ARTICLE
SPECIAL THEME ISSUE ARTICLE

# The Ethics of the Pharmaceutical Alliance with Psychiatry: A Developing Country Perspective

**Jonathan Kenneth Burns MBChB (UCT), MSc(Edin), FCPsych(SA)**

**Department of Psychiatry, Nelson R Mandela School of Medicine**

**University of KwaZulu-Natal**

**Durban**

## ABSTRACT

The socioeconomic and political conditions of developing countries must be considered when evaluating the ethics of Industry involvement with psychiatry in this context. Specifically, the medicalisation of distress and the globalization of biomedical psychiatry undermines local methods of coping as well as community efforts to change society. It creates a market for expensive psychotropics in an environment characterized by poverty, unemployment and a lack of basic material needs, raising issues of distributive justice. Patients, subjects in drug trials and psychiatrists themselves should be regarded as 'vulnerable' in relation to their interactions with Industry. Poor regulation and control of both Industry and professionals in many developing countries invariably leads to ethically questionable behaviour. Partisanship by Industry towards the private sector and a lack of interest in and commitment to public and academic sectors is a destructive influence. Industry's prime objective of profit does not serve mental health needs of developing countries.

## Key Words:

Ethics, Pharmaceutical Industry, Psychiatry, Developing countries

## Introduction

The relationship between the pharmaceutical industry and the discipline of psychiatry is increasingly a focus of discussion and sometimes heated debate. Seminars and symposia at psychiatric congresses regularly address the issue while psychiatric journals often dedicate entire sections to the topic. *World Psychiatry* for example published a feature article by Giovanni A Fava in its June 2007 edition (Fava, 2007) with a number of invited commentaries. Interestingly, most of these commentaries, authored by individuals with close links to Industry, adopted a defensive and even combative tone towards Fava's critical paper. What is less commonly the focus of discussion in the psychiatric literature however is the relationship between Industry and Psychiatry in so-called 'developing world' contexts. This then is the subject of this paper. Specifically, a case is made for the particular 'vulnerability' of developing country contexts in relation to three issues pertaining to Industry – psychiatry engagement: the medicalisation of mental distress and questions of distributive justice; drug trials and the private sector; and Industry involvement with public and academic sectors.

Many of the issues raised in debates emanating from 'developed countries' are shared with 'developing' contexts, for example issues of drug licensing and regulation, long-term availability of trial drugs to participants and the giving of gifts to clinicians. However there are some issues that are perhaps of greater importance and have greater impact in developing countries (DCs) by virtue of the socio-economic, cultural and political environments therein. For example, the development and marketing of expensive pharmaceutical agents within societies characterized by widespread poverty, income inequality and poor access to health services, raises ethical questions relating to distributive justice (Benatar, 2002.)

Furthermore, the concept of 'vulnerability' – familiar to discussions of ethics and research – needs to be understood in a much broader manner in DC contexts. This is particularly important in relation to the Industry's engagement with Psychiatry in DCs. Of course poor socio-economic conditions, lack of education and political disempowerment cause patients, who are potential research subjects and also recipients of medications, to comprise a particularly vulnerable group (Ogundiran, 2004; Park & Grayson, 2008.) However, the concept of vulnerability in DCs also should be extended to include mental health professionals, professional societies and organizations, governmental legislators and policy-makers and the consumer public as a whole. This is because in contexts where professional salaries are poor, funding for mental health care is limited and the public is generally uninformed about mental health and its treatment, opportunities exist for the Pharmaceutical Industry to wield far greater power and influence


 (ISSN: 1916-2405)

than is possible in more 'developed' countries. Exploiting these opportunities may, in many cases, not be a deliberate strategy. In fact the Industry is, for the most part, careful to conduct its activities with adequate attention to ethics. But the reality remains – financial rewards, opportunities for travel and the pampering that accompanies it and the ego-boosting possibilities of being invited to be an 'opinion leader' or member of an advisory board, all constitute major forms of inducement to serve the needs of Industry. And while individual professionals are subject to the charms of individual rewards, so the consumer public – who in most DCs are not exposed to a strong public mental health system – are susceptible to rampant and aggressive marketing and the blatant promotion of medical models of distress. In a context where multiple other social, economic and health priorities give rise to significant individual need as well as competing financial demands on government, the damaging effects of unscrupulous marketing tactics by Industry cannot be overstated.

