

Pharmaceutical Law

CONFLICT OF INTERESTS – CRITICISING THE CRITICS

Roy G Beran *

Abstract: Examining the relationship between the pharmaceutical industry and medical profession the BMJ raised concern including: describing doctors as ‘lapdogs to drug firms’; unethical recruiting in third world countries; manipulating codes of conduct; and medicine corrupted by industry largess. This paper offers an alternative perspective, questioning if largess is automatically contrary to societal needs. Serving on advisory boards allows critical input. Critics who denigrate those who accept support often have undisclosed conflicts of interest. These critics usually do not come from private practice and hence responsible for their own expenses and do not acknowledge costs faced by private practitioners when attending meetings. Private practice does not provide salary when not consulting, has no trust fund support and cannot amortise sponsorship as is often done in the public sector. Failure to disclose this represents concealed conflict of interest, amplified by the ‘publish or perish’ philosophy, which may well underwrite some publications.

Keywords : Doctors; pharmaceutical industry; relationship; conflict of interest; alternative perspective; criticise critics.

INTRODUCTION

When submitting a paper on the relationship between the pharmaceutical industry and the medical profession¹ the reviewer indicated that reference should be made

* MD, FRACP, FRCP, FACLM, B leg S, MHL. Australia

1. Beran R.G., Doctors and the Pharmaceutical Industry, *Med Law* – Submitted article.

to the series of articles published in the *British Medical Journal (BMJ)*²⁻¹¹. This brought back memories of a doctoral thesis, on the epidemiology of epilepsy, which was criticised because it did not include the history of epilepsy¹².

With regards to the inclusion of the history, the candidate indicated a willingness to submit a separate review thereof, by way of an additional paper, but was unwilling to proselize the thesis as addition of the history did not contribute to the case being made within the thesis and did not enhance the findings relevant to the epidemiology being investigated. Similarly, the articles in the *BMJ* fail to contribute to the original hypothesis and premise concerning the relationship between big pharma and the medical profession espoused in the submitted article¹. The articles did generate a new line of thinking and raised quite different concerns which will be addressed within this rejoinder to the reviewer.

BMJ ARTICLES

The BMJ articles questioned whether doctors are 'lapdogs to drug firms'^{2,13-18} with a suggestion of only a spurious separation of interests³ which demanded

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2. Fugh-Berman A., Doctors must not be lapdogs to drug firms, *BMJ* 2006; 333: 1027.
 3. Knietowicz Z., Website aims to distance doctors from drug firms, *BMJ* 2004; 329: 1409.
 4. Iheanacho I., Now and then, *BMJ* 2007; 335: 1098.
 5. Fitzpatrick M., Selling sickness: How drug companies are turning us all into patients, *BMJ* 2005; 331: 701.
 6. Kunkler I., Why did we do that? *BMJ* 2005; 330: 426.
 7. Iheanacho I., Drug trials – The dark side: This world, *BMJ* 2006; 332: 1039.
 8. Spence D., The bitterest pill, *BMJ* 2007; 335: 1098.
 9. Spence D., Bend it like...? *BMJ* 2008; 336: 776.
 10. Roberts I., Confession of a climate criminal, *BMJ* 2005; 331: 643.
 11. Waxman J., Shark cartilage in water, *BMJ* 2006; 333: 1129.
 12. Beran R.G., MD Thesis *Epidemiology of Epilepsy in Sydney Australia*, University of NSW, Sydney 1983.
 13. Blumsohn A., Doctors as lapdogs to drug firms: The beast is ourselves, *BMJ* 2006; 333: 1121.
 14. Pimazoni A., Doctors as lapdogs to drug firms: Not lapdogs, not pit bulls, *BMJ* 2006; 333: 1122.

legislatively 'divorce' to establish a more legitimate relationship divorced of coercion⁴. It was argued that doctors should avoid all drug company representatives and advertising, thereby suggesting that the medical profession was so shallow as to be unable to defend itself from being perverted by the overtures of unscrupulous profiteers as presented by the big pharma^{5, 19-20}.

