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EDITORIAL

The dominance of Big Pharma: unhealthy relationships?

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"He who sups with the Devil should have a long spoon."
English 14th Century Proverb.

The multinational pharmaceutical industry is seldom out of the news for a variety of reasons. "Breakthroughs" in drug treatment are acclaimed in the press, yet the industry's reputation is frequently tarnished by claims of profiteering, data "massaging" and inappropriate marketing techniques that include inducements offered to healthcare professionals, promoting misleading data and questionable direct-to-consumer advertising. The industry has also been accused of ignoring low-incidence diseases in developed Western countries and common, life-threatening disease in others on grounds of poor profitability. At heart, there are pressing concerns about power relationships, and considerations of trust at several levels that have never been fully resolved.

Most of the papers included in this themed section emerged from those presented and discussed at a seminar held during a conference of the *European Society for Philosophy, Medicine and Health Care* at the University of Tübingen during August 2009. These papers are supplemented by a contribution that considers the potential for bias in the uncertain process of appraisals by the UK *National Institute for Health and Clinical Excellence*, a process whose outcomes are crucial for patients, prescribers and manufacturers, together with a polemical debate between two general medical practitioners, one from Germany and one from the UK concerning their personal views on attempts by some industry employees to subvert or evade regulatory practices to maintain progress.

The paper by Badcott, *Big Pharma: a Former Insider's View* summarises the main components that support a generally instrumental justification for the commercial and highly competitive nature of the industry. It is argued that the established operational model optimises development of increasingly more effective and better tolerated new medicines, funded by investment and maintained through the profits of direct market competition. Nevertheless, major ethical problems are acknowledged within the industry and whilst their seeming ubiquity and refractory nature is in itself problematic—human ingenuity at circumventing codes and regulation that are perceived as more of a challenge than a bar is undeniable—there are encouraging signs that some major multinational Big Pharma companies are beginning to adopt more rigorous and accountable ethical codes, some of which reflect acknowledgment of the value of adopting a triple bottom line policy and shouldering wider social and other responsibilities.

General medical practitioners and hospital doctors are the principle targets for pharmaceutical promotion. In *Of Mugs, Meals and More—the Intricate Relations Between Physicians and the Medical industry*, Sahm explores some of the main aspects of this relationship which has often been plagued by ethical problems for both parties. Physicians are the principle gatekeepers for the accessibility of potent medicines by patients and Sahm recognises that "co-operation between profit-driven manufacturers of medical products and physicians caring for patients is

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desirable and necessary for the advancement of medicine". At the same time, he emphasises that a physician's judgment on what represents the best interests of patients may be compromised by a less than cautious relationship with the industry in the form of close ties with company representatives, remunerated consultancies or the acceptance of funding to attend conferences etc. Experts in the field, opinion leaders who promote a company's products directly or indirectly, or who recommend inclusion in a hospital formulary may be swayed in their opinions, possibly subconsciously, by financial or other rewards. Sahm concludes that in view of the pervasive conflicts in their dealings with the pharmaceutical industry, "it is time for physicians to take the leadership in the process of creating transparency and curbing undue influence through clear rules". The English proverb quoted above, "He who sups with the Devil should have a long spoon" is perhaps an apt if rather histrionic reminder for all physicians and healthcare professionals with prescribing responsibilities to exercise caution, judgment and restraint in their dealings with the industry.

But the pharmaceutical industry does not only target the medical and healthcare professions. In some countries such as the USA and New Zealand, direct-to-consumer advertising (DTCA), is both legally permitted and becoming more widespread. Womack's paper *Ethical and epistemic issues in direct-to-consumer drug advertising: where is patient agency?* tackles the key implications of what such promotion means with respect to a patient's ability to comprehend, process and act (make good choices) from DTCA. She notes that opponents point out that advertisements may be misleading or deficient regarding safety, recommended indications, and effectiveness, and also may have negative effects on doctor-patient relationships. Promotion of drugs to healthcare professionals and DTCA are linked by a state of asymmetric vulnerability. Healthcare professionals are susceptible both to the industry's marketing strategies and to patients demands, whereas most patients who generally lack expertise may readily and uncritically translate the elements of DTCA into those very demands. What are required are informed policies, practices and regulatory structures that respect and promote patient agency within the health care marketplace. The author advocates more research that links the complex relationships that exist between information and agency in medical decision-making with a more detailed understanding of patients' experiences within medical and therapeutic contexts.

The National Institute for Health and Clinical Excellence (NICE) is an agency of the UK National Health Service with its origins in 1999. It is acknowledged by the Government that a publically-funded healthcare system is unable to pay for every available new medical treatment and the objective of the Institute is to promote clinical excellence by making recommendations on cost-effective (a combination of therapeutic effectiveness and value for money) medical treatments and care using the best available evidence. The system of quality-adjusted-life years measurement (QALY) is routinely employed to compare the effectiveness of different drugs, with cost effectiveness expressed as £ per QALY. But the system is not immune from external influences such as the mass media and the pharmaceutical industry which is prone to view NICE as a hurdle to innovation to be overcome. Consequently, in their paper *NICE technology appraisals: the potential for bias in the midst of uncertainty*, Brown and Calnan emphasise that the regulatory powers of NICE are exercised and are themselves regulated within an inherently social process. Competing interests, such as those of the industry are brought to bear directly on NICE and particularly indirectly, through their influence on patient *special interest groups*. The mass media often respond to harrowing human stories with a high cultural resonance and robustly promote the cause of individuals or groups of patients considered to have been *deprived* by NICE's failure to approve a life-saving or life-sustaining treatment. Governmental bodies such as NICE have been established in several European countries.[1] Yet, the rules that govern their activities differ, e.g. the use of the QALY as a criterion to measure effectiveness is not accepted in Germany, but heavily debated. What is of interest is that the potential for biases are quite the same. So, the insights offered in that paper relate to even different systems. Overall, the authors indicate that the regime is polycentric in character where there are multiple state and non-state contributors, opaque knowledge and power boundaries, and is characterised by uncertainty (epistemic, procedural and social), fragmentation, complexity and the impact of multiple inter-dependent contributors. Brown and Calnan propose a framework for investigating the impact of such uncertainty. Key to this is the extent to which layers of uncertainty and the various formats of responses to them may act as avenues through which outside interests, such as those of the pharmaceutical industry, are manifest and may exert influence which skews the regulatory process.

