming.”

#### a) Payment Amount

Sponsors should pay physicians less than an amount which is “designed to encourage favorable outcomes from the physician,” but also higher than an amount which would undervalue their work.

#### b) Payment Method

Sponsors may pay physicians for their research in different ways,

- <sup>1</sup> ACRE is a non-profit organization of medical professionals dedicated to the advancement of patient care through collaboration between the pharmaceutical industry and physicians.
- <sup>2</sup> The Statement can be accessed at <http://aace.metapress/cp/content/k12021244705x03w/fulltext.pdf>

depending on the rules of the research institution affiliated with the study. The following are four potential options for payment:

- the sponsor pays the research institution affiliated with the study, which then pays the physician as part of his or her salary;
- a foundation associated with the study pays the physician directly;
- the sponsor pays the physician directly; or
- the sponsor pays the physician royalties if the physician makes a significant discovery during the study, as long as the physician's equity interests are clearly disclosed.

c) Payment Timing

Sponsors should be cautious about the timing of their payments to physicians involved in the study to avoid the appearance of physician conflicts of interest. The payment may be perceived as creating a conflict of interest if the sponsor pays physicians after the study results are analyzed; increasing payment based on favorable results could compromise the objectivity of the results. As such, once the study's database is complete and the data is being analyzed, ACRE warns physicians that "the appropriateness of receiving compensation from a sponsor should be reconsidered."

3. Physicians as Public Spokespeople

Frequently, pharmaceutical companies request that physicians speak publicly on their behalf. ACRE recommends permitting faculty physicians who serve in this capacity to speak about scientific and clinical data results from their research. Further, ACRE suggests allowing faculty physicians to speak about scientific facts in any underlying research if this discussion illustrates important issues, even if the physicians did not conduct the underlying research. According to ACRE, pharmaceutical companies should have their own internal spokesperson who can explain company positions.

4. Continuing Medical Education

ACRE provided certain specific guidelines for interactions at CME activities.

a) Acknowledgment of Physician/Industry Relationship Outside of CME

Even if a CME activity is not supported by a pharmaceutical company, an individual presenter may consult or have conducted research for a pharmaceutical company which may lead to bias. In this scenario, ACRE advises acknowledging disclosing this relationship.

b) Honoraria

If a pharmaceutical company provides for a speaker's honorarium, this amount should reflect the fair market value of the services. The fee should reflect the amount of work required to prepare for the presentation, including writing syllabi, travel, delivering the speech, and participating in any panel discussions.

5. Peer-to-Peer Educational Events

A pharmaceutical company sometimes sponsors events where a company representative, such as a medical science liaison or key opinion leader, delivers a presentation on one of the company's products to other physicians. Some academic institutions prohibit faculty members from attending these events.

In order to address this prohibition and increase collaboration between physicians and the pharmaceutical industry, ACRE recommends that institutions permit faculty members to participate in the events as long as certain criteria are met, including:

- a) the CME contributes to improved patient care by enhancing the audience's "clinical reach;"
- b) the presentation is accurate; and
- c) faculty lecturers avoid the appearance of selling the product.

6. Publications

Pharmaceutical companies that seek to publish studies about their products may encounter certain issues related to their relationship with the physicians involved in a particular study and publication.

a) Decision Whether to Publish

ACRE strongly recommends that only academic or community physicians decide whether to publish articles on industry-sponsored studies in which the physicians had primary responsibility, and this decision must be made before the study begins. There should be no impression that the sponsor prevented or delayed the study's publication if the results appeared to be unfavorable to the sponsor.

b) Ghost Writing and Editorial Assistance

ACRE strongly discourages "ghost writing" or "editorial assistance," i.e., the publication of articles attributed to academic authors but actually written by professional writers who were hired by a third

party such as a pharmaceutical company. On the other hand, ACRE allows for articles to be published if the articles' authors accept editorial assistance involving complex information in which the professional writers have technical expertise such as intricate methodological, design, or statistical matters.

c) Authorship

A pharmaceutical company should not name physicians as authors in a study in order to reward them for services other than writing the article, such as frequently prescribing one of the company's products. Authorships of pharmaceutical company sponsored studies have come under increasing scrutiny by medical journals.

d) Author Compensation

The guidelines permit companies to pay authors for their work in major publications such as monographs or textbooks, where fees or royalties are paid through a publisher.

7. Travel Compensation

The pharmaceutical industry must be extremely cautious about the travel payments they make to physicians. Travel payments made to physicians should not:

- a) correlate with the frequency of a physician prescribing a certain product or any other action that creates the appearance that the physician endorses the product; or
- b) compensate a physician for attending meetings as a member of an audience.

The following are examples in which the pharmaceutical industry may pay for physician travel expenses:

- a) the physician presents research at a scientific meeting.
- b) the physician formally presents at a CME.
- c) a young faculty member or trainee attends an important scholarly meeting through a company travel grant to a medical society.

8. Disclosure

ACRE suggests disclosing relationships between physicians and industry "when relevant," in publication and research activities. For example, disclosure is necessary when the faculty member is or has recently been

an investigator, consultant or speaker for an entity related to the pharmaceutical company publicizing or sponsoring the study. The actual amount of payment, however, need not be disclosed according to ACRE.

## 9. General Payment Issue: "Fair Value"

It is common for pharmaceutical companies to pay physicians involved in the aforementioned activities based on the "fair value" of their work. According to the Statement, factors which companies should consider in determining "fair value" include:

- a) income levels of physicians in the same specialty in the geographic area in which the activity took place.
- b) special considerations for academic physicians (i.e., incomes of fully-salaried medical school officials), and academic or private practice physicians (i.e., loss of practice income).
- c) cost of lost vacation days if physicians must relinquish them.
- d) time spent in preparing for assignments and travel time.

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Although the Statement contains many requirements already followed by academic, industry and professional institutions, it provides a helpful summary of the activities to consider to minimize risk. Pharmaceutical companies should consider the ACRE guidelines as part of their overall compliance program.

*Ms. Bugar acknowledges the assistance of Sari Bourne in the preparation of this article. Ms. Bourne is a recent graduate of Emory University School of Law and an employee of Arnall Golden Gregory, LLP in our Food and Drug Law practice. Ms. Bourne is in our Washington, D.C. office but is not yet admitted to practice.*

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