## The Medicalisation of Mental Distress and the Question of Distributive Justice

A number of authors have critiqued the manner in which biomedical psychiatry has become globalised hand-in-hand with the expansion of western free-market economics and politics (Thomas et al, 2005; Moncrieff, 2006.) These authors argue that there has been a gradual expansion of the boundaries of what is considered mental disorder over the last 3 to 4 decades so that one now finds biological explanations for such 'disorders' as 'compulsive buying disorder' and 'premenstrual dysphoric disorder.' The result of this medical expansionism is that more and more people now define themselves as psychiatrically ill and in need of medical treatments – especially pharmacological treatments. This of course translates into an expanded market for pharmaceutical companies; and it is not surprising therefore that one finds the Industry actively involved in disease awareness campaigns and other educational activities aimed at increasing consumer demand for medications and altering the prescribing habits of clinicians. Moncrieff (2006) links this process of the medicalisation of distress to the growth of neoliberal policies since the 1970's, whereby extensive deregulation and privatization have led to a massive transfer of wealth from the public sector to the private sector. It is undoubtedly serving the interests of Industry for more and more variations in human behaviour and experience to be brought under the umbrella of biologically based 'mental disorder', amenable to pharmaceutical treatment. Moncrieff (2007) argues that this expanding medicalisation of distress serves to undermine people's confidence in their traditional methods of coping and makes them "more vulnerable and less able to challenge social forces that act against their interests." In this way, the pharmaceutical answer to distress acts as a panacea against resistance to social and political change. The distress caused by rising unemployment, socioeconomic deprivation and growing income inequality that accompanies the neoliberal economic programme is defined in pathological and biomedical terms and is palliated with chemical solutions. And in the process, the pharmaceutical industry benefits from the ever-expanding market that results. The psychiatric profession is a willing partner in this process, lending professional credibility to what might be termed a brilliant marketing strategy. Whether or not one agrees with this sentiment and its obvious political stance, it is a useful analysis when looking at the ethics of the pharmaceutical alliance with psychiatry in the developing country context. One important issue here is the reality that the increasing use of pharmaceutical agents is accompanied by an increasing risk of inappropriate or excessive prescribing and potential adverse effects. This is particularly relevant to the increasing use of psychiatric medications in children, adolescents, the elderly and those with organic brain diseases. In well-resourced countries such as those of North America, Europe and Australasia these concerns are present and are the subject of much debate and careful regulation and control. In many developing countries however, the risks are likely to be much greater as there are generally fewer psychiatrists, poorer community mental health services to monitor patients and, in some cases, inadequate systems of regulation and control. It is inevitable that where there are few human and infrastructural resources for mental health care, there is a greater risk of indiscriminate and inappropriate use of psychotropic medications in vulnerable populations. For example, the prevalence of tardive dyskinesia (a neurological disorder resulting from the chronic injudicious use of antipsychotic medications) is much higher in developing countries than in developed countries (Kasper et al, 2006.)

A further issue of concern relates to the potential that exists, in contexts of poor regulation and control of psychotropic prescription and dispensing, for either covert or overt corruption. For example, Khan (2006) has described how in Pakistan most psychotropics are available over-the-counter and are often dispensed by untrained staff not subject to regulation by any professional body. Furthermore, these 'chemists' have considerable influence on psychotropic sales as many people present primarily to them with their complaints. Thomas and colleagues report that local pharmaceutical companies in India and Pakistan produce cheap 'bootleg' versions of psychotropic agents which are then freely available to consumers on the streets and in private clinics (Thomas et al, 2005.) While the argument might be offered that this is in the interests of the poor in these countries who cannot afford highly expensive original ('ethical') versions, one wonders whether this practice is actually in the best interest of patients (or merely another clever marketing strategy.) One might ask whether the provision of cheap generics in developing countries is a form of altruistic 'charity' or whether in fact it amounts to 'poor drugs for poor people.' This is a complex ethical debate that extends well beyond the scope of this paper.

