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Original article

Patients with "dates": Wrong for doctors but acceptable for drug companies?

Pacientes con citas: ¿Es incorrecto para los médicos pero aceptable para las compañías farmacéuticas?

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Abstract

Direct interaction between pharmaceutical representatives and consumers is an issue that is still under-researched. In fact, the underlying ethical issues are completely absent from the radar of regulators. However, this type of communication without a mediating interface (such as a TV broadcaster or an electronic platform) or an intermediary (healthcare professionals) provides a space where consumers are highly exposed to industry influences. While the putative aim of those activities is to educate patients about their health condition, the management of their symptoms and the available treatments, the industry is seeking to replace the traditional role of health professionals. A case study, involving face-to-face interactions, allows a better understanding and provides clarifications to show that it is not the industry's role to provide

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health information to consumers. Mechanisms are suggested to support government agencies in ethically regulating this practice.

Keywords: Conflicts of interest; Direct-to-consumer advertisement; Health information; Pharmaceutical marketing; Patient education

Resumen

Las interacciones directas entre los representantes farmacéuticos y los consumidores es un problema que todavía está infrainvestigado. De hecho, las cuestiones éticas subyacentes están completamente ausentes del radar de los reguladores. Sin embargo, este tipo de comunicación sin una interfaz mediadora (como una emisora de televisión o una plataforma electrónica) o un intermediario (profesionales sanitarios) proporciona un espacio donde los consumidores están muy expuestos a las influencias de la industria. Si bien el objetivo putativo de estas actividades es educar a los pacientes sobre su estado de salud, el manejo de sus síntomas y los tratamientos disponibles, la industria está tratando de reemplazar el papel tradicional de los profesionales de la salud. Un estudio de caso, que implica interacciones cara a cara, permite comprender mejor y proporcionar aclaraciones sobre por qué no es el papel de la industria proporcionar información de salud a los consumidores. Se sugieren mecanismos para apoyar a los organismos gubernamentales en la regulación ética de esta práctica.

Palabras clave: Conflictos de intereses; Anuncio directo al consumidor; Información de salud; Marketing farmacéutico; Educación del paciente

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Introduction

"Over the past year I've received five or six such invitations. . . In addition to dinner, the format includes a talk with a Q&A by a local neurologist, who I assume is being paid by the drug company to participate in the event" (Richardson, 2015).

Would you like to be invited on an appointment with a pharmaceutical representative? The appointment would likely focus on your disease, involve other patients and

industry key opinion leaders, and could lead to more if there is chemistry between you and a certain drug. Would you prefer that such a date take place at a fast food chain or at a fancy restaurant? Would you like to hear more about the drug you are taking or maybe about other alternative treatments for your disease?

These are some of the questions that Jennifer Richardson, a multiple sclerosis (MS) patient presents in an article detailing her experiences with a patient support program offered by the company that produces her MS drug (Richardson, 2015). Richardson uses the word "date" to describe the invitations that pharmaceutical companies send to current or prospective patients who already or might soon use their drugs. The purpose of the invitation is clear: "while couched in the language of general outreach to MS patients, the presumed outcome is to get more people signed up to take [their drug]" (Richardson, 2015). Richardson's use of a dating metaphor raises interesting questions about the relationships that a pharmaceutical company can or should develop with its customers, and whether and how such practices should be regulated.

In this article, I analyze such ethical issues and suggest a means to monitor and supervise direct interactions between pharmaceutical companies and patients. I recommend that national governments mandate transparency regarding pharmaceutical commercial interests and launch national organizations and programs to cultivate and regulate patient education activities regarding pharmaceutical products so that patients can make more informed choices to manage their health and well-being. Further, these organizations and programs should be protected from industry interests to ensure that patients have access to credible and validated information and support.

The problem

Pharmaceutical industry codes of ethics focus primarily on industry relationships with healthcare professionals (PhRMA, 2009) and patient organizations (PhRMA, 2012). There is no guidance addressing the relationships that industry representatives have with individual patients.

