**Combating Corruption in the Pharmaceutical Arena**

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**Word Count:** 3047

**Key Words:** corruption, medical profession, pharmaceutical industry

**Competing interests:**

In 2015-2017 Joel Lexchin received payment from two non-profit organizations for being a consultant on a project looking at indication based prescribing and a second looking at which drugs should be distributed free of charge by general practitioners. In 2015, he received payment from a for-profit organization for being on a panel that discussed expanding drug insurance in Canada. He is on the Foundation Board of Health Action International. Jillian Clare Kohler is the Director of the WHO Collaborating Center for Governance, Accountability and Transparency for the Pharmaceutical Sector at the Leslie Dan Faculty of Pharmacy. Paul Thacker reports receiving travel funding from universities to give talks about conflict of interest. Marc-André Gagnon reports grants from Canadian Institutes for Health Research (CIHR), during the conduct of the study; personal fees from Prescrire International, personal fees from Canadian Association of Pharmacy in Oncology, grants from Canadian Federation of Nurses' Unions, outside the submitted work. James Crombie and Adrienne Shnier report no conflicts.

**This manuscript is not under consideration by any other journal.**

**Abstract**

Corruption in health care generally and specifically in the pharmaceutical arena has recently been highlighted in reports from Transparency International. This article focuses on four areas of corruption: legislative/regulatory, financial, ideological/ethical, and communications. The problems identified and the solutions considered focus on structural considerations affecting how pharmaceuticals are discovered, developed, distributed and ultimately used in clinical settings. These include recourse to user fees in the regulatory sphere, application of intellectual property rights to medical contexts (patents and access to research data), commercial sponsorship of ghostwriting and guest authors, linkage/de-linkage of the funding of research and overall health objectives from drug pricing and sales, transparency of payments to healthcare professionals and institutions and credible regulatory sanctions. In general, financial and other incentives for all actors in the system should be structured to align with desired social outcomes – and to minimize conflicts of interest among researchers and clinicians.

**Introduction**

The governance of public healthcare and medical research is strategically important for public policy; however, its technical complexity creates the potential for corruption that can undermine public health objectives. The issue of corruption has been highlighted in recent articles (1) and especially in two 2016 reports from Transparency International which document how “corruption is part of doing business in the healthcare sector all over the world”(2) and which defend the view that “combatting policy and structural issues that increase corruption vulnerabilities in the pharmaceutical sector will help prevent unnecessary medicine expenditure costs and ideally improve health outcomes for all.”(3)

Many types of corruption in the pharmaceutical sector are equally rampant in high-income countries and low-income ones, for example, conflicts of interest, misrepresentation, lack of transparency and corporate influence over prescribing habits.(4) Of equal import to documenting instances of corruption is identifying strategies and tactics to reduce corruption. This undertaking is particularly meaningful given the inclusion in the Sustainable Development Goals (SDGs) of the reduction of corruption (and bribery) as one of the necessary target actions needed to achieve Goal # 16 “(to) promote peaceful and inclusive societies for sustainable development, provide access to justice for all and build effective, accountable and inclusive institutions at all levels.”(5)

Following on from the Transparency International reports, we focus specifically on corruption in the pharmaceutical sector. We identify some core weaknesses in this sector’s governance practices that incentivize corruption and illustrate these weaknesses with examples from the United States (US) and Canada, and also from India to emphasize the global nature of the problem and its relevance to both developed and developing countries.

Corruption and unethical practices in the pharmaceutical sector have been well documented (6, 7) including corruption in clinical trials,(6) pharmaceutical companies,(8) the medical profession (9) and drug regulatory systems, such as the US Food and Drug Administration (FDA).(1) Here we broaden the scope of previous scholarship and take a thematic approach and focus our discussion on four types of corruption: legislative/regulatory, financial, ideological/ethical, and communications, with a final discussion of possible structural solutions. These categories are by no means mutually exclusive and in fact they often occur in combination. We use a wide definition of corruption that includes not just illegal activities, but also an impairment of integrity or moral principle that, among other outcomes, hides the true effectiveness and safety of products and/or makes them unavailable to the populations that need them by virtue of their cost. By understanding the weaknesses within the sector, we can seek solutions to best address them – the subject of the final section of our article.

