Pharmaceutical Law

DOCTORS AND PHARMACEUTICAL INDUSTRY

Roy G. Beran*

Abstract: The pharmaceutical industry is seen as seducing doctors by providing expensive gifts, subsidising travel and underwriting practice expenses in return for those doctors prescribing products that otherwise they would not use. This paints doctors in a very negative light; suggests doctors are available to the highest bidder; implies doctors do not adequately act as independent agents; and that doctors are driven more by self-interest than by patient needs.

Similar practices, in other industries, are accepted as normal business behaviour but it is automatically assumed to be improper if the pharmaceutical industry supports doctors. Should the pharmaceutical industry withdraw educational grants then there would be: fewer scientific meetings; reduced attendance at conferences; limited post graduate education; and a depreciated level of maintenance of professional standards. To suggest that doctors prescribe inappropriately in return for largesse maligns their integrity but where there is no scientific reason to choose between different treatments then there can be little argument against selecting the product manufactured by a company that has invested in the doctor and the question arises as to whether this represents bad medicine?

This paper will examine what constitutes non-professional conduct in

* M.D (University of NSW, Australia), F.R.A.C.P (Royal Australian College of GP's, Australia), F.R.C.P (Royal College of Physicians, England), F.R.A.C.G.P (Royal Australasian College of Physicians, Australia), F.A.C.L.M. (Australian College of Legal Medicine, Australia), F.A.F.P.H.M (Royal Australasian College of Physicians, Australia), F.A.C.B.S. (Australasian College of Biomedical Sciences, Australia), B Leg. S. (Macquarie University, Sydney Australia), Grad. Dip. Tert. Ed. (New England University, Armidale, Australia), Grad. Dip. Further Ed. (Adelaide College of Advanced Education, Australia), M.H.L. (University of Sydney, Australia). Conjoint Associate Professor University of NSW, Australia. Professor, School of Medicine, Griffith University, Brisbane, Australia.
response to inducements by the pharmaceutical industry. It will review: conflict of interest; relationships between doctors and pharma and the consequences for patients; and the need for critical appraisal before automatically decrying this relationship while accepting that there remain those who do not practice ethical medicine.

Keywords: Doctors and pharmaceutical companies; relationship; corruption; opportunity costs; educational grants; largesse; changing prescribing; non-professional conduct; benefits

INTRODUCTION

Australian research has documented the gifts and grants afforded doctors by the pharmaceutical industry\(^1\)\(^-\)\(^2\). The implication of this research has been that doctors would be prepared to sell their soul for sponsorship to attend a conference or in return for comparable generosity\(^1\)\(^-\)\(^3\).

Popular opinion suggests that the pharmaceutical industry can seduce doctors with expensive gifts, subsidised travel and the provision of a free lunch\(^4\)\(^-\)\(^7\). So strong is this preconception that governing bodies, such as Medicine Australia,
the World Health Organisation, the Association of the British Pharmaceutical Industry and the Researched Medicines Industry, have imposed rigorous constraints upon the largesse that pharmaceutical companies can bestow upon doctors\textsuperscript{8–11}. Specialised colleges, such as the Royal Australasian College of Physicians, have also published codes of conduct to cover the relationship between their members and the pharmaceutical industry\textsuperscript{12}.

As a consequence of such perceived capacity for the potential to exert undue influence, doctors are seen in a negative light. The argument that prevails is that doctors are willing servants to the highest bidder and would proselytise their values in return for a free meal\textsuperscript{3}. Some may suggest the price is as little as a pen, a pad of 'post it’ notes or some trivial office equipment such as a stapler or a ruler with imprinted logo\textsuperscript{1–3}.

Associated with this notion is the implication that doctors fail to act as independent agents and are purely motivated by self-interest rather than patient needs\textsuperscript{5}. It is of some concern that those proposing such negative representation of the medical profession are often drawn from without the profession without actually experiencing clinical medicine\textsuperscript{13}. Alternatively they are drawn from the ranks of staff specialists who are on salary, have trust funds to cover travel costs and other extraneous expenses, have conference leave and other job related gratuities not available to those in private practice\textsuperscript{14}.