Kunkler⁶ referred to antibiotic resistance and acknowledged that, "... All of them (namely the medical profession, pharmaceutical industry and patients) had good intentions...". Iheanacho⁷ identified the difficulties in recruiting patients/subjects into clinical trials, especially in the wake of the "disastrous trial" of the monoclonal antibody TGN1412 which focused attention on Parexel, one of the largest international clinical research organisations conducting and supervising trials on behalf of sponsoring pharmaceutical companies. The article identified the questionable use of third world countries (also implying access to Eastern European people, after the fall of the 'iron curtain') in which to test questionable products with disregard to the consequences. He described the pharmaceutical industry as "well ahead of the game" and returned to the theme of le Carre's best seller book, *The Constant Gardener*²¹ which highlighted totally unacceptable behaviour on the part of at least one pharmaceutical company when trialling an anti-tuberculosis medication and the hiding of adverse findings.

One can never fully protect against unacceptable behaviour in any industry and it behoves all those involved, be they regulators, therapists, pharma or patients to be ever vigilant against unethical practice. There are ways to counter such behaviour with the development of novel approaches to the sponsoring of trials in which the trailists, rather than big pharma, own the data with regard to potential publication and reporting while the pharma provide the funds to underwrite costs of the studies and retain the intellectual property discoveries

15. Harvey M., Are doctors really lapdogs, *BMJ.com*, 11 Nov 2006

16. Lavine P., All fluff and no substance: Doctor's as lapdogs, *BMJ.com*, 11 Nov 2006.

17. Konotey-Ahulu F., Doctors must not be lapdogs to drug firms: even more relevant in third world. *BMJ.com*, 12 Nov 2006.

18. Pimazoni A., Not lapdogs, not pit bulls, *BMJ.com*, 15 Nov 2006.

19. Footman J., From one (of many) who definitely wasn't seeking, *BMJ.com*, 24 Sep 2005.

20. Fraser D., Selling sickness review, *BMJ.com*, 25 sep 2005.

21. le Carre J., *The Constant Gardener*, Hodder & Stoughton, London 2001.

which may emanate from the trial²².

The profitability of the pharmaceutical industry is being challenged⁸ with the ever increasing hurdles imposed on drug development on the one hand (with which there can usually be no debate if their purpose is to design and produce safer and more effective therapeutic agents) and ever growing encumbrances on marketing products (which seem to be based upon the implication that the medical profession comprises disreputable doctors and pharma devoid of consideration for patients' needs or well-being). Spence⁸ also referred to doctors being "bent" as pharmaceutical companies "twist and turn" the voluntary code of conduct.

The largess offered by the pharmaceutical industry is seen as corrupting and perverting of good medicine with doctors being akin to 'climate criminals'⁹. The medical profession is portrayed as 'fractionated' in 'faithless days'¹⁰ having sold its role to big pharma and hence devoid of ethical consideration and constraint and essentially behaving like whores available to the highest bidder.

ALTERNATIVE PERSPECTIVE

No industry or profession is absolutely righteous and above reproach and every sphere of life includes those who wilfully ignore ethical standards. Were it not for criminals, and those who knowingly transgress society's norms, there would be no need for police and law enforcement procedures. Having said that, it must also be appreciated that such police and law enforcement does not prevent criminal behaviour but rather fulfils a punitive role to apprehend offenders and punish perpetrators of crime once such activity has taken place. Many argue that society is now overgoverned²³⁻²⁵ with civil liabilities being threatened by

22. Beran R G, Ainley L.A.E. & Beran M.E., A novel method for the conduct of pharmaceutical company funded clinical drug trials which ensures the independence of the investigators", *Int. J. of Pharm. Med* 2005;19 (5-6): 309-316.

23. Worrall J.L., Marenin O., Emerging liability issues in the implementation and adoption of community oriented policing, *Internat J Police Strategies & Management* 1998; 21: 121-136

24. Kirby M, Freedom of expression – Some recent Australia developments, *Cth Law Bulletin* 1993; 19: 1778.

25. FOX News, America Mired in Morass of Laws and Regulations, <http://www.foxnews.com/story/0,2933,113861,00.html> 2004.

excessively intrusive laws^{26, 27}. The hypothesis is that the pendulum has swung too far and is stifling novel and challenging activity. Such intrusion has the capacity to threaten free thought and inhibit enterprise without contributing to the welfare of society.

While there are those who avail themselves of the largess provided by big pharma, this does not automatically translate into a lack of benefit to the society as a consequence of such support. The paper which examined the relationship between the medical and pharmaceutical industry explored both positives and negatives that might emanate from the relationship^{1, 28} including the potential for conflict of interest. To discuss this issue further, within the context of this supplementary paper, would amount to double publishing which of itself would be unethical².