**Types of corruption**

*Legislative/regulatory corruption*

Legislative/regulatory corruption happens when legislators – yielding to pressure – enact laws or regulations that benefit a particular sector or weaken the government’s ability to regulate and advance the public interest. For example, user fees create government dependence on industry, favour big pharma by making it more difficult for smaller players to enter the market and, more seriously, increase the ease with which new, potentially harmful, products are approved for use. This is evidenced by the fact that, soon after the initiation of user fees in the US, a survey found almost one in five FDA scientists felt pressured to approve drugs, despite safety concerns.(10) A wealth of research demonstrates a link between shorter drug approval times and a subsequent increase in safety problems in the postmarket phase, as well as a greater need for drugs to be removed from the market.(11-15)

As another example of legislative corruption, the act that established Medicare Part D, providing coverage of outpatient medicines for people 65 and over in the US, specifically forbade the government from negotiating prices.(16) This prohibition occurred despite prescription drug prices for 7 top-selling drugs in the US being significantly higher than those in multiple other countries, even after taking discounts into consideration.(17) Overall, the price of patented drugs in the United States is, on average, 138% more than the media of OECD countries.(18) Figures from the Organisation for Economic Co-operation and Development (OECD), put per capita US spending in 2013 at $1026 versus the OECD mean of $515 for all 29 industrialized countries included in the survey.(19) In such a context, a legislated impediment to market competition through negotiation of prices is clearly unethical and inefficient. The fact that this impediment could have been instituted at all is a symptom of underlying corruption, plausibly attributable to the undue influence of interested parties over the legislative process – and to the predominance of the desire to be re-elected over the duty to serve the greater public good.

A third area where the governments have adopted the interests of the pharmaceutical industry to advance the latter’s objectives has been intellectual property rights (IPRs). IPRs came to the fore during the negotiations that led to the 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), one of the fundamental treaties of the World Trade Organization (WTO). Prior to the WTO, governments especially in low- and middle-income countries (LMICs) often did not grant patents for pharmaceuticals. In the case of India, the country only allowed process patents, i.e., patents on how the product was made but not on the actual product itself. After sustained lobbying by the pharmaceutical, entertainment, and software industries, governments in the US and the European Union pressed for, and eventually were successful in having a 20-year patent term incorporated into the TRIPS Agreement.(20) Longer patent terms delay the introduction of low cost generics, the most effective way of lowering drug prices in LMICs.(21)

The establishment of the global intellectual property regime under WTO was the result of negotiations where not all relevant interests were represented, where few LMICs had full information about the consequences of the agreement, and where coercion was used in persuading importers of intellectual property rights to sign the agreement that significantly increased the costs of prescription drugs.(22)

Since 2005, one of the conditions for Indian membership in the WTO has been allowing full product patenting. As a result, in 2016, India granted a patent to Pfizer for its pneumonia vaccine Prevnar 13, thereby ensuring a monopoly for the company until 2026.(23) Regulatory corruption in India contributes to why substantial numbers of unapproved formulations of non-steroidal anti-inflammatories, anti-depressant/benzodiazepine and anti-psychotic fixed-dose combination products remain on the market despite concerns about their effectiveness and safety.(24)

*Financial corruption*

In the context of this paper, financial corruption is defined as the use by pharmaceutical companies of financial power to create undue influence over medical research and prescribing habits. Corrupt practices include illegal or lavish promotion, misrepresentation of harms and benefits, ghostwriting and guest-authoring, ghost management, payments to physicians and outright fraud. Since 1991, drug companies have paid $35.7 billion in civil and criminal penalties in the US more than any other industry.(25) GlaxoSmithKline alone has paid $7.9 billion, of which $127 million was in criminal penalties for withholding data from the FDA.(26, 27) Unfortunately, profits generated through violations currently far outweigh penalties.(28, 29) Companies budget for expected penalties and, what is deeply concerning, almost no major pharmaceutical company executive has ever gone to jail for criminal acts.(29, 30)

*Ideological/ethical corruption*

Ideological/ethical corruption speaks to the manipulation of public trust to benefit companies while harming or defrauding patients. Examples include funding patient advocacy groups to carry corporate messaging,(31) normalizing and downplaying financial conflicts of interest between industry and academic institutions and researchers (32) and using the World Health Organization logo in advertisements for medicines to imply WHO endorsement of the messages carried in the ads.(33) Incentives for corruption can result from a misalignment between financial benefits for drug companies and social good.