---


The paper to follow will explore the relationship between doctors and the pharmaceutical industry from the perspective of those in private clinical practice and examine both the positives and negatives that emerge.

COMPARABLE PRACTICES

Providing incentives is routine practice in many industries\textsuperscript{15-17}. Advertising includes taking prospective clients to ‘working meals’ in which the merits of a product or proposal are discussed\textsuperscript{8}.

It is accepted that educative conferences are conducted at locations that are sufficiently inviting to entice registrants to attend\textsuperscript{19} and companies will sponsor registration fees to attend special displays. Fashion week is renown for its lavish functions and the underwriting of expensive parties\textsuperscript{20}. Manufacturers will often donate expensive products, such as cars with prominent logos, as advertising gimmicks\textsuperscript{21}. Companies such as Lexus\textsuperscript{1} cars run golfing weekends provide free parking at the opera house (in Sydney) and offer other inducements to encourage prospective customers to consider and use their products\textsuperscript{22}.


Cointreau co-ordinates a ball of such magnitude that there is a status symbol attached to being included in the guest list and the same could be said for Lancôme cosmetics annual fashion show. Airlines offer free, or heavily reduced, travel to advertise new routes or new airlines and resorts and travel agencies supply products as prizes to competitions and entertaining programmes by way of advertising. Magazines often include free sample products, such as cosmetics, to initiate their use and seek feedback. Despite such obvious inducements, together with the provision of monogrammed auxiliary items to enhance advertising, there is not the outcry that prevails within the medical profession.

The fact that a buyer for a retail outlet will be given free samples or be taken to tour a factory or attend an overseas trade display is accepted as routine and the cost thereof is considered the customary expense to conduct business. It is not automatically seen as reprehensible behaviour tantamount to corruption and subversion. Yet similar behaviour in medicine is portrayed as a conspiracy between the doctor and pharma.

The lobbyist or travelling sales representative is seen as a necessary component


of the sales team yet the drug representative for the pharmaceutical industry is viewed with suspicion.

COMMERCIAL DECISIONS

Research has confirmed that prescriptions for a specific company’s products increase after attendance at that company’s educative, company sponsored seminar or after a visit from a sales representative/product detailer. The inference is that such prescription is directly in return for the gratuities provided and that it represents an inappropriate surge in the use of that product.

As is the case in other industries, as cited above, the sponsoring of such activities is a commercial decision which companies would not underwrite if it did not result in increased use of their product. The issue raised is that medicine should be above such rank commercialisation. The case that is usually preferred is that most medications are provided via a formulary system which subsidises costs and hence those prescribing the products have become

34. Somerset M, Weiss M, Fahey T. Dramaturgical study of meetings between general practitioners and representatives of pharmaceutical companies. *BMJ* 2001; 323; 1481-4.
puppets of industry who are inappropriately prescribing and who function as a conduit to spend limited resources consequent to receiving marketing exposure. What is not considered within such argument is that it is possible that prior use of the product may have been inappropriately low due to ignorance of its existence or its possible advantages.  

The relationship between exposure to industry marketing and the increased use of a given therapeutic product is automatically assumed to be contrary to good medicine. This supposes that any such increased prescription cannot be justified on a scientific clinical basis. The corollary therefore is that it must represent a form of conspiracy between doctor and industry in which there is a subversion of clinical judgement in return for what many see as little more than 'bribery'.

Commercial reality ensures that companies will not waste resources if there is no expectation to yield profit as a consequence. Similarly pharmaceutical companies do not provide product promotion for those products with confirmed market niche in which there is little, to no, expectation of changed prescribing behaviour as a consequence of such exposure. It follows that companies only underwrite those products for which it is expected that doctors may change prescribing habits which once ingrained are difficult to change.

