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Response: The distribution and determinants of epidemiologic research

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Epidemiology is commonly defined as the study of 'the distribution and determinants of disease in human populations'. Thus, epidemiology is inherently focused on populations, and epidemiologists recognize that anecdotes about individuals cannot be used to refute evidence about populations. For example, an anecdote about someone who smoked one pack a day and lived to be 100, or someone who never smoked and developed lung cancer anyway, does not refute the evidence that people who smoke a pack a day get lung cancer at 10 times the rate of non-smokers. Similarly, anecdotes about individual epidemiologists acting ethically or unethically do not confirm or refute evidence about general tendencies.

In my commentary about corporate influences on epidemiology,[1] I was not intending to comment on specific individuals (with the occasional exception of extreme cases which are too blatant to ignore), but rather to comment on the distribution and determinants of epidemiologic research, particularly current corporate influences on what research gets done and how the findings are received. This does not absolve individuals from the responsibility to act ethically and responsibly (you cannot just blame the current problems such as the Vioxx scandal on 'the system', since they also involve bad decisions made by individuals), but that was not the main focus of my paper. Many of the factors that I discussed, e.g. the inability of clinicians to understand epidemiologic evidence and their unwillingness to accept welcome news, would occur even if there were no corporate influences on epidemiology, but it is the latter which has received the most attention in the responses to my commentary.[2–5] With regards to the latter issue, my focus was on 'independent' research based in universities, and the corporate influences on it, rather than on epidemiologic research that is based in corporations. This was partly because I am based in a university and am more familiar with research in that situation, but also because I have less concerns about corporate-based epidemiology, since in that situation the issues are relatively clear, and in most instances clear guidelines are in place (e.g. as discussed by White *et al*.[5]). In contrast, the situation of university-based researchers is often more ambiguous because they may benefit from their 'independent' status, while nevertheless receiving corporate funding. As I noted, they have the privilege of acting as 'lawyers for the defence' while maintaining the image of being an 'independent jury'.

Some of the varied responses that my commentary received[2–5] are therefore not particularly relevant since they focus on individuals (e.g. on my own motives, or the motives of university-based epidemiologists who receive corporate funding but believe that they are not influenced by it) or on the work of epidemiologists based in corporations. As noted above, this is not to say that individual decisions do not matter, but they are only part of the bigger picture. The responses also strongly reflect the US situation, where litigation plays a much greater role (and partly shifts the balance between corporate and other interests) than it does in other parts of the world. With regards to epidemiologists based in corporations, I agree with many of the comments of White *et al*. about the value of such corporate-based epidemiologic research, and with the comments of Sander Greenland about the existence of heterogeneity within and between various corporations.[2] I also agree that open and ethical behaviour can be in the enlightened self-interest of corporations, and that such behaviour can be strengthened and supported by requiring declarations of conflict of interest and mandatory disclosure of funding sources. Such requirements can support the positions of corporate-based epidemiologists, most of whom carry out valid and ethical research despite the pressures that are frequently placed upon them. However, what is required is a clear recognition of the pressures involved (as outlined in Sander Greenland's paper), rather than bland statements that 'we strive to seek the truth' and to 'maintain the highest levels of integrity and transparency'.[5]

Of course, such requirements are now commonplace, and have been adopted implicitly or explicitly by all of the relevant professional societies.[6–9]

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Despite some of the outraged reactions that my commentary has produced, I am not proposing anything new, or particularly unusual or radical, in this regard. Rather, I have attempted to describe the existing 'system' as it works in practice. In particular, I am interested as to why the existing ethical requirements and regulations do not seem to work very well, and that the source of funding still strongly influences the conclusions that are reached, e.g. as in the cases of tobacco[10] and calcium-channel antagonists.[11]

To gain a better understanding of the current 'system' (scenario 1) that I discussed in my paper, perhaps it may be useful to conduct two counterfactual 'thought experiments'.

The first thought experiment (scenario 2) is to consider what the situation would be if corporate funding was removed from significantly influencing what research gets done and how it is received. This could occur in a number of ways, e.g. if all university-based researchers were not reliant on research grants or consultancy fees for their salaries, and agreed not to, or were not permitted to, accept funding directly from any vested interests (corporate or otherwise). Suppose also that if a company was concerned about the possible safety of a product then it was required (or willing) to provide funds through an appropriate public funding agency with no strings attached (and no specification of the exact research to be done, and who would do it). Finally, also suppose that there were sufficient government funds available for investigator-initiated research, so that vested interests were not able to set the agenda, even indirectly, with regards to research into issues such as drug safety. Obviously, many current researchers would be attending fewer conferences, and would be travelling economy class. Apart from that obvious hardship, what would be the effects on epidemiologic research? Would there be a lessening of debate or criticism of published studies? Certainly not. Epidemiologists love to debate and to criticize each other, at scientific meetings and in the journals, both for the sheer pleasure of it, but also because that is what science is about. The main difference is that there would be a genuinely balanced scientific debate, rather than the 'manufactured dissent' that we see too often currently.[12–23] Of course, the 'hired guns' who currently attack published studies on behalf of industry would still be completely free to continue to do this—but it is highly unlikely that they would bother to do so if no-one was paying them.

