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POSITION PAPER

The need for a transparent, ethical, and successful relationship between academic scientists and the pharmaceutical industry: a view of the Group for the Respect of Ethics and Excellence in Science (GREES)

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Abstract
Summary This paper provides recommendations for fair and unbiased relationship between academic scientists and the pharmaceutical industry.
Introduction Real or perceived problems in the relationship between academics and the industry have been the subject of much recent debate. It has been suggested that academic clinicians should sever all links with the industry—a view that is rarely challenged.
Methods Academic experts and members of the pharmaceutical industry were invited to an expert consensus meeting to debate this topic. This meeting was organized by the Group for the Respect of Ethics and Excellence in Science. Conflict of interest, competing interest, right and duties of academic scientist, authorship, and staff and student education were discussed.
Results Guidelines for a transparent, ethical, strong, and successful partnership between the academic scientist and the pharmaceutical industry have been provided.
Conclusions The Group support interactions between the industry and clinicians provided that it is transparent and ethical.

Keywords Competing interest · Conflict of interest · Ethics · Ghost authorship · Medical education

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Introduction

The mission of pharmaceutical companies is to discover, develop, produce, and bring to the market medicines that address unmet medical needs. In order for the ethical pharmaceutical industry to be sustainable, it must make a profit from those products. To achieve this, drugs should have been normally considered by regulatory agencies such as the Food and Drug Administration or European Medicines Agency as having a clinically relevant margin of efficacy where the benefits outweigh the risks for a given target population. Once a product license is obtained, the product will be marketed, usually to the medical community for use in the appropriate patient segment to provide an adequate return on investment and to fund further drug development.

Practicing and academic physicians have a duty to act in the best interests of their patients or the public. Whereas practicing physicians are responsible primarily for delivering health care that is optimal for their patients or for the society that they serve, academic physicians also are commonly involved in all stages of drug development because of their expertise, to promote their work, and to educate the medical field. The recent conduct of both academic medicine and the pharmaceutical industry in regard to drug development and subsequent use of licensed products has been heavily criticized but also encouraged [1–13]. Criticisms of the industry include the manner in which drugs can be promoted in the guise of science, education, and information: the misreporting of industry-funded research, the use of ghost writers and key opinion leaders, and the provision of "free" courses and conferences [14]. Similarly, through their involvement in the process, academic physicians and scientists may have personal interests and often benefit in promoting their scientific careers. As an example, academic researchers have been criticized for the premature publication of new approaches to the treatment of diseases leading to considerable lay press coverage and raising inappropriately high expectations. It is fair to state that all participants involved in this process have tolerated the well-known situation and for a long time, little was done to change these practices.

Academic researchers and medical professionals interact with pharmaceutical companies in many ways. Aside from sponsoring clinical trials and funding basic research, companies often provide postgraduate education and deliver information regarding their products. Academic researchers participating in such programs, either as educators or attendees, were blamed for also having received personal benefits like honoraria, entertainment, or travel to attractive locations. This practice may cause conflict of interest and may influence health care professionals in their decision-making. As a consequence, the Royal College of Physicians, in a recent report, favored severing all links between the industry and medical education [15]. The report recommends that all undergraduate activity should be funded through public finance and that postgraduate medical education should be funded through the royal colleges and the Department of Health [15]. In the UK, the industry funds approximately half of all postgraduate education and some parts of undergraduate courses, lectureships, and fellowships. Another report made recommendations that would require many professional medical associations to transform their current mode of operation, with the consequence of having to forgo many of these valuable educational activities [16]. Whereas implementation of these suggestions might diminish the perception of commercial influence, in reality, it is the perception alone that would be addressed.

Although biomedical research has historically been funded in part by governments and private philanthropy, the industry has provided the majority of support in recent years [17]. In 2003, 57% of funding for all biomedical research in the USA came from industry sources. In comparison, the National Institutes of Health funded 28% of the biomedical research [18]. A recent European study called the Resource Allocation to Brain Research in Europe examined funding of brain research [19]. In 2004, migraine research was funded by nearly €315 million. Of this, €308 million was invested by the pharmaceutical industry, whereas public funding was estimated at €7 million. Although the majority of research funding in the USA still comes from federal sources in the academic setting, the research relationships, both financial and nonfinancial,

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between academic institutions and private companies are strengthening [10].

