LETTERS

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MEDICAL JOURNALS AND INDUSTRY TIES

Reasons to be cautious about competing interests

I agree that disclosure on its own is not an adequate response to competing interests.[1] There has to be a point at which the competing interest is so extreme that the person has to be ruled out of the article, review, decision, or whatever the activity. But defining that point is notoriously hard.

The subheading of the editorial says "zero tolerance," but it cannot really mean zero tolerance because that would rule out any author who had been given a pen, a pad, or lunch by a company. That would be virtually all doctors. The way the article defined "industry" would also exclude from authorship the many young doctors who are starting companies.

A broader point is that the policy might disengage *The BMJ* from companies and more importantly from the many academics closely linked with them. I've heard it argued that modern universities should be about not just scholarship, teaching, and research but also entrepreneurship—and many of the top universities (Stanford, Cambridge, MIT) already are. The point, as Marx said, is not just to study the world but to change it. You would not want *The BMJ* to seem anti-business.

The BMJ has chosen to concentrate on "industry," but I and others have argued that impartiality does not exist.[2] For example, I suggest that GPs, most of whom are in the private sector and for profit, have a huge financial interest in how general practice is organised. They don't seem to qualify as "industry," but I suggest that their financial competing interest is much sharper than most people working for companies that sell to general practice—because employees' compensation is unlikely to be directly affected by changes in general practice. So will GPs no longer be able to write editorials and other pieces on general practice?

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1 Chew M, Brizzell C, Abbasi K, Godlee F. Medical journals and industry ties. *BMJ* 2014;349:g7197. (28 November.)
2 Smith, R, Feachem R, Feachem NS, Koehlmoos TP, Kinlaw H. The fallacy of impartiality: competing interest bias in academic publications. *J R Soc Med* 2009;102:44-5.

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The BMJ should not take the law into its own hands

The case for discriminating against clinicians whose professional interest leads them to collaborate with industry needs to be built on evidence rather than perception.[1] Reference is made to two papers, both of which are low response questionnaires to doctors requesting their perception of validity and believability on hypothetical papers that made no declaration of interest, were grant funded, or were funded by a company with which the lead author was financially involved. Not surprisingly, these study designs came up with the answer that believability ratings were lowest for the industry funded paper.[2 3]

Research misconduct can occur at all levels, including the individual researcher, the department, the institution, the journals, and the funding bodies.[4] Bias in educational articles can reflect many factors, including associations with research funding organisations, government bodies, industry, or simply being employed by a university with a policy of "publish or perish."

Rather than take the law into its own hands, *The BMJ* should reinforce current conditions of publication, including a full declaration of all potential conflicts of interest, and editorial teams and peer reviewers should carefully assess the scientific content and validity of all papers, including editorials and educational articles. Readers should then be allowed to make their own judgment on the article's value to them. All contributors to medical journals need to adhere to professional standards, including probity, and if there is evidence that standards are being breached, referral to our professional bodies or law masters should be the way forward.

Finally, the same edition of *The BMJ* carries a full page advertisement from an international drug company. Does this represent an organisational conflict of interest for *The BMJ*? *The BMJ* authors state that they have no relevant interests to declare.

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Public healthcare systems should not fund private profit

We disagree with *The BMJ*'s new policy of restricting authorship of educational articles to those without perceived competing interests.[1]

Our experience highlights an unintended consequence of such a move. We are performing a population cohort study into the prevalence of valvular heart disease,[2] including the performance of auscultation as a predictor of disease found on echocardiography. To avoid having to declare a competing interest, and because we had charitable funds available, we decided to purchase the equipment (electronic stethoscopes) ourselves. However, if we do show that auscultation with this brand of electronic stethoscope detects valve disease, we will provide the manufacturer with an excellent advertising sound bite. Why should the NHS, which funds this study through the National Institute for Health Research, pay for marketing opportunities for private companies?

There are other reasons to oppose the ban. It will have a disproportionate effect on researchers in lower income countries with a lower level of governmental and charitable funding available for research than in higher income countries. Even in higher income countries, it is almost impossible to bring a new treatment to clinical use without industry support because of the cost of doing so. Is *The BMJ* going to ban any researcher successful enough to develop a clinically useful treatment?

Links with industry are all around us. Does the advertising that appears in *The BMJ* have a conscious or unconscious effect on the editors who, despite a financial and professional interest in *The BMJ* remaining profitable, have declared no competing interests? The unwritten competing interest for most researchers, especially early on in their career, is that their future financial livelihood depends entirely on having articles published. It is rare for an author with a link to industry to benefit so directly from publication.