If it is true that 'ingrained' prescribing habits are difficult to change, it follows that such change necessitates cogent argument substantiated by scientific fact consequent to properly conducted research. If this hypothesis is accepted,

and it is equally accepted that pharmaceutical companies are basically commercial organisations, rather than philanthropic benefactors, then it follows that company sponsored educative activities are designed to expose attendees to such evidence that might change attitudes and hence prescribing practices\(^{47}\).

To then automatically assume that a surge in prescriptions for a given product, following such exposure, is contrary to good clinical practice is where the argument fails. In reality, if prescribing habits are difficult to change, it is because doctors are satisfied with the outcome of what they do. To be offered an alternative, which may enhance such outcome and for which the clinician has been encouraged to reconsider current knowledge, does not imply corrupt or inappropriate behaviour. It may well represent better patient care and improved disease control. Were this not the case then it would be very easy to change prescribing habits a situation contrary to proven reality\(^{45}\).

**NEGATIVES**

If the doctor only sees representatives from 1 or 2 companies there is the potential to be given a very biased perspective regarding any member of a class of medications\(^{48}\). It follows that it behaves the clinician to speak to representatives from a variety of companies to gain balanced perspective. There is a need to remain sceptical to prevent such bias.

As with all commercial enterprises, it does follow that representatives who are good sales people will be better at amplifying the positives of their product as compared to competitors\(^{49}\). It follows that the same would apply to medications, hence the need to adopt a balanced approach which allows alternative views.

The placement of office supplies with a prominent product logo on same will keep that name at a heightened level of awareness\(^{50}\). It is acknowledged that


\(^{49}\) Hisrich RD, Jackson RW. Selling and Sales Management. Barron’s Educational Series, New York, 052.

this will maintain product awareness foremost in the prescriber’s mind but to suggest that this automatically translates into over utilisation of inappropriate medication is unacceptable. What does follow is that where there exists a valid choice it may favour the advertised product.

Underwriting overseas travel and attendance at conferences is viewed with suspicion\textsuperscript{32}. It is claimed that this generates an unhealthy relationship in which the doctor owes a debt to the sponsoring company and this might translate into over, or inappropriate, prescription\textsuperscript{31}. Inherent in this attitude is the perception that the beneficiary of the underwritten travel lacks the integrity to only prescribe that which is appropriate and necessary. As already discussed, it is difficult to change prescribing patterns\textsuperscript{45} and thus it is counter-intuitive to suggest that a lack of integrity, as suggested, is prevalent otherwise changed behaviour would be automatic despite a vacuum of convincing scientific evidence to justify such change.

**POSITIVES**

The counter-proposal to sponsored overseas conference attendance is the educative value\textsuperscript{41,51-53}. Especially for those in private practice, who do not earn an income while attending conferences, whose overheads continue in their absence and who need to work extended hours before and after such attendance, the sponsorship is always well below the actual cost. The personal and financial indirect cost of attendance is a direct cost for private clinicians, which far outstrips the subsidy, and amounts to many thousands of dollars to cover those additional costs. The fact that these doctors are prepared to shoulder these costs attests to their personal commitment to improved education\textsuperscript{54}. The prospect of those same clinicians also underwriting the direct costs of attendance

---


would probably result in a marked reduction of registrations at such conferences\textsuperscript{6}. This would translate into lowered educational standards with the potential for reduced medical care\textsuperscript{51}.

The educative value of drug representatives should not be underestimated\textsuperscript{48,55}. Representatives serve the profession by keeping them abreast with latest developments in therapeutics, comparative data and alternative treatment options\textsuperscript{48,55}. This does not negate the need for healthy scepticism.

The pharmaceutical industry also provides grants for investigator driven research\textsuperscript{56}, conduct of special interest group meetings\textsuperscript{57} and provision of patient information and educative material\textsuperscript{58}.

**NEUTRAL POSITIONS**

To suggest that a doctor would prescribe an unnecessary medication in return for a travel grant is to denigrate the profession\textsuperscript{1+3}, yet the company would not provide the support if it was without mutual benefit\textsuperscript{58}. Where there are comparable medications, in which there is no scientific validity to compel selection of one agent over another, then it is logical to expect the doctor to prescribe the product manufactured by the more generous company. This does not suggest unprofessional conduct as the patient is still receiving the correct medication of equal efficacy from a clinician who has been better educated consequent to sponsored attendance at teaching activities.

