Regulation of Physician Interactions with Industry: “… it matters who pays for the pizza”

“You must do the thing you think you cannot do.” Eleanor Roosevelt

Introduction

My interest in physician interactions with the pharmaceutical industry first arose over 20 years ago during my psychiatry residency, shortly after finishing medical school. My classmate at the University of Toronto (U. of T.) took a principled stand against accepting the free lunches which were provided to attendees of educational events at the former Clarke Institute of Psychiatry and other U. of T.-affiliated teaching hospitals. My colleague would bring her own “brown paper bag lunch” to the sessions while the rest of us chowed down on the company offerings. We considered her an oddity, a bit of an eccentric. Most of the other psychiatry residents did not spare a thought as to whether or how the gift of a free meal would influence the way we might practice medicine at that time or in the future. The drug company meal saved us from preparing a packed lunch or buying food at the cafeteria, which was the bottom line for a time-pressured resident, living in a fast-paced, high-priced city.

Long before the issue of physician-pharmaceutical industry relations, and physician-industry relations hit the radar, my former classmate was one of the lone souls in the mid-1990’s who attempted to resist what she correctly perceived as the insidious influence of Big Pharma in psychiatry and medicine. Until that time, I was oblivious to the inherent conflict of interest present in physician-industry interactions.

Although I had studied medicine at the University of Alberta and had been in the U. of T. Plastic Surgery Residency Program prior to my psychiatry training, I do not recall learning about how industry could cloud physicians’ judgment. We spent a lot of time on “evidence-based medicine” and critical evaluation of research methodology, but were oblivious that the apple might be harbouring a worm at its core. Since then, my concerns about industry’s negative influence on doctors (and presumably, on other health professionals) has only intensified, especially after being exposed to the law’s regulatory perspective.


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Like many practicing physicians, I was not aware of the Canadian Medical Association (“CMA”) Guideline,\textsuperscript{5} nor of the College of Physicians and Surgeons of Ontario (“CPSO”) Policies\textsuperscript{6} until I started to research this paper. Guidelines, unlike regulations, do not have the force of law behind them, and so are less likely to be followed, as they are voluntary, and therefore, unenforceable. However, regulation without enforcement will not achieve one’s desired objectives, as experience has shown recently with legislative attempts such as the \textit{Accessibility for Ontarians with Disabilities Act}. As well, initial education of physicians of the content policy directives and regular booster follow-up are necessary to create attitudinal shift.

\textbf{Outline and Scope}

This paper\textsuperscript{7} is divided into two parts. The first section deals with a review of the academic literature, using the Draft Policy as a framework, with \textit{underlined sub-headings} corresponding to those used in the Draft Policy. The second section is an appendix which details my recommendations based on my review of the “best available evidence”\textsuperscript{8} at to how the CPSO should revise its draft policy on “Physicians’ Relationships with Industry: Practice, Education and Research.”\textsuperscript{9} Due to time limitations, I have not commented on “4. Industry Sponsored Research.” I have decided to contextualize this paper by relating personal experiences, where relevant, from the perspective of having grown up in a physician family, being a physician, and now being a law student. I have deliberately chosen to interpolate the word “sales” into the phrase “product or industry reps.” or “pharmaceutical reps.” to keep the underlying objective of the interactions at the fore.\textsuperscript{10} Omitting the word “sales” tends to sanitize or “whitewash”\textsuperscript{11} the function and goals of the companies’ agents, who as their representatives, \textit{owe a duty to the company}, not to physicians or the public.

My review suggests that the CPSO is taking too timid and conservative an approach to the regulation of physician-industry relations, and must, as Canada’s “largest

\textsuperscript{6} CPSO Policy, “MD Relations with Drug Companies” (1992) and “Conflict on Interest: Recruitment of Subjects for Research Studies” (2006).
\textsuperscript{7} The author was a student in “Governance of Pharmaceuticals in the International Context” in 2014 at the Faculty of Law, University of Toronto. A similar paper to this submission has also been submitted as part of the course requirements.
\textsuperscript{9} Ibid.
\textsuperscript{10} Stanford University also “calls a spade a spade” by using the term “Sales and Marketing Representatives”
\textsuperscript{11} \textit{Infra}, note 12. This is also the term used by a well-known ethicist at the University of Manitoba to describe the CPSO Draft Policy.
medical regulator,”12 make a surgical cut in order to be true to its new vision of “Quality Professionals, Healthy System, Public Trust.”13 The “best available evidence”14 clearly shows that the CPSO should eliminate not just gifts, but also drug samples, meals, and speaker fees. The CPSO should also institute strict regulations by which doctors, both clinical-focused and research-oriented, must disclose industry financial (quantitative) and other sponsorship (e.g., travel and accommodation reimbursement) on the CPSO’s publicly accessible website. The CPSO must implement a policy similar to that of leading educational institutions such as Stanford University,15 with requirements such as those in the U.S. Physician Payments Sunshine Act (2010)16 if it truly wants to combat the pervasive influence of the “medical-industrial complex”17 on physicians and the practice of medicine and, ultimately, to fulfill its mandate to protect the public trust.

