Commentary: Collaboration between industry-based and academic epidemiologists

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The article by Neil Pearce in this issue, ‘Corporate influences on epidemiology’ questions the role and practices of epidemiologists working with industry. The author argues that ‘In many instances, academics have accepted industry funding which has not been acknowledged, and only the academic affiliations of the company-funded consultants have been listed’. He believes that this and other unethical practices are major threats to the integrity of epidemiological research. Although the article is addressed primarily to academic epidemiologists who consult with industry, there are a number of issues raised in the article that merit comment from those of us who practice epidemiology within a large, research-based pharmaceutical company.

We agree with a number of points in the article. Authors need to clearly declare potential conflicts of interest, including funding sources. Professional organizations such as the International Epidemiological Association and the International Society for Pharmacoepidemiology have important roles to play in asserting positive principles and developing guidelines for good epidemiological practice (http://www.pharmacoepi.org/resources/guidelines_08027.cfm). Results from epidemiological studies need to be interpreted with caution and should be considered in the context of other available information. We agree that empirical-based evidence is critical for optimal decision-making. Above all, we agree that scientists in companies, as well as in academic, governmental and non-profit organizations, should seek the truth.

There are a number of points in the article that deserve further clarification, however.

First, epidemiologic evidence is used in a variety of areas in the pharmaceutical industry, and drug safety is just one of them. At GlaxoSmithKline (GSK), the majority of our epidemiology work actually focuses on activities during drug discovery and development, rather than during the post-marketing phase. Our goal is to bring evidence on disease and medical need, derived from observational data, to strengthen assumptions underpinning decision-making in drug development, from early research through to the late-stage development process. This includes validating biological targets, evaluating associations between phenotypes and genotypes, contributing observational-based health data to inform clinical development programmes including clinical trial design and operations, and documenting disease burden and disease risk factors. We also put an emphasis on studying, proactively and systematically, the extent of comorbid conditions in diseases of interest, prior to marketing a drug, to enable us to rapidly assist in interpreting possible safety signals should they arise.

Second, when we do undertake pharmacoepidemiology studies on our marketed products, we often conduct these studies with academic and other research collaborators, who are committed to publishing the results in an objective, unbiased manner. Their reputations and livelihoods depend on it, as do ours. Furthermore, we believe that the greater threat to the integrity of epidemiological research arises from flaws in the conduct of such research. Thus, at GSK we have borrowed from randomized controlled trials the principle of developing and adhering to a detailed protocol. In certain circumstances, e.g. for studies undertaken in the General Practise Research Database (GPRD) in the UK, the study protocol is approved externally; in all cases the protocol is reviewed and approved through an internal protocol review forum. The results of safety studies of marketed products are submitted to regulatory authorities and also posted to GSK’s clinical trial register within a year of starting analyses (http://ctr.gsk.co.uk/welcome.asp). GSK standard research agreements specify a third party’s right to external publication and final editorial control. We believe that more can and should be done to improve the transparency in conduct of epidemiological studies.

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Third, Pearce provides no evidence to support his assertions of widespread unethical conduct among industry-funded consultant epidemiologists and he does not address the ubiquitous nature of sources of temptation for unethical conduct or advancement of personal or institutional agendas. Although unfortunately unethical conduct may occasionally occur, for each example of potentially unethical conduct, there may be tens or hundreds of examples of studies undertaken by industry consultants of exemplary epidemiological practice. We wonder if this ratio is any different among non-industry-funded epidemiologists. Contrary to Pearce’s assertions, at GSK and among epidemiologists across the industry, our interest is in presenting objective findings. The possible short-term gains of doing otherwise are potentially far too costly. Industry does not have a monopoly on errors in the design, conduct, analysis, interpretation or communication of data. However, assuming negative intention by industry or industry-funded epidemiologists in such cases and positive intention by ‘independent’ epidemiologists is an opinion but not an evidence-based finding. Similarly, it is wrong to assume that public health consequences of such mistakes are worse with industry-related research.

Finally, we do not fund consultant epidemiologists ‘to attack the research of other epidemiologists and to debunk it as junk science’. We seek out consultants who are strong methodologists with peer-reviewed publication records, who are widely respected in the field, and who can be objective and critical. We strive to seek the truth about the benefits and risks of our drugs. It is imperative to the wellbeing of patients to understand the effects of drugs as early as possible, and to manage any potential risks appropriately. If there are risks that emerge following approval for marketing, they should be identified as soon as possible using appropriate data and methodology and communicated rapidly. Maintaining the highest levels of integrity and transparency in all we do is critical for all epidemiologists. The risks associated with being linked to unethical conduct are great; there is no advantage for the research-based pharmaceutical companies.

References