In Europe, it should be acknowledged that medical research is predominately carried out in universities, which are mostly supported by local and national government agencies, which naturally have a short-term political interest in improving standards [20]. More recently, private funding is supplemented more frequently by private–public partnerships. While at the outset these partnerships focused on basic research and drug development for, e.g., commercially unremunerative medicines like rare diseases or diseases of the developing world, more recently, this concept has been expanded to drive research, which can only be pursued successfully by bringing together expertise from both the academic and the industrial research worlds.

A major undertaking in this vein is the "Innovative Medicines Initiative," a European public–private partnership initiative between the pharmaceutical industry (European Federation of Pharmaceutical Industry and Associations (EFPIA)) and the European Commission (Directorate-General DG Research—health priority) [21]. This project receives funds of €1 billion under the seventh European Research framework program (FP7); another €1 billion in kind is provided by EFPIA companies. The project's premise is to identify the main bottlenecks in the development of innovative treatments (predictive pharmacology and toxicology, identification and validation of biomarkers, patient recruitment, risk evaluation, and cooperation with the regulatory authorities).

Many companies have found that the high costs of internal discovery of new therapeutic targets provide a relatively low return on investment. Accordingly, they have increasingly focused on therapeutic targets identified at academic research centers [18]. The decision of several large pharmaceutical companies, and many biotechnology companies, to build new major laboratories near US, European, and Asian universities is just one example of the growing commercial value of academic innovation in biomedicine [10]. Companies also have increasingly tapped into the rich talent pool available and research being performed at high profile universities. As a consequence, universities all over the world have strong financial and nonfinancial incentives to start new companies and to participate directly in the development of drugs, devices, and diagnostic tests [22].

The growing costs of research is another important factor that favors collaboration. The volume and costs of both basic research and clinical research are increasing [20]. More than ever, such research is dependent on sophisticated technologies and complex equipment with high acquisition and maintenance costs. Such equipment and instruments are not affordable for many universities, and therefore, industry support or collaboration becomes indispensable. Moreover, most funders of research prefer to support researchers and programs (i.e., direct costs), rather than buildings, laboratory instrumentation, clinical databases, and other research infrastructure (i.e., indirect costs). This is a growing challenge for teaching hospitals and universities, which must increasingly rely on endowments and gifts for investments in infrastructure [18].

In an ideal collaborative environment, researchers from both academia and the industry would seek interactive, mutually beneficial relationships that involve the exchange of ideas, materials, and expertise, rather than relationships based on terms dictated by corporate and university technology transfer agreements, which tend to emphasize confidentiality, ownership, and valuation of intellectual property [10]. In contrast, some forces enhance the interdependence of the industry and academic laboratories, but others add to difficulties with regard to disclosure, ownership of intellectual property, and the interchange of researchers, information, and biologic materials [22]. Therefore, there continues to be great interest and passionate debate over whether interactions between individual physicians and/or institutions and the industry can lead to physician/institutional bias [1–6, 23–29].

This manuscript offers a perspective on the relationship between the pharmaceutical industry and academic medical professionals. This relationship is subject to both regulatory guidance and self-regulation. Industry and scientific associations, many universities, and most companies have policies in place, which set the boundaries for the relationships between researchers in the industry, healthcare professionals, patients, and public servants. For example, in the USA, the industry organization, the Pharmaceutical Research and Manufacturers of America; the independent organization, the Accreditation Council for Continuing Medical Education; and the government organization, the Office of the Inspector General, have provided guidance to impose regulation on interactions between health care professionals, including academic scientists and the pharmaceutical, biotechnology, and device industries [10]. Some of these guidance have been revised recently [30]. These policies are publicly available and subject to audit and reporting. Additionally, in many countries, legal instruments have been implemented, which define the rules by which companies and public partners may cooperate. For clinical research, the ethical standards are set by the Declaration of Helsinki. Other guidance, such as the Guidelines on Good Publication Practice (GPP) for pharmaceutical companies, is also of particular interest [31].