**The Need for Regulation**

My first experience of being “wined and dined” (although I do not drink alcohol, most of the other residents did) occurred when I was finishing my residency. I was attending the annual American Psychiatric Association conference in New York, where a drug sales rep. invited me to a residents’ dinner at an upscale restaurant. The venue was beyond the usual reach of a resident’s salary and featured a live performance from a well-known musician.

I cannot recall whether an “educational session” took place or even which company picked up the tab, but I do remember the positive feelings and the sense of obligation that resulted. It is human nature to want to recompense someone who has done something good for you. No doubt, the favourable feelings could easily invoke a sense of needing to “pay back” the company in some way, the most likely one being

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14 Supra, note 8.

15 Stanford University, “Policy and Guidelines for Interactions between the Stanford University School of Medicine, the Stanford Hospital and Clinics, and Lucile Packard Children's Hospital with the Pharmaceutical, Biotech, Medical Device, and Hospital and Research Equipment and Supplies Industries ("Industry")” http://med.stanford.edu/coi/siip/policy.html. Accessed on May 7, 2014.

16 S. 301 (111th), enacted as section 6002 of the Patient Protection and Affordable Care Act, 111 Congress HR 3590 2010.

prescribing its medications, so that revenue can be earned for future events like the residents’ dinner.

1. Practice

Industry Gifts

As noted by Katz, a researcher at the Centre for Bioethics at the University of Pennsylvania, “When a gift of any size or gesture is bestowed, it imposes on the recipient a sense of indebtedness. The obligation to directly reciprocate, whether or not the recipient is conscious of it, tends to influence behaviour.”

Katz goes on to cite Cialdini’s 1993 work, *Influence: The Psychology of Persuasion,* stating that “the social rule of reciprocity imposes on the recipient an obligation to repay, in kind if possible, for favors, gifts, invitations, and the like.” Gifts of nominal value, e.g., a monthly greeting card, a 50 cent key chain, and mailing address labels were all found to increase significantly purchases or donations. The old-fashioned phrase “much obliged,” as a substitute for “thank you” brings to light the underlying indebtedness to pay back the giver that results when one is the receiver of the transaction (largesse).

A simple analogy is the practice of bring a “hostess gift” to a dinner party. If the pharmaceutical company is the host of a dinner and possibly of an educational event, but the doctor does not bring a gift, how can (s)he relieve the feelings of indebtedness? Clearly, the “logical” way to reciprocate is by prescribing the company’s products. By eliminating acceptance of “All Gifts Large and Small,” (including meals), the CPSO has an opportunity to remove this important source of influence from the doctor-industry relationship.

Product Detailing

According to industry, product sales reps. convey information to health care professionals which is beneficial for patients, in that it keeps physicians apprised of new products and indications. However, Katz cites Lexchin’s (1989), Ziegler’s (1995), and Avorn’s (1982) research which shows “physicians rely heavily on detailers for information and that the more doctors rely on commercial sources of information, the less...

likely they are to prescribe drugs in a manner consistent with patient needs.”23 (Emphasis added.)

Lexchin, as early as 1989, identified problems with the quality of information conveyed by drug sales reps. to doctors.24 In 1993, he found that while prescribing indications were usually conveyed, safety information was not. Lexchin’s conclusion was that “only selected, usually positive, information” was provided; accordingly, he advised physicians not to be “passive recipients of information provided by sales representatives.”25 Interestingly, he advised physicians “who choose to continue to see reps. [to] critically compare the information they get from them with that contained in scientific publications.”26 (Emphasis added.) However, in 2003, Lexchin reported that “studies funded by pharmaceutical companies into the efficacy of a drug that they are developing are generally more positive than studies conducted by researchers with no connection to the industry.”27

The CPSO Draft Policy exhorts physicians to “ensure that they critically evaluate any information provided by industry representatives and do not solely rely on this information when making clinical decisions ….”28 How does the CPSO realistically expect a busy physician to perform this “critical evaluation”? Perhaps by attending a drug company sponsored lunch-time talk while consuming a “free” meal, paid for by the drug company?29 Or maybe by attending a conference where a highly paid speaker who, because he has “disclosed” his industry affiliations purports to give an “objective,” conflict of interest-free lecture?30 Or should (s)he do it by reading a ghostwritten,31 industry-initiated, double-blind, “gold standard” randomized controlled trial, given industry-sponsored research is known to show more positive results than independently-funded research?32

23 Ibid.
26 Ibid.
28 Supra, note 5 at lines 112-114.
29 Please ignore, as I was not able to renumber the footnotes.
30 Ibid.
31 “Ghost-managed articles are cited three times as often as their independent counterparts on the same medication,” in Sergio Sismondo, “Key Opinion Leaders and the Corruption of Medical Knowledge: What the Sunshine Act Will and Won’t Cast Light On” J. Law Med. Ethics, Fall 2013. 41(3):635-43.
“Physician-detailer interactions” are correlated with “marked physician preferences for new products that hold no demonstrated advantage over existing ones, a decrease in the prescribing of generics, and a rise in both prescription expenditures and irrational and incautious prescribing.”