Nevertheless, it is pertinent to question the ethics of both the rampant marketing of products and the scientific development of new agents by Industry, in partnership with psychiatrists, in contexts where there is little regulation and control. One hopes that efforts to enforce regulations in developed countries have played a part in minimizing the blatant use of perverse incentives by Industry and the acceptance of such incentives by professionals. Where there is still inadequate regulation in other countries, it is only too easy for such unethical practices to flourish. For example, Khan (2006) describes the situation in Pakistan where there is "little or no regulation of medical practice or drug prescribing and dispensing" and where "malpractice litigation against doctors is unheard of." He states: "The traffic is bidirectional – psychiatrists are as demanding of favours as companies are of providing them." Some of the inducements include: all-expenses paid trips

for self and spouse for a drug launch abroad; free drug samples, expensive gifts (such as watches, air conditioners, briefcases, laptop computers, etc); as well as the funding of a doctor's family wedding, holidays and other events of this nature. The issue at stake is the following: an environment where there is little regulation is a vulnerable environment – while doctors are clearly complicit in this unethical trade of favours for scripts, their circumstances need to be considered carefully. In low-resourced settings where remuneration for professional services may be low and rewards few, the persuasive offering of gifts is likely to constitute a significant temptation, difficult to refuse. While undoubtedly unethical, the acceptance of such rewards can be understood and contextualized. Viewed in this fashion, I would argue that the socio-economic conditions and the unchecked forces of a globalised, free-market system that emphasise material gain are primarily to blame for this blatantly unethical alliance.

One also needs to consider whether the biomedical development of new products by Industry in developing countries is justifiable. The scientific development of new agents is hugely expensive and consumes extensive resources – both material and human. Clinicians are routinely involved both in the early laboratory-based stages and the later clinical trial stages of drug development. If salaries are low for clinicians (as they are in many low-and-middle-income countries) the significant financial payouts for participation in clinical trials becomes a serious option to augment income. This means that the existing shortage of psychiatric expertise for clinical work is exacerbated as specialists give large portions of their time to the well-rewarded service of Industry. Furthermore, as is increasingly acknowledged by leaders in the field, we already have effective drugs; and the challenge now becomes how to improve delivery of and access to existing drugs, rather than how to develop new agents (Kane 2007.) Of course questions of access are of great importance within developing countries. Finally, one should ask the question as to how developing countries are supposed to sustain hugely expensive biomedical developments where there are so many other competing financial needs (such as fighting poverty and unemployment, managing HIV-AIDS, etc.) As Thomas and colleagues (2005) state: "Whether in the guise of new drugs or new therapies, technology is costly. How long should we reasonably be expected to go on paying for these developments … How are economically disadvantaged countries supposed to fund these developments, given the competing priorities of providing food and combating illnesses like AIDS?" (Thomas et al, 2005.) These are issues of distributive justice and are linked inextricably to the spread of the neoliberal programme across the globe. In an excellent review of the ethics of research in developing countries, Benatar (2002) states:

> "Erosion of the economies of many poor countries, under the impact of globalisation and debt, has prevented the introduction of effective forms of modern medicine into deprived communities and thus prevented achievement of widespread access to even basic health care for billions of people. In the 1990's, 89% of annual world expenditure on health care was spent on 16% of the world's population who bear 7% of the global burden of disease in DALYs (Iglehart, 1999), and of the estimated US$56 billion spent annually on medical research, less than 10% is spent on health problems of the developing world (Commission on Health Research for Development, 1990.) These are examples of global injustice that should surely be intolerable if there were genuine commitment to universal human rights and human dignity."
>
> (Benatar 2002)

## Drug Trials and the Private Sector

South Africa is popular with the Pharmaceutical Industry when it comes to finding investigators for large multi-site drug trials. This, I am informed by both psychiatrists and Industry representatives, is because South African investigators are efficient, reliable and are easily able to produce the numbers of subjects required of them. Furthermore, the large numbers of available patients, together with the fact that many cannot afford newer psychotropics, means that there are always willing subjects available and keen to participate. Generous payments to subjects further increase the attraction for those without great means. Although consent procedures are taken seriously and generally adhered to with rigor by investigators, I would argue that the pool of potential trial subjects represent a vulnerable group. This is because they are very often coming forward to participate, not for altruistic reasons such as contributing to the progress of science, but because of financial difficulties and their desire to receive newer, apparently more tolerable agents. They have been lectured on the great benefits of such novel drugs by their doctors and are often desperate for another option (having either experienced undesirable side-effects from or failed to improve on other medications.) Enrolment in a drug trial is for many the only way to access this new 'wonder drug.' What about free choice then – free choice to choose treatment and research participation without coercion? I would argue that the difficult social and economic conditions that strongly influence the patient's decision to enroll in a clinical drug trial are in fact a form of environmental coercion. For this reason potential research subjects in developing country contexts represent a particularly vulnerable group. In my view it is unlikely that either Industry or clinician participants in drug trials take account of this complex ethical problem related to patient involvement.