On the other hand, academic policies managing relationships between academic scientists and the industry are available but vary widely among universities [32]. Financial disclosure policies, given the uniform requirements recommended by the International Committee of Medical

Journal Editors (ICMJE), are becoming the norm for all authors of journal articles. Members of scientific committees are being held to similar financial disclosure standards [7, 33]. In international or national congresses, it is also the rule to publicly disclose the funding source of a study as well as the presenter's potential conflicts of interests, whether presenting an original research or state-of-the-art or meet-the-professor sessions. Transparency is also enhanced through public disclosure of financial contributions to public institutions, patient organizations, academic institutions, and charities. In many countries and regions like the US, Europe, some South-American countries as well as Asia (China, Japan, and India), clinical trial designs and their results now have to be shared with the public through publicly accessible databases and registries [34]. Recently, the Food and Drug Administration Amendments Act of 2007 (FDAAA) mandated the public registration and disclosure of results of clinical trials of drugs, biologics, and devices on www.clinicaltrials.gov. FDAAA requirements differ in a number of ways from those of the ICMJE and other journal editors, creating potential conflicts for sponsors and investigators who must comply with the law [35].

In this manuscript, we review potential (real or perceived) problems in the relationship between academics and the industry and discuss how they might be overcome.

Materials and methods

In order to review the topics addressed in this article, a literature search was performed on the Medline database. English-language articles from 2000 to April 2008 were included. Search terms used were conflict of interest, competing interest, academic medical center, pharmaceutical industry, medical school, and authorship. A manual search of the database was also performed. Key academic experts from various areas (epidemiology, genetics, geriatric medicine, endocrinology, rheumatology, and rehabilitation) and members of the pharmaceutical industry were invited to an expert consensus meeting to develop the current consensus document. This meeting was organized by the Group for the Respect of Ethics and Excellence in Science (GREES). This nonprofit organization has expertise in literature research and in expert consensus meetings [36–44].

Conflict of interest or competing interest?

Conflict of interest is probably the most debated issue regarding the relationship between academic scientists and the pharmaceutical industry [1–12]. Conflict of interest, even the appearance of potential conflict, has long been a concern for physicians and scientists. Even by the early thirteenth century, the Holy Roman Emperor Frederick II of Hohenstaufen enforced legislation which no longer allowed physicians to sell medicines and separated the professions of physicians and pharmacists ("Edict of Palermo").

Conflict of interest arises when an activity is accompanied by a divergence between personal or institutional benefit when compared to the responsibilities to patients and to society, and can be in the context of research, medical education, guideline development, purchasing, leadership, and investments. It is not restricted to the industry or to financial benefits. Fraud and misconduct in academic research are vivid evidence of this issue. Academic careers are based on scientific success often defined by the number and quality of publications and scientific reputation. Promotion of career, demand for recognition of scientific work, and success of research ideas are factors which can create substantial conflict of interest when a research project does not deliver what is expected.

Nonindustry or nonfinancial interests could also create conflict. Could a smoker, a person who abhors exercises, or an obese person give fair, balanced recommendations for the management of cardiovascular [45]? As a matter of fact, nonfinancial interest may be at least as much a cause of concern [29] as a financial conflict of interest, but is only rarely disclosed [46, 47]. Financial conflict of interest can arise as universities and university scientists become increasingly dependent on funding from the pharmaceutical industry [48].

One extreme situation leading to a major potential conflict of interest is when a scientific organization, institution, or individual is dependent upon a single funding source. In this particular case and in the absence of rigorous external control guaranteeing the intellectual autonomy of a researcher or institution, direct and indirect pressure from the funder might result in an inappropriate and distorted relationship. Reluctance to disclose a potential conflict in this setting may be related to the stigma or concern that the opinion or information given is somehow less credible if attached to a single declared conflict of interest.