The Department of Veterans Affairs, Mid-South Healthcare Network, permits drug sales representatives to visit the medical center only “for the purpose of coordinating the procurement or recall of a particular product, or obtaining technical or professional information.”

The Chief of Pharmacy and Chief of Staff must authorize the visit which occurs only after a scheduled appointment, not on a spontaneous basis.

Stanford University also has placed strict limitations on industry sales reps. access to its staff and facilities.

Equally concerning is the fact that off-label uses of pharmaceuticals are frequently promoted during sale reps.’ interactions with physicians. For example, Eli Lilly’s internal marketing documents obtained by the New York Times revealed a systematic campaign, called “Viva Zyprexa” to encourage family doctors to prescribe olanzapine to elderly patients exhibiting symptoms of early dementia, even though the medication had only been approved for treatment of schizophrenia and bipolar disorder, manic phase. Because psychiatrists usually initiate medications for these major mental illnesses, the Lilly marketing executive advised sales reps. that “dementia should be the first message.” However, olanzapine carries increased mortality for just this patient demographic.

The campaign’s success was demonstrated by an increase of 49,000 new prescriptions within three months of its launch. In 2001, at a national meeting of company sales reps the “brand manager for Zyprexa” lauded 16 of the corps, specifically for the “number of prescriptions they had convinced doctors to write, … More than 100 other representatives had convinced doctors to write at least 16 extra prescriptions and thus “maxed out on a pretty sweet incentive.”

These and other marketing strategies resulted in $4.2 billion in worldwide sales of Zyprexa in 2005. However, in January 2009, Eli Lilly pled guilty to a federal criminal misdemeanor charge, brought under qui tam legislation, and paid a fine of $515 million, “the largest ever in a health care case, and the largest criminal fine for an individual corporation ever imposed in a U.S. criminal prosecution of any kind” for illegally marketing Zyprexa for off-label uses, not approved by the FDA. Lilly also agreed to pay up to $800 million in a civil settlement and forfeited $100 million in assets, bringing its

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33 Supra, note 19, citing reviews by Lexchin (1989, 1993), and Wazana (2000).
35 Ibid.
36 Supra, note 15, at “II. Site access by Sales and Marketing Representatives.”
total cost to $U.S. 1.42 billion. However, this seemingly enormous payment represents only the proverbial “drop in the bucket” at 34% of one year’s sales. Will such fines really effect any major change in drug company marketing, without accompanying changes in the ethos of physician-industry relations?

The mixing of food with information is also a major issue in which the Draft Policy endorses the status quo despite the fact that Katz highlights this issue in his research which the CPSO itself cites as “containing key evidence from the literature.” Almost 50 years ago, Janis noted that “individuals tend to be more receptive to information when it is received while eating enjoyable food.” Of course, after a busy morning or a full day at work, physicians will find any well-prepared food, even of “modest value” pleasurable. Food, like shelter and clothing, is a basic human need, and its fulfillment by drug sales reps. gives them a powerful advantage in their dealings with doctors. In addition, “[t]he act of dining helps foster cozier working relationships that may help break down professional barriers between physicians and sales reps.” Add a cocktail and a glass of wine, and the doctor’s inhibitions and judgment will be further diminished. In 1940, Razran noted that food is the “most commonly used technique to derail the judgment aspect of decision making.”

Stanford University has recognized the validity of the evidence that food is a powerful marketing tool and has stated “[m]eals or other types of food directly funded by Industry may not be provided at Stanford School of Medicine,” or at its related hospitals and clinics, including its affiliated children’s hospital or even “at Stanford-sponsored events off site.”

In the face of this research, the Draft Policy’s stance on product detailing and meals is not reconcilable with an evidence-based framework of decision-making or policy development. Free food is a gift. If I take you, the reader, out for lunch, you owe me. If I take you out to lunch regularly (perhaps once a month, or even once a week), and you do not reciprocate, you will owe me more and more as time passes, that is, your debt will accrue. This is an inevitable result of the “reciprocity rule.” One way

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39 Supra, note 8 at Draft Policy footnote 1.


41 Supra, note 8. Draft Policy footnote 2 states “… Physicians should have regard to this regulation [s. 16(a) of O. Reg. 114/94 under the *Medicine Act*, 1991] and to the reasonable expectations of the general public in assessing whether a meal is “modest.”

42 Supra, note 19.

43 Supra, note 19.

44 Supra, note 15 at “IV. Support for Educational and Other Professional Activities.

individuals minimize potential conscious or subconscious feelings of indebtedness in social interactions is to “go Dutch,” a method of dividing the bill used by people dating in the Netherlands. Doctors, as one of society’s most highly paid professionals can certainly afford to pay for their own “modest meals.” It is embarrassing and problematic that we still look for freebies.

One reason for this unseemly but pervasive behaviour may be what a deputy editor of JAMA and UCSF researcher calls the “culture of gift giving, which starts with medical students, and breeds a long term sense of entitlement.” Contrary to the opinion of the head of the Australian Medical Association, cited below, this deputy editor/researcher does not situate the problem with the drug companies. “I don’t criticize the marketers for behaving like marketers. What they do is make people feel entitled – so it’s not a bribe; it’s their due.” Physicians need to start acting like the professionals they purport to be, if they want to maintain or regain rapidly eroding public trust in the medical profession.