As in Richardson's experience, industry sponsored events for patients tend to focus on the presentation of the merits of a specific drug. In discussions over a meal paid for by the company, pharmaceutical representatives tell patients and their relatives about the benefits of their company's drugs (Richardson, 2015). A medi-

cal specialist uses "a drug company-scripted PowerPoint presentation [that] anyone could have given," thereby making it clear that he is restricting himself to the content that has been pre-approved by the company. Afterwards, a company spokesperson presents how she manages her own medical condition using the company's medication (Richardson, 2015). The event is also an opportunity for company representatives to directly interact with prospective customers.

From the development of a drug to its use by patients, responsibilities are fragmented and shared between the various actors involved. Research, development and marketing are the responsibility of companies; evaluation, approval and surveillance of drugs are the responsibility of government; and prescribing and monitoring are the responsibility of health care provider (Bélisle-Pipon, 2013). Personal interactions are largely restricted to provider-patient relationships. Companies do communicate with patients via different advertising and promotional activities, but these are most often not specific to individuals. This raises an important question: do drug companies have a social duty (and legitimacy) to directly inform and educate patients?

In every industrialized country except the United States and New Zealand, direct-to-consumer advertising is restricted and even prohibited due to concerns about the negative consequences of industry influence on patient and health care provider behavior (e.g., disease-mongering, over-prescription). Even regulated direct-to-consumer information (DTCI) activities — informational messages disseminated through media such as TV spots, websites, brochures, or newspapers — can be a source of concern (Bélisle-Pipon & Williams-Jones, 2015b). DTCI, in most jurisdictions around the world, may not be transparent about the source of the informational message, i.e., that it is coming from a corporate sponsor rather than a government public health agency, thus obscuring the potential commercial interests underlying the message. Commercial messages that raise awareness about a particular health condition aim to familiarize the public with a condition or drug and thus influence subsequent treatment-seeking behavior (Bélisle-Pipon & Williams-Jones, 2015a). This drug familiarization effect can then trigger therapeutic misconceptions among patients. "Therapeutic misconception" is a concept taken from research ethics where patients misinterpret the dual role of their physician during clinical trials: as clinicians, they are trying to improve their patients' health, as researchers they seek to produce generalizable knowledge which will not necessarily benefits their current patients. Reapplying the concept to DTCI (Bélisle-Pipon & Williams-Jones, 2015a), patients' familiarization with a certain drug may lead to them having misconceptions about disease incidence and the risks/benefits of drugs, while also having legitimate

desires to find appropriate treatments for conditions to which they have become sensitized through DTCI.

Whether the companies have good or bad intentions and whether or not patients are aware of the underlying commercial interests, there is a risk for conflicts of interest that "may exploit the vulnerability of the patient. . .and ultimately may be detrimental to the patient's well-being" (AMA, 2014). Nonetheless, patients may suspect that their participation is being instrumentalized by pharmaceutical companies in order to drive the sale of the drug; and so as Richardson's reflection shows, there is a major problem, both in terms of the perceptions that patients may have about "dates", as well as aim of the companies organizing these the "dates" (Richardson, 2015).

The solution

Self-Regulation

Considering that conflicts of interest linked to the pharmaceutical industry are already controversial (e.g., paid scientific expert panels and gifts to physicians) and have undermined the industry's reputation (Lexchin, 2016; Rodwin, 2019), it is all the more important for companies to demonstrate responsible behavior. This requires self-regulation to limit direct encounters with patients, either by pharmaceutical companies themselves or by their national associations (e.g., PhRMA in the USA, Innovative Medicines Canada, LEEM in France). In being proactive, the industry would place itself on the moral high ground by demonstrating the capacity for "policing its own members to ensure they abide by the guidelines that govern their behaviors", while also avoiding the threat of more stringent government regulation (Katsanis, 2016, p. 129).