A further issue related to patient enrolment in drug trials in developing countries without strong public health systems is the following: Most trials are conducted by psychiatrists working in the private sector. Many patients join the trial for the reasons given above, hopeful and expectant of positive results and improvement in their mental health. However, at the end of the trial period of 4 weeks or 8 weeks or longer, the new medication (on which they may well have improved and now lay their hopes upon) is no longer available. The drug may be available for private purchase at high and often unattainable cost, but for most individuals they cannot afford ongoing care in the private sector and are forced to turn to the public health system for treatment. The problem is, because of the high costs of these newer medications, most are not available in the public sector and these patients are then forced to change to older psychotropic agents, risking relapse or the return of unpleasant and debilitating side effects. This is the reality of being a trial subject in most developing country contexts. What we should be asking is whether it is ethical for Industry and psychiatrists to collaborate in drug trials in an environment where this is often the outcome for many of the subjects involved.

Finally, it is well known that participation in a drug trial as a

psychiatrist raises a number of ethical issues and challenges which are often unapparent at first glance and place the doctor in a questionable position. Firstly, the ethics approval process for drug trials is invariably handled by the pharmaceutical company and not the clinician. If the clinician is within the academic or state sector, trial protocols are required to pass through research ethics committees at institutions such as universities and hospitals. This provides a measure of control and peer review. However, for psychiatrists in the private sector, no such additional review processes are required and the ethical procedures preceding the trial are the responsibility of Industry alone. As Fisher (2008) discovered in a survey of private sector physicians involved in drug trials in the USA, "[they] often feel that third parties are responsible for determining the ethics of the clinical trials they are conducting." Fisher cites one physician who felt "his conduct was ethical because he followed the protocols as given to him by the pharmaceutical company sponsoring the studies." Thus, by involving themselves in drug trials, clinicians are able to rationalize their own ethical position by pushing responsibility for safeguarding ethical standards onto a third party – the Industry who are in fact the owners and beneficiaries of the trial. Of course Industry has a major vested interest in the success of the trial and cannot be said to be objective when it comes to evaluating the professional ethics of the project. Psychiatrists are therefore placing their own ethical standards in the hands of a party that has clear financial objectives in running a trial.

A more obvious challenge for individual professional ethics is the fact that most trials employ a method of contracting doctors whereby remuneration from Industry is directly related to numbers of trial subjects recruited. The more subjects a psychiatrist recruits the more he or she is paid. Furthermore, if a clinician proves he or she is particularly adept at recruiting the required sample efficiently and within the given time frame, it is highly likely that site will be invited to participate in further trials – thus securing future income and benefits from Industry. Successful trial doctors are invariably rewarded with sponsorship to international conferences, honoraria for speaking at Industry sponsored events and a host of other gifts and material expressions of gratitude that are dressed up in acceptable language designed not to offend one's ethical sensibilities. The problem with these inducements to perform well as a trial doctor is that numbers of patients recruited counts everything. And where there is a pressure to recruit the numbers, clinical judgment of what is actually in the individual patient's best interests may become blurred. It becomes only too easy to stretch selection criteria or ignore borderline laboratory results when one is desperate to enroll a patient in a study and keep them in the study to the end. In Fisher's interviews with trial physicians she quotes one doctor who stated:

> "There's all sorts of ways people will justify blurring lines of distinction, which may or may not be clear actually. Throwing away a lab value is way over the line, right? Does it have to be fudged when you're doing a blood pressure study and this person is two points out of range on their fifth visit, and you've already put in a month of time on that person? I don't know. Does that betray the spirit of what you're trying to do? As opposed to 10 points out of line, then they're out."
>
> (Fisher 2008)

## Industry Involvement with the Public and Academic Sectors

In South Africa public sector and academic psychiatrists are generally not involved in drug trials. One reason is the difficulty Industry encounters in having trial protocols passed by institutional research and ethics committees. Common concerns raised by such bodies include: What happens to the subjects' ongoing need for the drug after the end of the trial? How can one justify placing seriously ill patients on placebos? The already over-burdened public psychiatric hospitals cannot justify keeping patients in a hospital bed for 8 or 12 weeks for the sake of research and cannot justify the expense and time spent on multiple, repeated laboratory investigations and assessments. Furthermore, the value of drug trials on agents that will probably never become available within the public health services is questionable, especially when other types of research are so urgently needed (for example epidemiological studies and research on health service development.) For the most part, Industry is not interested in service-related research or public health service development. Their marketing strategies are not focused on older cheaper agents used in the public sector. Where companies do occasionally woo public sector and academic psychiatrists they do so because they need their advice and guidance on how best to get their newer more expensive psychotropics onto the state essential drug list. On these occasions, these psychiatrists receive the same attention and rewards routinely provided to their colleagues in the private sector. Such partisanship towards the private sector gives rise to resentment and petulance amongst those working in academia and the public services where funding is limited for conference attendance and other educational and research-related activities. In low-and-middle-income countries it is very often the case that without pharmaceutical sponsorship most psychiatrists do not have the financial resources to attend conferences abroad.