A glaring example of such “bribes,” occurred in 2006, when Roche spent $65,000 for one dinner alone for 330 oncologists at Aria, a restaurant at the Sydney Opera House. For its “gift” of $A215 per individual, Roche was subsequently fined $A75,000 by Medicines Australia, which “represents the discovery-driven pharmaceutical industry in Australia,” for violating its Code of Conduct. However, the “national president of the Australian Medical Association, the main doctors' group, believes the onus is on drug companies not doctors to ensure any hospitality complies with the code.” This ridiculous comment clearly reflects a “sense of entitlement”: it is like saying that the onus for ethical conduct rests entirely on the individual offering the bribe, not on the one accepting it.

While the Draft Policy seeks to ban “All Gifts Large and Small,” leaving such a glaring loophole open for industry and continuing to allow detailing is incomprehensible. Without a doubt, industry, like water, will find a way to maximize the potential of the gift of a meal and unlimited access to physicians that the Draft Policy is permitting it to retain. In fact, Hodges found paradoxically that the “more gifts a physician receives, the

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47 Supra, note 8
51 Ibid.
52 Supra, note 19.
more likely he or she is to believe that they do not influence behaviour.”

Doctors naively believe they are being “educated” though their interactions (with or without meals) with drug sales reps. In fact, doctors are being willfully blind to the reality that pharmaceutical companies are systematically using “target marketing” which a former President of Pzifer Pharmaceuticals described as “almost as scientific as anything we do” to render physicians mere pawns in their profit-making schemes. “When informational messages are mixed with food, flattery, friendship, or sex appeal, critical thinking can be derailed,” with patients paying the ultimate price, e.g., as evidenced by Zyprexa-associated mortality.

It is unfathomable that, although Lexchin advised 25 years ago, that “seeing detailers is detrimental to the practice of good medicine, and the best interests of doctors and their patients would be served if physicians had nothing further to do with detailers” the Draft Policy does not incorporate the vast body of evidence which has accumulated during the ensuing years, by banning not only gifts, but also product detailing and meals.

**Drug Samples**

The CPSO should take the lead in prohibiting the practice of accepting prescription drug samples, which are euphemistically known as “Clinical Evaluation Packages,” if the CPSO genuinely wants its Draft Policy to be formulated on the “best available evidence.”

Despite common assumptions held by the medical profession and the self-serving claims of the pharmaceutical industry, sample medication has little or no role in 21st century medical practice. Problems of sample use include, but are not limited to: unregulated and unmonitored use by physicians, their family members and office staff, pharmaceutical reps., failure to reach the intended audience, i.e., patients, cost of sample distribution, failure to evaluate clinical indications for a given product and environmental impact. Chimonas and Kassirer cite 39 other authors in their comprehensive summary

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56 *Supra*, note 25.

57 *Supra*, note 8.

of the issues involved in distributing samples. I will focus on only a few, due to space limitations.

**Pharmaceutical Sample are Susceptible to Unregulated and Unmonitored Use and Abuse**

As a child, I recall my parents, who are both physicians, regularly bringing home samples of cough and cold medications, antibiotics, topical preparations, etc. for our family’s use. Although my family did not have an extended health plan, the cost of medication was certainly not an issue.

More disturbingly, after I graduated from medical school, I did the requisite backpacking trip to Europe with three other women - my classmate, an intern, and friend from the faculty of arts. When we took an overnight train from one European capital to another, the intern took out a clear plastic bag full of sample medications and offered them to the rest of us “to help us get a good night’s sleep.” At that time, hypnotics, such as Imovane® (zopiclone) were provided as samples to physicians. I was horrified to see my friend and colleague consume and promote the use psychoactive substances after having imbibed alcohol with her dinner. I declined her offer, but I recall one or both of the others accepted. Not surprisingly, this colleague later developed a significant polysubstance abuse disorder, including narcotics, benzodiazepines and other psychoactive substances, which eventually resulted in her being admitted to a drug rehabilitation program under an agreement with the provincial licensing body. In retrospect, I see that the pharmaceutical samples were my colleague’s legal “gateway drugs” to other substances. I wonder how many other physicians self-medicate, rather than seeking professional care, with similar disturbing outcomes.

My experience is not uncommon; other physicians use sample medications too; in Westfall’s study (which had a 96% response rate) of physicians, residents, nurses, and office staff in a family practice residency, only 2 of 53 respondents reported no use of prescription samples. Easy and unregulated access to sample medications exposes health care practitioners to the risks of unmonitored self-prescribing and family prescribing, contrary to the CMA’s and CPSO’s ethical principles.

Drug sales reps. themselves have been found to misuse samples. In Tong’s and Lien’s 3-month anonymous survey of 27 pharmaceutical reps. in a Vancouver-based family practice, almost 60% admitted to giving prescription drug samples to nonphysicians, most frequently friends and spouses. While the study’s sample size was small, its 100% response rate shines a light on a likely underreported problem.