Profits depend on maximizing drug sales, not optimizing health outcomes, for which the public bears all the risk. Accumulating capital through product sales requires controlling public perceptions and shaping social narratives about health, illness and medicines and is accompanied by strategies, including ghost management and ghostwriting that shape both the demand for medicines and the research to support their development and use.(34) We believe that ghostwriting is an example of ethical corruption in so far as it is an abuse of power by the companies that produce or sponsor the ghostwritten articles and the clinicians or scientists who are named as authors on the published articles. Ghost authorship requires the guest authors to shirk their professional responsibilities and abandon their concern for the objectivity and integrity of research, and the wellbeing of patients. Ethical concerns here surpass plagiarism and the misattribution of authorship. Misinterpreting and manipulating trial data often minimizes or masks unwanted side-effects, and exaggerates treatment effectiveness—both to the detriment of users. In ghostwritten studies, moreover, the raw data related to the trial are protected as intellectual property and typically remain under the control of the pharmaceutical company.(35) Maintaining data control also means that companies control the way these data are published. For instance, most negative clinical trials examining the effectiveness of antidepressants are either not published or are published in a manner that makes them appear as positive.(36)

Another concern relates to unethical behaviour in the production of clinical data. The clinical trial for two human papilloma virus (HPV) vaccines on tribal girls, a marginalized population, in Andhra Pradesh in 2009 is a good example. The HPV vaccines were administered to girls through “vaccination camps” held at schools and hostels. In one case, consent for vaccination was given by the teacher in charge of a hotel and in another probably by the hostel warden. In some cases, the parents of the girls were not told about the vaccinations. Many of the girls who received the vaccine were prepubescent although the consent form states that the vaccine would be administered to adolescent girls.(37)

*Communications corruption*

The pharmaceutical communications industry is critical for developing and guiding spin-strategies by shaping the disease narrative through publication planning. Publication planning involves extracting “the maximum amount of scientific and commercial

value out of data and analyses through carefully constructed and placed papers.” The entire process of undertaking clinical research, analyzing and writing up its results and submitting articles to journals is performed with a commercial motivation that is ultimately under the control of the company seeking to market a product.(34) For the pharmaceutical industry, the real market value is no longer in producing drugs but in producing the right medical discourse.

A systematic review has demonstrated that when physicians receive their information directly from the pharmaceutical industry, that with very few exceptions prescribing, as measured in three dimensions – cost, frequency and appropriateness – either does not change or it deteriorates.(38) Another example from the US of the corruption in communication is the $5.8 billion spent on direct-to-consumer advertising of prescription medicines, (39) when the evidence that this type of activity improves patient outcomes is, at best, extremely weak.(40)

Although direct to consumer advertising of prescription drugs is not allowed in India, companies are able to get around this restriction by using social media. On the patients´ discussion forum, Cancer Compass, a friendly medical representative gives the information that the anti-cancer drug Nexavar (sorafenib), marketed by Bayer, is available in India without stating the price.(41)

**Recommendations for reducing corrupt practices**

To reduce current corrupt practices, we must de-link profits from drugs sales so that financial incentives for pharmaceutical companies are structured to align with desired social outcomes that make unethical and corrupt practices possible and profitable. For example, payers should not be paying for drugs, but rather for the desired therapeutic effect obtained. This type of “value-based pricing” not only reduces the incentive to oversell the benefits of drugs, but it also provides financial incentives for medical research that is focused less on me-too drugs, and more on breakthrough drugs that could significantly improve health outcomes. While value-based pricing is attractive, obstacles need to be overcome. At present, value is based on industry-funded clinical trials, which are more likely to yield positive results and conclusions compared to trials with any other type of funding.(42) This model would probably also not be possible in LMICs because of affordability issues and the total cost of medicines. Even in high-income countries, it may need to be accompanied by other strategies such as tendering and price-volume agreements.

To deal with the problems of companies controlling clinical trials and the data that comes out of them, Schafer has proposed what he calls the “sequestration thesis” or the separation of researchers from the process of commercialization that would include the complete isolation of industry from clinical trial data.(43) There are, what we term “weak” and “strong” variations to this thesis. The weak model is exemplified by the proposal form Finkelstein and Temin.(44) They suggest creating an independent, public, nonprofit Drug Development Corporation (DDC) that would act as an intermediary to acquire new drugs that emerge from private sector R&D. Rights would then be transferred to sell the drugs to a different set of firms that would then compete on price.