In reality, the likelihood is that multiple conflicts of interest exist. The problem of credibility therein is accentuated by the practice of partial disclosure. For example, a publication arising from a single source of funding may be duly acknowledged in the paper, but the fact that an investigator or institution received funding from many competitor companies for other projects would not normally be disclosed. Providing complete disclosure would place conflicts of interest in a more suitable perspective than a single disclosure and would leave the informed reader better placed to judge the significance of

the information provided. A corollary to this suggestion, although difficult to know where to draw the line, is that several government agencies, academic institutions, and nongovernmental organizations ask committee members, employees, or officers to declare all competing interests in their field of expertise. We see no reason why similar demands could not be made in the case of postgraduate education or publication. A move in this direction would decrease quite rightly any stigma attached to the declaration of an apparent single conflict of interest.

To be provocative, scientists without any potential conflict of interest, i.e., without any relationship with commercial entities or external agencies, could also generate concern. In principle, pharmaceutical and non-pharmaceutical companies seek advice from researchers who are considered leaders, and who have a high degree of expertise, in their respective field of interest. We could wonder, without direct evidence for this and with the exception of leaders who deliberately reject any relationship with industrial parties, if those who are never approached could be less knowledgeable and less current in their field. Indirect support for this view comes from the observation that the increase over time (from 1990 to 2005) in quality score of evidence-based guidelines in a dermatological oncological care as measured by the Appraisal of Guidelines Research and Evaluation instrument is correlated to a possible conflict of interest in the development of the guidelines [49].

It has also been shown that the quality of published medical education research is associated with the level of funding, whatever its source [50]. Some authors suggest that attainment of $20,000 or more in funding per study is associated with higher-quality medical education research [50]. One systematic review concluded that the methodological quality of industry-funded studies was superior to that of studies funded by other sources, but this review did not examine comparisons with unfunded studies [51]. As regard publications themselves, on the other hand, after a few years of experience with the loss of some of the most knowledgeable editorialists because of financial conflicts of interest, the *New England Journal of Medicine* changed its policy from "no conflict" to "no significant conflict" [52, 53]. This policy change acknowledges that it is not the objective to avoid any conflict of interest completely, but to manage it.

Relationships and personal interests should not be considered automatically as "conflicts of interest," but rather "competing interests." This latter term is likely to better reflect most situations observed. As defined by various journals, a situation of competing interests exists if the validity of a contribution to the journal (article, review, letter, peer review, or editorial input) could be influenced by an author's/editor's/reviewer's interest, whether or not judgment is, in fact, affected. Competing interests may be personal, commercial, political, religious, academic, or financial. "Financial" interests are probably the most obviously disclosed and may include employment, stock or share ownership, payment for lectures or travel, consultancies, company support for staff, or research funding. Financial interests also include the prospect of promotion or salary increases as benefits of successful research.

Competing interests may also impact the peer review process of manuscripts. At least, if it is obvious that a declaration of competing interest must always be provided when acting as an author on a manuscript [54], it should also be provided when acting as a reviewer of a manuscript. Such statements to this effect could be published by the editor of the medical journal. Interestingly, peer reviewers tend to be more critical of papers reporting research supported by the pharmaceutical industry than those without such sponsorship, even if the reasons are not fully understood [55]. Despite this, it has been suggested that articles written with pharmaceutical company support are more likely to be published in prominent journals with higher impact factors than articles written by researchers without such involvement [56]. These latter researchers can be reassured that their abstracts are as likely to be accepted for an oral presentation as those from sponsored studies [57].

Even in the setting of publications, however, there are currently no uniform official guidelines for the management of competing interests, let alone in the research setting. In a recent study, it has been shown that the policies of only 57 of 120 US academic medical centers make reference to disclosure of financial competing interest to potential research participants [11]. Of these institutions, only 33 included template language in their policies that could be used in informed consent documents. These policies showed considerable variability concerning the specific information that should be disclosed, and most policies seemed designed to address regulatory requirements or to protect against potential legal action, rather than permitting a potential research subject to make the best informed decision regarding their study participation.