Where there are numerous forms of the same medication and one company has provided patient educative material it is logical for the doctor to use that product and that material thereby providing mutual benefit to the patient, doctor and the company.


\textsuperscript{56} Beran RG, Ainley LAE, Beran ME. 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


Educative meetings supply attendees with additional knowledge to be applied to their patient care\(^{54,55}\). Where doctors work long hours, have limited spare time to devote to their spouse and family and are under pressure to better time allocate, there may well be need to offer additional incentive to provide their time to attend weekend meetings or cancel consultation sessions in favour of conferences\(^ {59}\).

Such inducement may dictate spouse or family attendance at reduced fees or holding the meeting at a more inviting venue. Acceptance of such accommodation, by both doctors and industry, should not equate to non-professional conduct as attendance still necessitates a personal commitment and cost for both the doctor and the pharmaceutical company which ultimately should benefit both patients and industry.

**OFF-LICENCE PRESCRIPTION**

The advocacy of off-licence product, namely product that might be approved by a registration body (such as the Therapeutic Goods Administration (TGA) in Australia or Food and Drug Administration (FDA) in the United States of America) for a different indication to that which is being proposed, is usually deemed unacceptable\(^ {60}\), especially if its off-licence status has not been stated clearly. It is possible for a well meaning clinician to inadvertently fall into the trap of supporting such off-licence use without providing the necessary disclaimer namely that (a) it is for an ‘off-licence’ indication and (b) such advocacy may be premature within the body of available evidence\(^ {61}\).

Doctors who endorse ‘off-label’ (equivalent of ‘off-licence’) therapeutics may find themselves subject to litigation for such promotion\(^ {62}\). The FDA has gone


so far as to require a sponsored speaker, at a pharmaceutical initiated function, such as an educative dinner meeting, to relinquish any right to speak openly about personal off-label experience unless same is proffered in response to a directed, unsolicited question from the floor\textsuperscript{63-64}.

Such restriction acknowledges the potential to act as an industry puppet, especially if that same speaker serves on advisory boards or is handsomely rewarded for speaking at pharma sponsored functions\textsuperscript{65}. The counter argument is that without such dissemination of information it may well be the patient who is the loser consequent to delayed appreciation of what opinion leaders and experts take for granted\textsuperscript{66}. Nevertheless it is imperative for anyone supporting off-licence therapeutics to fully advise patients of this status (as an off-licence use) as to do otherwise would be to ignore patient rights and would remove their empowerment to have informed consent\textsuperscript{61}. The fact that a product is being used for an off-licence indication may well constitute a material risk\textsuperscript{67}, the knowledge of which might influence agreement to use it.

OPEN DISCLOSURE

Advocacy for off-licence use of a treatment modality is not the only area in which therapeutics should be disclosed to patients. Where there may be a potential to perceive ‘conflict of interest’, it behoves the therapist to pre-empt any potential accusation. This is now accepted practice when presenting at meetings, publishing in journals and in any scientific endeavour where bias


may be perceived\textsuperscript{68}.

To suggest that such disclosure eliminates the conflict is questionable. Most opinion leaders have served on industry advisory boards, have presented at industry sponsored functions, have been involved in trials that were pharma initiated and funded and have accepted some form of gratuity as is clearly demonstrated in statements of possible 'conflicts' as presented by speakers at international meetings. So prevalent is this practice that doubt may emerge if anyone does not acknowledge potential for seen – or even unforseen - possible 'conflict of interest' when presenting scientific data\textsuperscript{68}.

Similar potential should be an open fact with patients who would understand that largess is provided to their therapist. To claim otherwise would amount to a dishonest relationship and to be seen as someone whom industry would not wish to support may, in fact, represent a negative for a patient who might consider the clinician to be deemed as unworthy by those in the know. Based upon the appreciation that no one wishes to waste resources, it follows that industry would only support those considered worthy of such grants. The converse theory is that those who were not supported are unworthy and hence less knowledgeable or suitable as therapists.