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In a comprehensive review of 23 papers with at least a partial focus on sample medications, Groves et al noted the following issues: influence on prescribing behaviour, resultant drug expenditures, unregulated handling in delivery and receipt, self-medication issues, disposal problems, and resale or trading to pharmacies.\textsuperscript{62}

**Pharmaceutical Samples Influence Physicians’ Prescribing Behaviour**

Symm et al’s study of 23 family physicians providing care in three clinics of a large (180,000 member) U.S. health maintenance organization found that distribution of free sample medication is associated with a greater likelihood of physicians prescribing those medications.\textsuperscript{63} However, many physicians who dispense sample medications [and the CPSO, if it retains the current Draft Policy’s wording regarding samples)] … do not necessarily believe that their prescribing behaviour is influenced by pharmaceutical companies.\textsuperscript{64} Other research, including physician self-report and more disturbingly, research with resident physicians, bears out Symm’s findings.\textsuperscript{65}

**Pharmaceutical Samples Drive up Medication Costs.**

Symm’s study also found that the clinic in which physicians distributed sample medications had higher average 30-day prescription costs than those clinics which did not distribute samples. This finding is expected because drug sales reps. generally provide samples for new products with current patents. Because generic versions are not yet available, these drugs will, therefore, be more expensive.\textsuperscript{66}

Rapidly climbing health care costs are an issue not just in the U.S., but also in Ontario and Canada. Once a patient is stabilized on a new medication, initiated because of availability of samples, the physician will have difficulty changing the medication in the future. Symm comments that “a free sample medication today may seem to reduce the cost of care for the moment but may result in a long-term prescription much more expensive than is perhaps necessary.”\textsuperscript{67} This cost implication is relevant whether the patient pays for the prescription himself, or the government or a third party insurer is responsible for costs. Some health organizations are attempting to reduce the monetary effects of pharmaceutical marketing by placing restrictions on drug sales reps.’ access to prescribers, by limiting or eliminating sample distribution, and by “counterdetailing efforts.”\textsuperscript{68}

There are also other indirect costs. Samples accounted for “slightly more than half of the total promotional dollars spent by industry,” between 1996 and 2000.\textsuperscript{69} A

\textsuperscript{62} Supra, note 60 at 446.
\textsuperscript{63} Ibid.
\textsuperscript{64} Supra, note 60 at 447.
\textsuperscript{65} Supra, note 61, citing Adair (2005) and Chew (2000)
\textsuperscript{66} Supra, note 60 at 447.
\textsuperscript{67} Ibid.
\textsuperscript{68} Ibid.
\textsuperscript{69} Supra, note 61.
study of 2004 data found the “retail value of samples [to be] approximately [U.S.$]16 billion. As even Big Pharma does not get a free lunch, it must recover these marketing costs through increased drug prices and sales. Individuals and the health care system ultimately bear the financial (and other) consequences of accepting “free” drug samples, which are designed to increase profit for corporate shareholders.

Pharmaceutical Samples’ Fail to Reach Intended Populations

Physicians often rationalize their acceptance of samples by thinking that these medications go to patients who could not otherwise afford them. However, Cultrona et al.’s 2008 U.S. study showed that those in the highest income category were most likely to have received samples while fewer than 1/3 of individuals classified as “low income” (< 200% of the poverty line) were beneficiaries of the physicians’ largesse. Another American study corroborated these counterintuitive findings.

Pharmaceutical Samples Have Unintended Adverse Health Consequences

Drug sales reps. usually distribute samples, as a marketing device, to encourage doctors to prescribe the newest medications to increase sales of the product. Consequently, these drugs will have the shortest track record for safety. Vioxx® (rofecoxib) provides a textbook example of such a danger. According to Cultrona, within three years of its release, Vioxx® became the “most widely distributed sample” but only two years later, it was also found to cause excess cardiovascular and cerebrovascular mortality, and was withdrawn from the market. The rest is history; Merck settled potential lawsuits in the U.S. for $4.85 billion.

Cultrona has also pointed to more worrying concerns relating to sample distribution to children, namely that “four of the 15 medications most frequently given as samples to children in the U.S. received new or revised “black box” warnings from the [FDA] within two years of approval.” Children are especially vulnerable as they may be less likely or able to articulate adverse drug effects and are also more susceptible due to their physiology and limited reserves. As well, most physicians do not record lot numbers for samples which will make identification of patients who have received a particular batch difficult, if not possible, in the event of a recall or identification of new adverse effects.

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70 CPSO President, Marc Gabel is quoted as saying “the College Policy also allows doctors to accept drug samples, as many argue they can help disadvantaged patients.” in Supra, note 12.
72 Ibid.
74 Supra, note 74.
75 Ibid.
I myself have accepted samples of various medications from physicians for my own or my family’s use; most recently, a new long-acting beta agonist, without a concomitant discussion of its risks and benefits. This lack of patient education cannot solely be attributed to the fact that I am a physician and am deemed not to require an explanation. I am clearly unfamiliar with these medications, both because they are not ones for which I would have prescribing experience, given my specialty, and also because they are new. My experience anecdotally supports Cultrona’s claim that “in doctor’s offices … detailed patient education regarding sample use rarely occurs, and when it does it usually lacks information about drug interactions or instructions on how the drug should be taken.” Cultrona contrasts this situation with that in a pharmacy, where computer programs check for potential interactions, and the pharmacist includes a detailed patient information leaflet when (s) he dispenses the prescription, often with verbal instructions.