As a matter of fact, management of competing interest in clinical practice can be achieved in a manner that follows basic ethical and medical principles and maintains the benefit of the physician's best care of the patient. The academic medical center must be empowered to enforce the main mission and commitment of its staff to the care of the patient and, if necessary, to require cessation or modification of the relationship with a commercial entity. This management approach differs from the absolute trigger of recusal with personal financial interest of more than $5,000 or $10,000 per year mandated by some institutions.

In fact, at many academic institutions, individuals who have competing interests generally would be excluded from voting on purchasing, including formulary, decisions. Similarly, academic scientists are expected not to be part of business decisions of companies in which they (or immediate family members) have significant personal interest when these companies conduct business with their academic medical center.

In conclusion, we believe that while competing interests exist in many different forms and may affect all stakeholders in research, they always must be fully declared (e.g., financial and nonfinancial) and should be managed by policies on a case-by-case basis (i.e., depending on the competing interest or the field of the competing interest).

Right and duties of academic scientists

Concern is often raised about the diminishing participation of the academic scientist in all stages of industry-funded clinical research, specifically involving new investigational agents and devices. Until recently, academic, independent clinical investigators were the key players in the design, patient recruitment, and data interpretation of clinical trials. The intellectual and working home of these investigators, the academic medical center, traditionally had been the hub of this enterprise, with many institutions having developed complex infrastructures devoted to the design and conduct of clinical trials. As a critical part of the process, the academic enterprise has contributed to the quality, intellectual rigor, and impact of such clinical trials, leading to the introduction of many new treatments into medical practice [58]. However, only approximately one third of the commercially sponsored research is now being conducted primarily by universities and academic medical centers, the remainder being run by commercial profit-oriented research companies. However, the academic researcher still has an important role in the partnership with the industry. It has been suggested that the shift of commercially sponsored clinical research trials away from academic centers gives pharmaceutical companies greater control over the design of studies, analysis of data, and publication of results [59], including the likelihood that negative results do not get published. It should be pointed out that there are several plausible and legitimate reasons why industry participation may give results that are different from, and more positive than, those of independent research (e.g., experience in trial design and use of more rigorous international and scientific quality standards) [29]. That said, academic investigators, often as members of steering committees, ethics review committees and drug safety monitoring boards for a clinical trial, should be more accountable for major input into trial design, conduct of the clinical trial, independent and full access to raw data, independent validation of results, and all editorial and publication decisions. The decisions made by the academic investigator should also include support of publications of studies with negative results.

Nonpublication of studies performed by the academic scientist but supported or not by the industry is also of major concern because it does introduce potentially harmful publication bias [6]. Public trial registries, particularly those that include the results of unpublished trials, ensure that the literature more accurately reflects all studies or at least, demonstrates publication bias. These registries will hopefully encourage all investigators supported or not by the industry to publish their results [34]. Many journals now mandate registration of the trial at study initiation as a prerequisite to review the manuscript documenting the study outcomes.

Journals themselves have their own competing interests. In serving the important role of communication of medical information, they too aim for scientific credibility and the ability to support their work via advertising dollars. In addition to readership (e.g., specialty and general), journals are often rated and attract key publications on the basis of their "impact factors," a measure of how much impact the journal has on the medical profession via its publications, driven in part by how often articles published in the journal are referenced by other publications. Therefore, editors and reviewers of scientific publications also play a significant role in the potential for publication bias and should be motivated to consider publishing negative results with the same enthusiasm as they do positive results.

Ghost authors

Most medical journals have policies mandating disclosure of potential competing interests; however, an acknowledgment of financial support from a commercial sponsor may not fully reflect a company's actual involvement in the research and the publication. Full disclosure of the sponsor's role at all stages of the research is crucial. When an individual is not named in the by-line or in the acknowledgments but contributed substantially to a manuscript, one commonly calls this "Ghost Authorship." The topic of ghost authorship remains an issue with many publications even today. The guidelines of journal editors (ICMJE) now require extensive transparency in the development of manuscripts such that any major contributor to a publication including the initial draft must now be acknowledged in the final publication [60]. Moreover, the new good publication practice (GPP2) guidelines published in the British Medical Journal recently make recommendations that will help individuals and organizations maintain ethical practices and comply with current requirements

when they contribute to the communication of medical research sponsored by companies [61]. Medical writers may be employed by the industry to prepare the first draft of a manuscript of clinical trial results for publication, but this should be based on an agreed manuscript outline a priori with the authors of the paper [62, 63].