Perhaps of greater concern is the close relationship that often exists between Industry and professional psychiatric societies. In South Africa for example, there is a particularly close relationship with the production of Industry-sponsored clinical guidelines, routine sponsorship of branch meetings and a not very transparent system for allocating Industry sponsorships to society members for conferences, etc. This has led to friction within the professional society with a number of individuals canceling their membership and withdrawing from society activities. While these kinds of problems undoubtedly occur in developed countries, I would argue that they are intensified and are potentially more destructive in contexts of socioeconomic difficulty and need. Resources are fewer, support from state and academic institutions is limited and work-loads are enormous and endless. Introduce the pharmaceutical industry, bearing gifts and favours for some but not others and you have a recipe for conflict and division.

## Conclusion

For these reasons I believe that on balance the Industry plays a negative and divisive role within the psychiatric profession as a whole in developing countries such as South Africa. It has its agenda and that is profit. Within poorly resourced and over-

stretched public and academic sectors, it is largely disinterested and uninvolved in the work of professional training and education and the provision of mental health services to the majority of the population. In its interaction with the private sector it provides inducements that test the ethical resilience of the most honest and scrupulous practitioner. In many 'developing countries', the pharmaceutical industry reaps in billions of dollars every year in sales of drugs from a population characterized by considerable levels of poverty, unemployment and a widespread absence of basic needs. Generally speaking the involvement of Industry with the psychiatric profession in realizing its prime objective of profit represents an unhealthy and regrettable alliance.

## References:


Benatar, S.R. (2002). Reflections and recommendations on research ethics in developing countries. Social Science and Medicine, 54, 1131-1141.

Commission on Health Research for Development. (1990). Health research: Essential link to equity in development. Oxford: Oxford University Press.

Fava, G.A. (2007). Financial conflicts of interest in psychiatry. World Psychiatry, 6, 19-24.

Fisher, J.A. (2008). Practicing research ethics: private-sector physicians & pharmaceutical clinical trials. Social Science and Medicine, 66, 2495-2505.

Iglehart, J. (1999). The American health care system: expenditures. New England Journal of Medicine, 340, 70-76.

Kasper, S., Lowry, A.J., Hodge, A., et al. (2006). Tardive dyskinesia: analysis of outpatients with schizophrenia from Africa and the Middle East, Asia, Central and Eastern Europe, and Latin America. Schizophrenia Research, 81, 139-143.

Khan, M.M. (2006). Murky waters: the pharmaceutical industry and psychiatrists in developing countries. Psychiatric Bulletin, 30, 85-88.

Moncrieff, J. (2006). Psychiatric drug promotion and the politics of neoliberalism. British Journal of Psychiatry, 188, 301-302.

Moncrieff, J. (2007). Co-opting psychiatry: the alliance between academic psychiatry and the pharmaceutical industry. Epidemiologia e Psichiatria Sociale, 16, 192-196.

Ogundiran, T.O. (2004). Enhancing the African bioethics initiative. BMC Medical Education, 4, 21.

Park, S.S. & Grayson, M.H. (2008). Clinical research: protection of the "vulnerable"? Journal of Allergy and Clinical Immunology, 121, 1103-1107.

Thomas, P., Bracken, P., Cutler, P., et al. (2005). Challenging the globalization of biomedical psychiatry. Journal of Public Mental Health, 4, 23-32.



***Acknowledgements:*** *None*

***Competing Interests:***

*The author has received research funding in the form of a grant from the National Research Foundation of South Africa. He has previously received sponsorships from Lundbeck, Eli Lilly and Janssen Cilag Pharmaceuticals for international conference attendance. He has also served on an academic advisory board for Janssen Cilag Pharmaceuticals.*



***Address for Correspondence:***

*Department of Psychiatry*
*Nelson R Mandela School of Medicine*
*University of KwaZulu-Natal*
*Durban*
*4000*

***Tel:*** *2731 2604321*

***Fax:*** *2731 2604322*

***Email:*** *burns@ukzn.ac.za*