The second thought experiment (scenario 3) is to consider what things would look like if 'the shoe was on the other foot' and various NGOs (Greenpeace, trade unions, community groups, etc.) had millions of dollars to spend on hiring consultants to attack 'negative findings' about the health effects of occupational and environmental exposures, drug safety, etc., whereas the corporations had none. Would individual epidemiologists change their views about the safety of particular exposures? Would former industry consultants now embrace the precautionary principle and accept funding to attack studies that showed that particular exposures were (relatively) safe? In most cases, probably not. However, the overall debate, and the influences on what research is conducted and how it is interpreted, would certainly change. Once again, funding would set the agenda, but by 'selection' rather than 'coercion'. There would also be, as Sander Greenland notes,[2] an increase in false positives, penalties against innocent parties (although this is primarily a US problem), and misguided public health actions that siphon resources from effective actions. In this regard, I do not wish to comment on the particular events discussed in Carl Phillips paper, since I do not know enough about them, but I do agree that there are vested interests on both sides of most debates. The examples he cites are perhaps extreme cases (the tobacco industry is perhaps the only industry that most epidemiologists would accept that it is unethical to accept research funding from), but I have had plenty of examples in my own research of public health activists that are every bit as biased and unwilling to accept 'inconvenient truths' as are the apologists for industry. However, apart from in my second thought experiment, they usually don't have the funding to have as much influence as the corporations do.

These two thought experiments (scenarios 2 and 3) make the current situation (scenario 1) clearer, and particularly that the availability of large amounts of corporate funding distorts current scientific debate, and is a determinant of what research is conducted and how the findings are interpreted and received. Of course, there are plenty of individual anecdotes about researchers who are not influenced (or believe that they are not influenced) by their source of funding, but when epidemiologists are considered as a group, then if you 'follow the money' then you can, most of the time, predict the findings and interpretation of corporate-funded studies, and you can also strongly predict the conclusions of consultants who are hired by vested interests to attack published study findings that yield 'inconvenient truths'. This particularly applies to industry consultants who rely on such funding to pay their own salaries, in contrast with, for example, epidemiologists based in public universities whose salaries are state guaranteed.

However, rather than branding individuals as 'corrupt', my own interpretation was that deliberate corruption is very rare. Rather, a company which intends to prepare the 'case for the defence' may seek out academics who (usually because of sincerely held beliefs) have been very critical of similar studies in the past. Thus, the shaping of the 'case for the defence' usually involves 'selection' rather than 'coercion' of experts.[24] What we have is a system in which almost all of the individuals are acting ethically (or believe that they are) and doing 'good science',

but the influence of money distorts the process so that it often produces unethical and unscientific results. This can occur even if the funding is given with no strings attached. For example, in some fields of research it is almost impossible to find any leading researchers who have not received funding from industry (with or without strings attached), and the resulting close relationships and networks set the parameters of the debates, albeit by osmosis rather than by coercion.

So what can be done about this? Well, if you are working in scenario 1 (the current reality) I agree that it is naïve to simply say that no researcher should ever accept any funding from any vested interest. My colleagues have been quick to point out that that would leave the consultancy field open to 'hired guns' whose views are very predictable, and industries (and other vested interests) that genuinely want to seek independent advice would not be able to do so. Within scenario 1, you can certainly make a case that it is better for independent university-based epidemiologists to engage with vested interests, and to offer them independent advice, with clear rules for ethical behaviour and full disclosure. There are some academics who offer good role models for this, and have been prepared to testify against their own funders, sometimes at some personal cost. So, within the current reality, a valid argument can be made that it makes sense for academic epidemiologists to engage with vested interests.

The problem is that, despite the integrity and courageous actions of some (but not all) of the individuals involved, in general the current reality is not working well, and vested interests can massively influence, both directly and indirectly, what research gets done and how it is received. These problems are likely to get worse as the most hazardous exposures are increasingly located in developing countries, where there is even less regulation of research ethics than there is in industrialised countries.[25,26]

So how can we mitigate the worst effects of the current reality (scenario 1) while also attempting to move towards a better reality (scenario 2). Talking and writing about these problems is a good start, which was the purpose of my commentary. In contrast to the assumptions of Carl Phillips,[4] I am not suggesting the imposition of any new restrictions on research, or new bureaucracies or professional committees (and I am certainly not suggesting that the existing committees should have more power, or who should sit on them!). I do however consider that professional organizations can play a major role in exposing and mitigating the worst excesses of the current reality, and in moving towards a better reality in which science and the public health come first. This should involve encouraging and supporting epidemiologists to assert positive principles of how science should work, and how it should be applied to public policy decisions, rather than simply having a list of what not to do.

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