Pharmaceutical Samples’ Have Detrimental Environmental Impact

As a teenager in the early 1980’s, my parents frequently asked me to cull their office cupboards of expired products. I would fill garbage bags with medications, and think about the waste of plastic, foil and paper - long before environmental sustainability was in vogue. Standards of maintaining and disposing of medications were not as rigorous as today, but I would hazard a guess that many physicians are not complying with current waste disposal standards, as they have no regulatory requirement to file reports on their waste management practices.

I have reluctantly accepted samples from drug sales reps. on a handful of occasions for specifically identified patients (not just to stock my office cupboards), but drug reps. have repeatedly offered me samples. I have also received samples of cleaning products in my mailbox, cans of Pepsi Next® at my front door, and bottles of shampoo and conditioner (and cute cans of Red Bull® Energy Drinks) at Union Station in Toronto, a favourite locale for marketing activities, as well as for more altruistic soliciting of charitable donations. These marketing devices are obviously intended to introduce the consumer to new products and, ultimately to increase sales.

“The Gift of Drug Samples” in the health care industry is no different from “free” samples for other consumer products – they are marketing wares - and doctors and the CPSO should stop deluding themselves, in the face of mounting evidence of samples’ detrimental effects. Samples function as “loss leaders” for pharmaceutical companies and provide a “foot in the door” for drug sales reps., giving them almost unfettered access to the gatekeepers of health care, physicians. Drug sample “gift-giving creates moral ties or generosity, respect, and honor that constitute an ingenious

76 Ibid.
77 Ibid.
79 Supra, note 19.
80 Supra, note 61.
psychological marketing scheme... Sampling exploits physicians’ altruistic impulses, and on the surface, the benefit seems to redound to the patient.”^{81} Samples represent an unlimited “gift” that doctors can accept, in good conscience, but one that comes with strings attached, for all stakeholders – physicians, their patients, the public, the health care system and the regulators.

Stanford University took a bold and ethical stance towards gifts and samples over 7.5 years ago, when it banned physicians from accepting gifts from industry. Stanford’s policy^{82} states “**Free drug samples are considered gifts** under this policy and may not be accepted anywhere at the Stanford School of Medicine, Stanford Hospital and Clinics, … or at [any affiliated clinical facilities].” (Emphasis added).

### 2. Continuing Medical Education/Continuing Professional Development (CME/CPD)

Fact: The pharmaceutical industry sponsors more than 300,000 educational events annually in the U.S. alone, and 10,000 in Australia.^{83} CME is “dominated by industry funding, a fact apparently accepted by the many physicians who participate.”^{84} However, I have been increasingly troubled by my experiences at CME events since completing my psychiatry training. During my residency, at the Clarke and at other academic training sites of the U. of T., a cornucopia of psychiatry, psychotherapy and psychopharmacology topics were presented at seminars, workshops and rounds. But a gradual, almost imperceptible shift in content occurred – to a monoculture of psychopharmacology, especially, novel drugs. I cannot pinpoint when this shift occurred, but I know it happened.

I have given only two talks sponsored by a pharmaceutical company – one during my residency and one approximately ten years ago – because the conflict of interest they fostered were discomfiting. On the first occasion, the drug sales representative gave me a “canned” talk, i.e., a full set of overhead transparencies from which I was to deliver the lecture.^{85} I cannot recall whether I received compensation for my time, but, as it was early in my career, the experience of presenting and adding the lecture to my resume (without realizing it had been promotional) might have provided sufficient recompense.

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^{81} *Supra*, note 81.

^{82} *Supra*, note 15.


^{85} *Supra*, note 87. “To reduce the chance of speakers saying anything that might be construed as off-label marketing, which could become fodder for lawsuits, sponsoring companies provide PowerPoint slides …”
The second talk was sponsored by Lilly, the manufacturer of Zyprexa (olanzapine). Because the drug sales rep. was in attendance, I felt compelled to mention olanzapine, which I did once or twice, even though the subject of the rounds was utilizing a nurse practitioner for managing seriously ill patients in a community psychiatry setting. I received an honorarium of $1000 for the talk which I shared with my two co-presenters – a family physician and a nurse practitioner. The drug sales rep. did not invite me to give another talk for Lilly, perhaps because I had not mentioned its product by its trade or even by its generic name a sufficient number of times.

However, what struck me at the time was the subtle pressure I felt – that I needed to reciprocate by saying the name of the drug as compensation for the promised payment. I am sure that I am not unique in having experienced such a feeling of obligation similar to that described by Katz et al in the context of nonmonetary gifts. Drug sales reps. continue to attend various teaching rounds at hospitals around Ontario and I wonder whether the talk is subtly (or not so subtly) altered by their presence, as the following anecdote illustrates.