The stronger version of this model would see an institution such as the National Institutes of Health organise and manage clinical trials and the resulting data with funding from taxes collected from the pharmaceutical industry and/or general tax revenue.(45, 46) “Drug companies would no longer directly compensate scientists for evaluating their own products; instead, scientists would work for the testing agency”.(45) In both cases, the authors argue that the companies should continue to fund a significant portion of the research agenda “in order to discourage the wholesale testing of marginal drugs with little therapeutic value, or candidate medicines with little chance of clinical adoption.”(45) While companies would continue to develop and market their products they would be separated from the process of generating and interpreting the clinical data. Baker goes even further in arguing for a system whereby all clinical trials would be publicly financed with the cost of the trials in the US being covered through lower drug prices under the Medicare drug program and other public health care programs.(47)

On the global front, there have also been proposals directed at increasing research and development into neglected diseases. One of the key recommendations of the Consultative Expert Working Group on Research and Development, established by the World Health Assembly (WHA) in 2010, was a legally binding research and development treaty to which all countries would allocate 0.01% of their GDP.(48) However, when this proposal was put forward as a resolution at a subsequent meeting of the WHA, it was rejected by member states in favour of a voluntary mechanism.(49)

Increased accountability and transparency can also counter corrupt practices. Citizens do not always understand or have full information about the drug regulatory process, or how and why governments make decisions. Government transparency must thus be coupled with the appropriate accountability mechanisms, which ought to cut across financial, performance, and political domains. In addition, sanctions for pharmaceutical companies that violate laws must be punitive enough to discourage such activity. This could involve an escalation pyramid of sanctions such as that which has been advocated by Ayres and Braithwaite whereby as the number and severity of the violations increase so do the penalties.(50) This method should also be adapted for dealing with illegal promotion. Even fines in the range of billions of dollars have failed to control promotion since, as noted above, there are magnitudes of order more profits to be made from this type of activity.

The Physician Payments Sunshine Act (PPSA) in the US is part of the Affordable Care Act and has helped to drive transparency and the possibility for greater accountability by health practitioners and pharmaceutical and medical device companies in the United States. By mandating the public reporting of all payments to doctors and healthcare institutions of $10 or more, the PPSA helps address financial conflicts of interest (FCOI)—an endemic problem in medicine. These private dollars work to fund physician-researchers, who are also subsidized through public research funding mechanisms such as the National Institutes of Health in the United States. These physician-researchers often also have FCOI relationships with drug companies (51) and this relationship has been linked with skewed research results in favour of the product being tested.(52) Moreover, FDA safety panels and National Academy panels are stacked with physicians who have FCOI relationships with drug companies whose products are under review.(53-55) Companies also funnel significant amounts of money into continuing medical “education” for physicians,(56) raising questions about whether marketing has replaced education. While only a minor first step, the PPSA allows for researchers and journalists to examine the correlation between industry money and prescriptions and temporal changes in this relationship. In short, transparency creates the possibility of greater accountability, and these rules can help in other areas of science that lack such transparency measures.(57)

While FCOI disclosure is necessary it is not sufficient. The ultimate goal should be to exclude people with FCOI from decision-making capacity. As much as possible, payment for medical research should come from public funds and go to researchers who do not have direct conflicts of interest. More public funding for clinical research will help to prevent researchers from engaging in trials that are being conducted for marketing purposes.

Finally, the medical profession writ large must reform itself to focus on best treatments, instead of intentionally organizing itself based on the best ways to obtain external corporate funding including, but not limited to, for continuing education. One of the key ways for the medical profession to move toward this goal is to develop more effective methods of education and communication to clinicians about drug benefits and harms to improve the way that drugs are prescribed and to decrease reliance on biased medical literature and promotion.

**Conclusion**

We have seen that corruption occurs in the pharmaceutical sector when actors ostensibly responsible for promoting the health and well-being of the population allow themselves to be distracted from this duty by other considerations. The end result of that corruption has meant that instead of medicines primarily being a means to advance health care they have become a means to primarily increase corporate profits. Exploring ways of combatting corruption stimulates new discussions about the potential for systemic change. This type of change is necessary to realise societal governance goals and transform ideas of corporate social responsibility to ensure that consumers and their favourable outcomes remain the ultimate goal of pharmaceutical companies in the international market.

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