CONFLICT OF INTERESTS

Those who are so vocal regarding the potential conflict of interest which is perceived as corrupting patient care, in favour of big pharma, fail to identify their own conflicts. Failure to be nominated to serve on an advisory board or to speak at a pharma sponsored meeting may cause its own inherent conflicts and feelings of dissatisfaction and possible feelings of rejection.

"Sour grapes" tasted by those who have been overlooked for largess may generate its own form of conflict of interest. There are long established maxims including, "jealousy is a curse" and "pull up the ladder" once you have climbed to where you want to go. It is not unreasonable to suspect the motives of those who have not been offered such favours, especially if they fail to openly declare that they have not been so approached and hence have been denied the opportunity to refuse the offers on the basis of personally held principles which reject such acceptance.

Open criticism of doctors, based on a perception that doctors are whores or 'lap-dogs' is offensive to those who practice ethical and moral medicine designed

26. Smith M., Petrocelli M, Scheer C, Excessive force, civil liability, and the Taser in the nation's courts: *Implications law enforcement policy and practice* 2007; 30: 398-422.

27. Baldwin B., Invasion of Privacy In Pennsylvania Law, Legal Perspectives Wolf, Baldwin & Associates, P.C. <http://www.422business.com/articles/200705/InvasionofPriv.html>.

28. Beran R. G., Doctors and the Pharmaceutical Industry". *17th WCML*, Beijing, China 2008.

to deliver optimal patient care. Those who offer such criticism, based upon the fact that doctors have accepted funded attendance at educational meetings or have received company sponsored literature, need to state whether they have attended such meetings or read such literature. Unless they can assess, and have critically appraised, the educative value of such activities they should be disqualified from offering criticism of those who have attended or benefited from the material on offer thereby rendering such criticism both biased and ill-informed.

Unless those, who condemn doctors who accept largess are responsible for their own incomes, rather than operating within salaried positions, for which they have to calculate and compensate for the real 'opportunity costs' to attend funded meetings they are ill-positioned to criticise those who have accepted these very real expenses on a personal basis and at their personal cost. Such 'opportunity costs' include: lost income from not practice for the duration of the conference; continued overheads during this period; and the potential for referring doctors to choose to change their referral patterns because the doctors who attend these meetings spend too much time seeking the possible educative input that the meetings promise to offer. This failure to walk in the shoes of others and, even more so, the failure to declare this fact, of itself represents a real conflict of both interest and perspective.

As stated in the submitted paper¹ those in private practice pay heavily for sponsored attendance at educative meetings for which the only true compensation is the enhanced knowledge obtained and the improved level of patient care that should ensue as a consequence.

Failure to state that the critic is salaried and hence not responsible for such 'opportunity costs' represents a failure to declare a potential conflict of interest. Equally, failure to have been offered similar largess may also represent failure to declare potential conflict of interests which may, of itself, simply motive criticism on the basis of jealousy.

Criticising the profession, without experienced it from within, as may be the case with academic non-clinical doctors who criticise those in private practice, who operate with heavy workloads which prevent attendance at clinical meetings in working hours, also constitutes a form of conflict which is rarely, if ever, acknowledged in academic publications which criticise those accepting pharma sponsored invitations to attend evening, 'out of hours' meetings.

Similarly a very light work load of clinical responsibility, which may prevail

within salaried position in institutions that are responsible for overheads, without declaring this when attacking "avaricious" colleagues constitutes a form of failure to declare a potential conflict of interest.

CONCLUSION

The arguments posed in the initially submitted paper¹ are independent of the series of publications in the *BMJ*^{1-10, 13-20} and represent the views of a clinician who practices within a very busy private clinic environment yet still finds the time to research, write and publish. The current paper resulted from the suggestion to include commentary regarding the BMJ articles within that submitted paper but review of them generated a quite different perspective on conflict of interest.

It is easy to claim a conflict of interest when the largess is so apparent but for more subtle to do so when (a) academia demands publication and critics publish their commentary which satisfies the need to do so, thereby satisfying their own position (b) those who claim poor practice, devoid of direct exposure to such situations fail to declare their lack of equality with those whom they choose to criticise and (c) lack of nomination to appropriate industry funded advisory boards denies such critics the capacity to change the situation from within while seeking notoriety from without.