Edgar's paper *The Dominance of Big Pharma: Power* explores the exercise of power by Big Pharma companies and considers a normative assessment model. The author describes how the pharmaceutical industry is one of the most distinctive and highly regulated. Pharmaceutical products are controlled through a continuing need to

[1] For a summary of some other European agencies that undertake cost-effectiveness or cost-utility analyses for new medicines see for example, Corinna Sorenson, 'Use of Comparative Effectiveness Research in Drug Coverage and Pricing Decisions: A Six-Country Comparison' in *Issues in International Health Policy* July 2010.

demonstrate efficacy and safety, and are generally prohibited from sale directly to consumers. Patient access is available only through a complex system of gate keepers within the health service and importantly in the UK and many other countries, the ultimate consumer rarely pays either directly or in full for the pharmaceutical medicine. Although its power is ostensibly highly restricted and regulated in the interests of patients and the general public, Edgar indicates how the industry is nevertheless able to exercise a subversive *Lukesian third dimensional power* (conflicts of interest and grievances between the parties may become largely invisible and the respective parties themselves may be generally unaware of the conflicting power relations). Edgar argues that the justice and fairness of Big Pharma's activities can be understood by assessing the extent to which the industry actively seeks to influence the perceived legitimacy of government health policies, through manipulation of patients, patient advocacy groups, physicians and other medical professionals. But more widely, the mass media, government agencies and health departments may also be targeted in attempts to shape public opinion in favour of the industry itself or with respect to particular products. Edgar's primary concerns are with Big Pharma's undue influence in shaping conceptions of the patient-consumer, in *disease mongering* and in distorting public debate over resource prioritisation. In his opinion, these formidable adverse influences can best be countered by the intervention of those whose voices are currently excluded from debate. This might be advantageously achieved through a genuinely open engagement by Big Pharma with a range of patient advocacy groups, particularly where there are no obvious shared or distorting interests, bringing the prospect of long term stability and a renewed trust in the industry.

Debate over whether or not the dominance of Big Pharma hinges on *unhealthy relationships* of one sort or another is unlikely to be readily curtailed. Passions often run high and entrenched positions are not easily dislodged even by documentary evidence or cogent argument. This themed section includes two personal opinions in the form of a polemical debate between Calinas-Correia a Portuguese general medical practitioner working in the UK (*Big Pharma—a story of success*) and Sahm, a German medical practitioner and academic (*On Markets and Morals—(Re-) Establishing Independent Decision Making in Healthcare*). As in Badcott's paper, Calinas-Correia argues instrumentally that the activities of Big Pharma deliver a continuing succession of safer and more effective medicinal drugs. Where he differs markedly from Badcott is to assert rather provocatively that slavish adherence to unduly restrictive regulation of the industry would lead to mediocrity. He considers that it is the challenge to such regulation which provides a creative stimulus through which pharma company employees sometimes circumvent such strictures and in doing so enhance innovative progress. Analogy between battling warriors and pharma executive action does not readily spring to mind but Calinas-Correia considers it to be appropriate in making his case for resistance to regulation. A response to this polemic is given by Sahm, who challenges the fundamental assertion that the undesirable aspects of marketing are *caused* by the political and legal framework in which Big Pharma operates. Democratic societies have a right to control powerful institutions such as the pharmaceutical industry which takes precedence over rights to individual freedoms. Such control does not exclude encouragement of market mechanisms where they are held to be appropriate to achieve desirable results. However, Sahm maintains that physicians are obliged to be and to be seen to be wholly independent and to apply their knowledge and skills in the best interests of their patients. And as a key part of the healthcare system, a clear set of rules governing the relationship between physicians and Big Pharma is essential: "Big Pharma has been successful both despite *and owing to* the checks and balances imposed". Behind this debate one may identify a well known conflict which is familiar in political philosophy, that is between on the one hand individual freedom, i.e. freedom of choice, and on the other, the common good. Additionally, Calinas-Correia's *hidden assumption* that the pharmaceutical industry launches only products that are called for by the needs of their customers (patients and doctors) is refuted by Sahm who maintains that in the case of Big Pharma it is often supply (the products made available) that controls demand rather than the more familiar economic pattern.

A healthy pharmaceutical industry engaged in worthwhile research and development has the ability to greatly reduce the incidence and effects of serious and debilitating disease and illness throughout the world. There is much to be gained by serious and open debate between governments, relevant international bodies, patient advocacy groups and members of the wider public, in determining how an optimum moral and operational framework might best be achieved to the advantage of all. These papers provide a valuable contribution to several aspects of that debate.