UNSCIENTIFIC BEHAVIOUR

To claim that for which there is no evidence, or even worse for which there is strong contradictory evidence, without acknowledging the discrepancy is to act in an unscientific manner\textsuperscript{69} amounting to potential accusation of fraud. To do so willingly, in return for pharma support, would allow successful suit for unprofessional conduct, especially if such behaviour was done knowing the true status of the claims being made\textsuperscript{70}.

To publish false data or to claim research that is not properly performed, in


accordance with the publication, also amounts to scientific fraud\textsuperscript{71}. To do so at the behest of pharma influence or largess is even more damnable and such behaviour is both irresponsible and reprehensible and cannot be condoned in any shape or form\textsuperscript{72}.

In all endeavours there are some dishonest people and same will be true for medicine but this paper cannot account for the small minority of dishonest scientists who may well misbehave in response to inducements. Less obvious are those who either withhold or suppress negative data which is counter to industry interests. Why is it more difficult to publish negative studies than it is to publish positive findings\textsuperscript{73}? If the above recognition, that all opinion leaders have enjoyed significant industry support, might it not be true also that those same leaders, who often comprise journal referees, may be subliminally biased and hence support views held by industry? While this may be true there is insufficient evidence to make a valid claim thereof although suspicion does remain as a consequence of such appreciation there has been a move to register all studies\textsuperscript{73} and to provide incentive to publish negative findings\textsuperscript{73}.

NON-PROFESSIONAL CONDUCT

To prescribe what otherwise one would not prescribe in return for favours provided by the pharma constitutes non-professional conduct. To offer patients remedies known to be ineffective or contraindicated in response to inducements from industry would be unconscionable. To offer potentially comparable or more efficacious treatment – produced by a company that has provided incentives to the doctors - would only constitute non-professional conduct if the doctor offered that therapy believing it to be inferior despite its status later proving to be at least equal to alternative available remedies.

For the therapist to act professionally he / she must have reason to believe that the treatment being offered is no worse that competitive therapies. The therapist must not place the patient at any disadvantage to avoid accusation of non-


\textsuperscript{72} Marcovitch H. Research misconduct: can Australia learn from the UK’s stuttering system? \textit{MJA} 2006; 185 (11/12): 616-8.

\textsuperscript{73} Hilbrich L, Sleight P. Progress and problems for randomised clinical trials: from streptomycin to the era of megatrials. \textit{European Heart Journal} 2006; 27 (18): 2158-64.
professional conduct. In other words the therapist must act in the patient’s best interest irrespective of any consideration offered by the pharmaceutical industry. So long as this criterion is satisfied the therapist has acted in a professional manner.

CONCLUSIONS

This paper has highlighted many facets of the doctor-pharmaceutical industry relationship but has focused special attention on doctors in private practice who have: no access to departmental trust funds; are not on salary; and are responsible for all overhead costs irrespective of whether they are treating patients or attending an educative congress. It has compared this relationship to other industries and questioned the aggressive overt criticism which paints doctors as avaricious recipients of largess and hence taints their profession. There has been recognition of potential for abuse but also an acknowledgement of both benefits and negatives that might ensue from a symbiotic relationship.

The paper recognises there is always the minority who wilfully behave badly, but suggests the majority act in the best interest of their patients. There may be a positive advantage from clearly acknowledging possible ‘conflict of interest’ because inherent in the same is the acceptance that thefavoured doctor has sufficient standing to justify industry support. Also identified is the possibility of covert bias that may influence the difficulty to publish negative studies and the need for ongoing vigilance. The paper does not ignore the potential of abuse of the doctor-pharmaceutical industry relationship but provides examples which suggest there can also be positive benefits which should not be ignored.

It examined both the positive and negative factors that may emerge from the relationship and the need for honesty when considering such aspects as off-licence prescribing. It further explored issues relevant to unscientific behaviour and non-professional conduct.