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1 Chew M, Brizzell C, Abbasi K, Godlee F. Medical journals and industry ties. *BMJ* 2014;349:g7197. (28 November.)
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Authors' reply

There seems to be some confusion about the extent of *The BMJ*'s new policy as set out in our recent editorial. The policy applies only to editorials and clinical educational articles designed to guide patient care and does not extend to other types of article published in *The BMJ*. Moreover it precludes only those authors with a relevant commercial interest—one that relates directly to the topic of the article. Authors with relevant ties to commercial companies will still be welcome to write articles that are not editorials or clinical education articles for the journal. They may also be invited to write clinical education articles if their commercial interests have nothing to do with the article's topic. In answer to Richard Smith, GPs will still be invited to write articles on clinical care, and if Smith happened to be an expert on vaccines, the fact that he is also chair of Patients Know Best (a commercial company that provides software for patients to manage their own health data) would not preclude him from writing an editorial or review article on a new vaccine for us. He might also write non-editorial opinion pieces on the rights and wrongs of access to data, with full declaration of his interests. But we would probably not invite him to write an editorial on how best to give patients access to their data, as readers might have difficulty in perceiving such a piece as truly independent of his affiliations.

And yes this is about perception of bias as much as reality. The research on perceived bias is, as Forsyth points out, limited. But there is longstanding evidence of actual commercial bias in reviews and commentaries.[1 2] We greatly value our authors but we make no apology for prioritising the needs of our readers and their patients. Authors with industry ties have many other outlets if they wish to publish clinical educational articles on topics related to those ties.

In his full response online, Smith raises concerns about academic prejudice as a potent source of bias, which our policy does not address. And Coffey and Prendergast make a similar point—that authors may take controversial rules in order to get published. We agree that this is a problem. Our defences against it, on behalf of readers, are pre-publication peer review to ensure as far as possible that articles are properly evidence based, and the fact that *The BMJ*'s authors are accountable to readers through our rapid responses should they fail to keep their prejudices in check.

Coffey and Prendergast also ask why the NHS should pay for what may become a marketing opportunity for manufacturers. I would answer that the NHS should be funding, and in this case probably is funding, good independent science regardless of the results.

Yes, some authors will not properly declare their interests, as the *New England Journal of Medicine* found when trying to enforce a similar policy in the 1990s. But we are using rigorous processes that we hope will make this less likely. We hope too that authors will choose complete honesty up front rather than risk post-publication embarrassment in the journal's rapid responses. This is one of several aspects of this experiment that we will audit and report back on in the journal.

As for our own conflicts of interest, *The BMJ* sits within a commercial company, but the journal's editors do not own shares or have other interests in industry as defined in the editorial. *The BMJ* gets some of its revenue from pharmaceutical advertising and sponsorship but as with all good journals there is strict purdah between the editorial and commercial teams.

Finally, Forsyth chides us for taking the law into our own hands. To my mind, this is a journal editor's job, within reason: to set policies that in small ways push and prod the worlds of clinical and academic medicine towards what we judge will be a better future. And yes, I hope this will eventually mean no more promotional pens.

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MIDWIFE LED DELIVERY

NICE guidance on place of birth falls short of neutrality

The National Institute for Health and Care Excellence (NICE) guidance on intrapartum care guideline belies the evidence.[1] Birth can be considered straightforward only in retrospect—classification beforehand implies a predictive accuracy that neither obstetricians nor midwives possess.

It is not immediately obvious from the guideline that "the small increase in risk for nulliparous women" means that complications as grave as stillbirth and neonatal death make

up 13% of adverse outcomes, and that the risk for nulliparous women is almost double that for multiparous women. In nulliparous women, serious problems occur at home in 9/1000 births versus 5/1000 births in an obstetric unit.

The evidence cited comes from the English Birthplace Study,[2] where morbidity was defined by a heterogeneous composite outcome measure. A fractured clavicle and serious encephalopathy were both component outcomes, but their health impact on the baby is hardly equivalent.

The guideline based its statement, "Planning for home births was associated with reduced risk of interventions and complications," on a study that was too small to make a meaningful statistical comparison of perinatal and neonatal mortality.[3] NICE did not cite a large US meta-analysis that included 500 000 planned home births in healthy low risk women, which showed that neonatal mortality tripled with home birth.[4]

Given the limited evidence on the true risks of home birth, the guideline's recommendations rely on the development group's collective opinion. This may not be apparent to women choosing their birthplace. Only by communicating the uncertainty underlying the evidence can women be at the centre of decision making and make a fully informed choice of birthplace. The NICE guideline development group has fallen short of a neutral analysis of the available evidence.

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