My husband, who is a surgeon, and I attended a Primary Care Update a few years ago in London, Ontario where we attended a lecture by a dermatologist from an academic teaching centre. My husband counted that the speaker mentioned the name of a particular drug 19 times during a talk of less than an hour’s duration. When my husband asked her whether there were any other drugs for the condition, other than the one she had mentioned 19 times, the speaker did not have a response. A roving facilitator quickly took away the microphone, presumably before my husband could further expose this “expert” by highlighting her lack of objectivity.

The room was packed with hundreds of doctors, who were being not so subtly influenced by this “key opinion leader” or “thought leader.” She may have felt a subconscious pressure or perhaps she was even directed by the pharmaceutical company to mention the drug’s name repeatedly to ensure it remained in doctors’ minds – and found expression on their prescription pads - long after the conference had ended. (The latter explanation is much more plausible as the speaker was likely being paid a significant sum, given the venue and the captive audience). The drug’s name has certainly been etched in my brain.

However, the most intrusive examples of the pharmaceutical industry’s influence occurs at large scale conferences, such as the recent Canadian Psychiatric Association Annual Meeting, held in Ottawa in September 2013. I had not attended the CPA Annual Meeting since I had completed my residency, so I was eagerly anticipating the opportunity to be updated, especially since the new DSM-5 has recently been released. At lunch, “big name speakers” or in the industry jargon, “key opinion leaders” were lecturing in the largest ballroom. In order to be granted entry, I had to present a ticket

86 Supra, note 19.
which entitled me to a boxed sandwich lunch; which, in fact, one might describe as “modest.”

Of course, one’s natural inclination is to sit down to eat the meal with one’s colleagues. However, rather than a collegial conversation with one’s peers, the corralled audience is inundated with pharmaceutical marketing promotion in the guise of education. I repeatedly see the same “stable of paid speakers” speak at the same industry-sponsored talks at the same psychiatric and family medicine conferences, promoting the latest products. While I used to listen to the talk at face value and be impressed with the credentials of the “expert” speakers, I now see the whole exercise as a marketing extravaganza. I wonder how many of the hundreds of audience members would attend without the carrot of a free lunch, and compare it to the paltry attendance (a handful to maybe 100 people) at the other lectures, workshops and symposia which are not “served with a meal.”

Again, Stanford University has taken the lead in this regard in its policy in two ways: the university requires industry-sponsored speakers, not merely to flash a slide of so called “disclosures,” but to “disclose at the beginning and end of the talk that he or she is being paid by the company for giving the talk.” Flasing a slide enumerating a long list of companies and claiming this is “disclosure” is an insufficient declaration of one’s conflict of interest. First, it can be missed by an attendee if (s)he blinks or turns away, as it is not often read aloud by the speaker. As well, it does not allow the viewer to decide with full information if the remuneration was reasonable, i.e., is the fee comparable to what a physician might bill under provincial health plans? Or does it translate to an exorbitant hourly rate commensurate with the expected marketing outcomes that will accrue to the company as a result of the “eductizing”? Another important fact that should be disclosed is the name of drug company which is paying the speaker for that particular talk. The main products of the company should also be clearly listed, so that audience members can determine whether the speaker is placing disproportionate emphasis on these drugs.

Whether the speaker has been paid, the amount (s)he and the drug that the company manufactures should also be disclosed on the conference website, in any written “educational” materials provided by the company and on the CPSO’s website, so that at any time, the information can be reviewed and the physician’s credibility can be assessed. This is what the U.S. Physician Payment Sunshine Act aspires to do.

Sergio Sismondo of Queen’s University makes a key point, that is, “the larger payments … that pharmaceutical and medical device companies make to physicians are primarily intended not to affect their prescriptions, but rather to purchase their influence

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87 Supra, note 8.
89 Supra, note 15.
90 A neologism which I have coined, using the words “Education” + “advertizing” = “eductizing,” cf. advertorial
on other physicians.”91 U.S. litigation has revealed that hundreds of physicians receive more that $100,000 annually and that many more are paid more than $10,000 for being “key opinion leaders, i.e., “to influence others and lead professional opinion in the directions that the companies prefer.”92

An academic psychiatrist from Harvard University provides a particularly egregious example of a “key opinion leader” who has now been discredited for foisting the “diagnosis” of “childhood bipolar disorder” on gullible physicians while he failed to disclose income of over $U.S.1,000,000 from pharmaceutical companies.93 In a disingenuous letter of apology to Harvard, he claims his error resulted from an “honest mistake.”94 It is beyond belief that a researcher of his stature would not be cognizant of his obligation to disclose such a large sum of money.