However, in certain circumstances, self-regulation will be helpful but may not be sufficient. In situations where they are in a position of being both judge and judged without the recourse of an impartial third-party (as in the case with "dates"), then self-regulation is clearly insufficient. It is expected that the industry will behave in a responsible matter and police its own practices, but the establishment of guidelines and rules must come from an authority that is not in a conflict of interest (i.e., having the opportunity to turn an activity into increased products sales).

Government regulation

Company "dates" with patients must also be regulated by the government, as are encounters between health care providers and patients. Government regulation could ensure that no adverse event, therapeutic misconception or undue influence resulting from direct patient-company interaction unjustifiably affects patients.

Mandating transparency

In the case of "dates" between companies and patients, it is important that the commercial sponsor's identity be transparent rather than hidden behind the smokescreen of supposedly independent patient-interest groups (Bruno & Rose, 2019; Lee, McGlynn, & Safran, 2019; Lexchin, 2019). Disclosing the financial and organizational links between patient-oriented events and the companies that sponsor them is one way to make evident the potential conflicts of interest, so that patients (and others) are able to more critically evaluate the medical information they receive and make better informed decisions. In fact, mandatory transparency is becoming an increasingly common way to minimize potential biases related to financial conflicts of interest (Institute of Medicine, 2009). The US Physician Payments Sunshine Act, for example, requires that companies publicly disclose annual payments and gifts to physicians and teaching hospitals starting with as little as $10. However, an annual declaration alone is insufficient to eliminate bias; without other mechanisms, transparency can simply have the effect of shifting "the problem from one of 'secrecy of bias' to 'openness of bias'" (Krimsky, 2010, p. 89).

Although there is intense scrutiny into manufacturer-physician relationships and corporate sponsorships, there are no equivalent initiatives to the Sunshine Act to deal with industry-patient relationships. It stands to reason that as for medical education, transparency should be compulsory for the financing and facilitation of educational and informational activities directly targeting patients. Without such transparency, it is not possible to even assess the magnitude and the scope of commercial influences over patients-oriented activities.

Regulating patient medical education

To ensure that patient medical education (PME) is independent from — and thus not influenced by — commercial interests, national governments would have to pass legislation allowing agencies such as Health Canada and the FDA to regulate

PME activities. These agencies could then delegate responsibility to independent non-governmental organizations (NGOs) that set standards, and review and license industry sponsored patient education activities. But these para-public organisations would need stable and adequate funding if they are to avoid corporate capture (Bélisle-Pipon & Williams-Jones, 2016).

Licensing patient medical education

For such NGOs to be publicly credible entities, they must also be sufficiently independent from government in order to be insulated from political disputes (e.g., changes in government) and economic turmoil (e.g., budget cutting in the context of deficits). Further, to carry out their role of licensing and surveillance, they must ensure the inclusion of a plurality of perspectives — i.e., diverse publics, with no focus on industry interests — in their development of sound and relevant standards that are based on the best available evidence regarding patient needs (and socio–cultural contexts). The governance structures of these NGOs should include as members a variety of stakeholders, notably health administrators, healthcare professionals, researchers (e.g., in health policy, the social sciences, bioethics), and patients. To participate, members must be clearly independent from both industry and government, and this requires robust conflict of interest policies and procedures to ensure that any interests (e.g., individual, institutional, political and financial) do not take precedence over the provision of trustworthy and independent information and education for patients.

In their operation and assessment of PME, the NGOs would need to take into account specific socio–cultural contexts, including the environment in which the PMEs occur (e.g., differences in healthcare systems, DCTI regulation, availability and costs of treatments). Further, in a context of globalized access to drug information made possible by the Internet, some form of international harmonization of PME standards is warranted to ensure that there are no extreme differences from one jurisdiction to another (i.e., coordinated licensing of international activities or those offered simultaneously in several jurisdictions).

