**Combating Corruption in the Pharmaceutical Arena**

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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-Andre 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.

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**Abstract**

Corruption in health care generally and specifically in the pharmaceutical arena has recently been highlighted in a couple of reports from Transparency International. This article focuses on four areas of corruption: legislative/regulatory, financial, ideological/ethical, and communications. By understanding the weaknesses within the sector, we can seek solutions to best address them**.** 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. Increased accountability and transparency can also counter corrupt practices through measures such as an escalating pyramid of sanctions and mandating the public reporting of payments to doctors and healthcare institutions. Decoupling funding from the performance of research will remove direct conflicts of interest from researchers. Finally, the medical profession must reform itself so that it is not reliant on money from the pharmaceutical industry.

**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 that documented how “corruption is part of doing business in the healthcare sector all over the world”(2) as well as how “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) Of equal import, identifying strategies and tactics to reduce corruption is particularly meaningful given the Sustainable Development Goals (SDGs) inclusion 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.”(4)

Following on from the Transparency International reports as well as the above SDG we focus specifically on the pharmaceutical sector and identify some core weaknesses in this sector’s governance practices in the United States and Canada that incentivize corruption.

Different forms of corruption and unethical practices in the medical field are normally well known: illegal promotion, misrepresentation of harms and benefits, ghostwriting, lobbying, regulatory capture, fraud, lavish promotion of products, conflicts of interest, and undue influence over medical practice and prescribing habits.(5, 6) We focus our discussion on four types of corruption: legislative/regulatory, financial, ideological/ethical, and communications. These categories are by no means mutually exclusive and in fact they often occur in combination. 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 happens when governments enact laws or regulations that benefit an industry or weaken that government’s ability to regulate and advance the public interest. For example, user fees create government dependence on industry. Soon after the initiation of user fees in the United States (US) Food and Drug Administration (FDA), a survey found almost one in five FDA scientists felt pressured to approve drugs, despite safety concerns.(7)

Pharmaceutical companies are arguably the worst offenders in financial corruption, or the use of financial power to create undue influence over medical research and prescribing habits. The industry uses practices which include illegal or lavish promotion, misrepresentation of harms and benefits, ghostwriting, ghost management, payments to physicians, or outright fraud. Since 1991, drug companies have paid $35.7 billion in civil and criminal penalties in the US.(8) GlaxoSmithKline alone has paid $7.9 billion, of which $127 million was in criminal penalties for withholding data from the FDA.(9, 10) However, profits generated through violations far outweigh penalties.(11, 12) Companies budget for expected penalties and, what is deeply concerning, almost no major pharmaceutical company executive has ever gone to jail for criminal acts.(12, 13)

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,(14) or normalizing and downplaying financial conflicts of interest between industry and academic institutions and researchers.(15) 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 this capital through product sales requires controlling public perceptions and shaping social narratives about health, illness and medicines. Accumulating revenue 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.(16) 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 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 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 typically remain the property of the pharmaceutical company.(17)

The pharmaceutical communications industry is critical for developing and guiding these 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.(16) For the pharmaceutical industry, the real market value is no longer in producing drugs but in producing the right medical discourse.

**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.

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.(18)

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 (19) and this relationship has been linked with skewed research results in favour of the product being tested.(20) Moreover, FDA safety panels and National Academy panels are stacked with physicians who have FCOI relationships with drug companies whose products are under review.(21-23) Companies also funnel significant amounts of money into continuing medical “education” for physicians,(24) 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.(25)

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.

Corruption in the pharmaceutical sector has meant that instead of medicines primarily being a means to advance health care they have become a means to primarily increase corporate profits. Combatting corruption is necessary to restore medicines to their societal goal.

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