Sismondo argues that the pharmaceutical industry, through co-option of physicians and researchers as “key opinion leaders,” has systematically changed the character of the medical profession. This “institutional corruption” has occurred because “a small number of companies with well-defined and narrow interests have inordinate influences over how medical knowledge is produced, circulated and finally used by physicians to make decisions concerning their patients.”95

The evidence-based restrictions for inclusion in the Draft Policy for which this paper advocates are based on almost 65 years of research. However, they will likely be met with resistance from doctors and perhaps other health professionals who are now being courted by industry sales reps. In fact, “psychology research suggests any imposed restrictions on physicians’ professional behavior are likely to be ill received and viewed as an affront to their personal integrity and professional freedom.”96

As one physician who “serves on the lecture boards of Wyeth Pharmaceuticals and Forest Pharmaceuticals” claimed in a letter to the Editor of JAMA, “[p]hysicians have been receiving these minor gifts for decades and our delivery of care continues to be ethical and superior. The gifts provide a little fun …”97 His self-serving comments (and the speaker fees he likely receives) only emphasize the blinders he wears. Doctors must ask themselves whether they “aspire to be viewed more like corporate salespeople or like

91 Supra, note 32.
92 Ibid.
94 Ibid.
95 Supra, note 32.
96 Supra, note 19.
97 Supra, note 57.
Doctors’ self-governing regulator, the CPSO, acting from an evidence-based framework, must “do the thing it thinks it cannot do.”99 It must “stop hiding its head in the sand” and implement stricter policy on physician industry relations. Otherwise, it will only be a matter of time before Ontario physicians’ privilege of self-regulation in the matter of physician-industry relations is removed and we get our own “Physician Payments Sunshine Act.”

Appendix – Recommendations

1. The Introduction to the Draft Policy (ll. 24-26) states that “the expectations set out in this policy are grounded in the principles of medical professionalism set out in the Practice Guide and are based on the best available evidence relating to physician-industry interactions.” However, the only section of the Draft Policy which footnotes the academic literature is the section dealing with Industry Gifts.

   - All sections should be supported by references if the CPSO wants the document to be credible, rather than viewed as arbitrary pronouncements from a regulatory body, especially if significant changes are contemplated, e.g., elimination of industry gifts and samples.

2. The CPSO policy should, in a similar manner to Stanford University’s policy,100 direct physicians to other relevant guidelines, by adding a sentence at l. 27 as follows:

   “Individuals should be aware of other applicable policies, such as the CMA Policy on Guidelines for Physicians in Interactions with Industry,101 the R&D Code of Ethical Practices102 [Note: this document provides the pharmaceutical industry’s perspective], and that of any universities, hospitals, specialty boards with which the physician may be associated.”

3. The CPSO website also states that the “Council of the College has adopted the CMA Guidelines on the Relationship between Physicians and the Pharmaceutical Industry as College policy.”103

   - Add the date on which the CPSO adopted the policy. However, this CMA document, for which the link is provided, is the 2001 CMA update of the original

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98 Supra, note 19.
99 Supra, note 19.
100 Ibid.
101 Supra, note 5.
103 CPSO Website
1992 policy. The link should be to the 2007 policy which is entitled “Guidelines for Physicians in Interactions with Industry”\textsuperscript{104} which clearly broadens the scope to include other health care industries, not merely pharmaceutical companies. (If the CPSO Council needs to adopt the new version officially, then it should do so at its earliest opportunity.)

4. \textit{At line 89}, the Draft Policy should be explicit about qualifies as “gifts or inducements,” by providing specific examples. Does a pen qualify? Does a trip to Vail to learn about musculoskeletal reconstructive procedures in which travel expenses, accommodation at a five-star resort, and some meals paid for by a surgical device company qualify?

5. \textit{At line 93}, the Draft Policy should specify what a “fee or equivalent consideration” means. Does this mean that the physician should not go out for lunch or dinner with drug or device reps. so that they can promote (detail) their products? Is accepting a meal and entertainment at an upscale restaurant after a day at a large conference appropriate?

6. \textit{At lines 112-114}, the Draft Policy exhorts physicians to “ensure that they critically evaluate any information provided by industry representatives and do not solely rely on this information when making clinical decisions regarding patient care.”

- \textit{Add a “black box” warning at ll. 112, as follows:}

\textbf{Physicians should be aware that information provided by pharmaceutical sales representatives, may contain biased content, omit safety information\textsuperscript{105}, be overly positive\textsuperscript{106}, and may promote off-label uses.\textsuperscript{107}} For these reasons, physicians must critically evaluate any information provided by industry sales representatives and must not rely solely on such information when making clinical and patient-care decisions. Where industry sales representative are providing information about products or services, physicians must not accept meals for themselves or their staff.

7. The CPSO has an opportunity to take a leadership role in Canadian health professional regulation by completely entirely eliminating sample acceptance by physicians.

- \textit{Modify lines 122-124, as follows:} In the past, industry representatives provided physicians with drug samples (clinical evaluation packages). Physicians are no longer permitted to accept such drug samples, unless they are for a particular patient who qualifies for a special access program. In such an instance, physicians must comply with the expectations set out in the \textit{Prescribing Drugs} policy.

\textsuperscript{104} http://policybase.cma.ca/dbtw-wpd/Policypdf/PD08-01.pdf
\textsuperscript{105} \textit{Supra}, note 25.
\textsuperscript{106}
\textsuperscript{107}
If the CPSO does not wish to act on the evidence (noted above about the numerous detrimental effects of sample medications) at least

- *the following sentences should be added at line 124,* However, physicians should not accept samples for their personal or their family’s use, nor for use by their employees. Physicians should also not distribute samples to children.