In terms of functioning, the national NGOs would independently assess the content and structure of PME programs to ensure that they will achieve clear educational objectives. Organizations such as pharmaceutical companies, patient groups, or universities that wish to provide PME activities would need to receive pre-approval (such as in the form of a license) from the applicable national NGO on the basis of established standards and robust surveillance, to ensure that PMEs are not simply another form of industry-funded DTCI. Based on the history and regulatory

experiences of CME activities (Barnes, 2017; Eggertson, 2016), additional attention should be paid when funding comes from industry, or even if there are suspicions as to where the funds may come from; industry interests should not bias educational outcomes. In case of misconduct or breaches of the licensing requirements, organizations should be sanctioned, ranging from reprimand and monetary fines to the temporary or permanent prohibition of delinquent institutions and groups from conducting PME activities.

A PME activity licensing assessment would thus ensure that PME activities: (1) do not advocate for one particular drug; (2) are not a way for companies to diversify their promotional channels (e.g., no overt corporate branding, gifts, one-sided messaging); and (3) are independently provided and evaluated. Regulatory bodies would need to evaluate PME programs on the basis of the stated educational objectives, as well as any contextual factors external to PME activities (e.g., reduced competition in a specific drug marketing environment, increased public sensitivity — receptive or stigmatizing — for a specific condition) that might unduly influence patients. In addition to helping to avoid problematic conflicts of interests, patient participation would have to be voluntary, and not associated with conditional benefits, such as improved access to drugs or reductions in co-payments. Further, the PME's content must be clear and its format not replicate an advertising campaign. So evaluations should ask participants questions such as: did they learn more about their disease? Did they learn more about symptoms management? Were specific treatments presented, and if so, how many? Was there a balanced presentation of benefits and risks? Did participants learn how to improve their global health beyond the medical condition for which they are taking a certain medication, and how to change their lifestyle for health improvement (e.g., by modifying their physical activity, nutrition, stress management, and healthy habits)? Did they receive financial incentives to participate to PME activities? Was the venue adequate for such event? Appropriate answers to these questions would then provide confidence that in the PME, patient-expert encounters are designed to address patient needs and not simply promote one specific drug or a class of drugs. Participant evaluation can contribute to detailing the content and context, far beyond what is described in the official program, and to assist in *a posteriori* evaluations of the relevance, utility and independence of a particular activity. Such evaluation certainly has inherent limitations; however, Richardson's vivid account is exemplary in showing that the perception of participants makes it possible to pinpoint important issues about the validity of such events. Additional mechanisms should also be implemented to periodically assess and monitor organizational practices for PME license renewal.

To ensure that these ethical considerations are taken into account by all national NGOs, it is important that standards are consistent from country to country, much like harmonized standards for clinical trials, which were first implemented in some countries and have subsequently become international. One might even imagine an international authority to facilitate collaboration among national NGOs, so that PME evaluation and regulation standards are optimal and reflect the constant evolution of PME, and also ensure that the NGOs tasked with oversight are credible and have the means to fulfill their mission.

Conclusion

Given the difficulty that many patients face in accessing health information — that they can understand — about the nature of their condition/symptoms and how best to manage them, it is not surprising to see the deployment of new forms of PME. But in this context, it is essential that patients be empowered through access to independent sources of information, and not through unregulated industry-sponsored direct patient interactions. This calls for the restriction of certain forms of promotional practices, specifically all forms of direct interactions. Rather than being invited on "dates", as described by Richardson (2015), that seek to woo patients to use a particular sponsor's drug, patients should be provided with balanced and credible information so that they can make informed decisions about how best to manage their health. In light of the evident conflicts of interest, regulators should acknowledge that pharmaceutical representatives and companies are not the best suited to directly support patients in their decision making. Indeed, regulators should define explicitly — and legally constrain — the nature and scope of PMEs, and then ensure that appropriate independent oversight structures (the aforementioned NGOs) are implemented and funded to conduct PME monitoring and evaluation. Such evaluation should also be mandatory rather than voluntary (a criticism made of current DTCI regulations) and cater to patients' instead of industry interests. All these conditions are necessary to ensure that there is an effective alternative to direct interactions between companies and patients, and that PMEs fulfill their mission of providing information, awareness and empowerment, and prevent drug familiarization and therapeutic misconception that undermine patient autonomy and decision making.