The credibility of a research article is vested largely in its acknowledged authors. With ghost authorship, it is not readily apparent that the company funded, conducted, and wrote up the study. Manuscripts discovered to be ghost written at the behest of the industry are often perceived as noncredible or less credible as the potential for conflict of interest in the reporting of results and data interpretation is perceived to be higher. Moreover, ghost authorship jeopardizes the integrity of academic publishing and disconnects authorship from accountability. Policies or clinical practice guidelines based on such ghost-written papers could be erroneous or incomplete, with negative implications for patients and the public. However, it should be acknowledged that some academicians willingly use ghost authors due to their own lack of time to draft an initial manuscript, whereas the companies are faced with tight timelines and competitive pressure to meet their business needs in a timely manner.

Ghost authorship has decreased based on the new guidelines and further assurances need to be made to prohibit their use. Every individual's role in the preparation (at any stage) of a manuscript must be transparent. If authorship assistance is provided by a medical writer funded by the industry, it should be duly reported to the journal, and also, the industry should have policies in place to ensure the involvement of the authors at all stages of manuscript preparation. The ICMJE (or the Vancouver Group) has issued guidelines stating that an author must play an active role in the production of published work, and must be able to accept public responsibility for its content [60]. Attribution of authorship should be based on substantial contributions to the conception and design of the study, analysis and interpretation of data, drafting the tables, figures and manuscript, or revising it for important intellectual content, and approving the final version that is submitted for publication, and finally, participating in the revision(s) of the manuscript dependent upon the journal's reviewers' comments. Rigorous standards for trial reporting (e.g., CONSORT [64]) should be more widely adopted and enforced.

Staff and student education

Even if it was possible to design policies to address all potential scenarios of clinical competing interest, one is still left with the challenge of ensuring that those policies are optimally enforced and fairly adjudicated. As such, it is imperative that an institution spend considerable effort educating its members about policies and procedures, making it apparent that the policies will be applied evenly regardless of an individual's professional stature, ability to generate revenue, or other confounding variables. These efforts will start with education of the medical staff and the office of intellectual property about potential competing interests. We recommend that each academic medical center includes courses addressing competing interests and the need for transparency in research in the educational curricula of medical students and physicians-in-training, and for established health care professionals in continuing medical education. The industry should also assume responsibility for this topic by educating their employees and their external contracted investigators. This education should also address the consequences and implication of data manipulation and other scientific misconduct which have been reported during the last decades in regular intervals. Identification of such practices and prevention of falsified results from being published in the literature are of major public interest.

Conclusion

Academic physicians have a primary duty to ensure the best care for patients. The industry, in addition to having a duty to patients and health care professionals, has a duty to its employees and shareholders. The notion that these duties are mutually exclusive and, therefore, that there should be no interaction between industry and academic medicine is counterproductive for the advancement of medicine. In fact, the underlying thread for both industry and academia is that they are both bound by medical ethics. Notwithstanding, the different priorities should be recognized and respected by both sides. Academic scientists and the industry need to maximize the benefits of collaboration and minimize the drawbacks through greater transparency and disclosure. For the health of the patient through the advancement of medical science, a transparent, ethical, strong, and successful partnership between the academic scientist and the pharmaceutical industry is needed. This involves the permission and even the expectation by society for academic scientists to have competing interests, as long as they are managed appropriately and declared openly. We believe that the adoption of too stringent competing interest policies is strategically unsound, inappropriate, and unnecessary. However, competing interests need to be actively and transparently managed by continuous education and clear regulations. At a minimum, we expect that all trial results will be published by the medical community, to better inform their practice as well as the development of other therapeutic compounds to the continuous advancement of science.

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