Conflicts of interest

The author has no conflicts of interest to declare.

References

AMA. (2014). *Code of medical ethics of the american medical association.*. Retrieved from http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics.page?

Barnes, B. (2017). Financial conflicts of interest in continuing medical education: Implications and accountability. *JAMA*, *317*(17), 1741–1742. http://dx.doi.org/10.1001/jama.2017.2981

Bélisle-Pipon, J.-C. (2013). *De la binarité au modèle AI3R : La bioéthique écosystémique comme modèle d'analyse normative de l'industrie biopharmaceutique* Master Thesis. Montréal, Québec: Université de Montréal.

Bélisle-Pipon, J.-C., & Williams-Jones, B. (2015a). Drug familiarization and therapeutic misconception via direct-to-consumer information. *Journal of Bioethical Inquiry*, *12*(2), 259–267. http://dx.doi.org/10.1007/s11673-015-9634-8

Bélisle-Pipon, J.-C., & Williams-Jones, B. (2015b). Regulating direct-to-consumer drug information: A case study of eli lilly's canadian 40over40 erectile dysfunction campaign. *Healthcare Policy | Politiques de SantÃ©*, *10*(4), 16–23. http://dx.doi.org/10.12927/hcpol.2015.24209

Bélisle-Pipon, J.-C., & Williams-Jones, B. (2016). Preparing for the arrival of "pink Viagra": Strengthening Canadian direct-to-consumer information regulations. *Canadian Medical Association Journal*, *188*(5), 319–320. http://dx.doi.org/10.1503/cmaj.150705

Bruno, B., & Rose, S. (2019). Patient organizations and conflict of interest. *BMJ*, *364* http://dx.doi.org/10.1136/bmj.l129, 1129

Eggertson, L. (2016). Debate sparked over pharma-funded CME. *Canadian Medical Association Journal*, http://dx.doi.org/10.1503/cmaj.109-5226, cmaj.109-5226

Institute of Medicine. (2009). In B. Lo, & M. J. Field (Eds.), *Conflict of interest in medical research, education, and practice*. Retrieved from http://www.nationalacademies.org/hmd/Reports/2009/Conflict-of-Interest-in-Medical-Research-Education-and-Practice.aspx

Katsanis, L. P. (2016). *Global issues in pharmaceutical marketing*. New York: Routledge.

Krimsky, S. (2010). Combating the funding effect in science: What's beyond transparency? *Stanford Law & Policy Review*, *21*, 101–123.

Lee, T. H., McGlynn, E. A., & Safran, D. G. (2019). A framework for increasing trust between patients and the organizations that care for them. *JAMA*, *321*(6), 539–540. http://dx.doi.org/10.1001/jama.2018.19186

Lexchin, J. (2016). *Private profits versus public policy: The pharmaceutical industry and the Canadian state*. Toronto: University of Toronto Press.

Lexchin, J. (2019). Association between commercial funding of Canadian patient groups and their views about funding of medicines: An observational study. *PloS One*, *14*(2) http://dx.doi.org/10.1371/journal.pone.0212399, e0212399

PhRMA. (2009). *Code on interactions with health care professionals.*. Retrieved from http://www.phrma.org/principles-guidelines/code-on-interactions-with-health-care-professionals

PhRMA. (2012). *PhRMA principles on interactions with patient organizations.*. Retrieved from http://www.phrma.org/sites/default/files/pdf/phrma_principles_paper_20120919_final.pdf

Richardson, J. (2015). Big pharma wants to date me, and other quirks of being sick in America. *The Rumpus.net*, (January). Retrieved from. http://therumpus.net/2015/01/big-pharma-wants-to-date-me-and-other-quirks-of-being-sick-in-america/

Rodwin, M. A. (2019). *Conflict of interest in the pharmaceutical sector: A guide for public management (SSRN scholarly paper No. ID 3317603).*. Retrieved from Social Science Research Network website: https://papers.ssrn.com/abstract=3317603