Physicians-Pharmaceutical Sales Representatives Interactions and Conflict of Interest: Challenges and Solutions

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Avinash R. Patwardhan, MD¹

Abstract

Physician-industry relationships have come a long way since serious debates began after a 1990 Senate Committee on Labor and Human Resources report on the topic. On one side, the Sun Shine Act of 2007, now a part of the Patient Protection and Affordable Care Act that mandates disclosure of payments and gifts to the physicians, has injected more transparency into the relationships, and on the other side, numerous voluntary self-regulation guidelines have been instituted to protect patients. However, despite these commendable efforts, problem persists. Taking the specific case of physician-pharmaceutical sales representative (PSR) interactions, also called as detailing, where the PSRs lobby physicians to prescribe their brand drugs while bringing them gifts on the side, an August 2016 article concluded that gifts as small as \$20 are associated with higher prescribing rates. A close examination reveals the intricacies of the relationships. Though PSRs ultimately want to push their drugs, more than gifts, they also bring the ready-made synthesized knowledge about the drugs, something the busy physicians, starving for time to read the literature themselves, find hard to let go. Conscientious physicians are not unaware of the marketing tactics. And yet, physicians too are humans. It is also the nature of their job that requires an innate cognitive dissonance to be functional in medical practice, a trait that sometimes works against them in case of PSR interactions. Besides, PSRs too follow the dictates of the shareholders of their companies. Therefore, if they try to influence physicians using social psychology, it is a job they are asked to do. The complexity of relationships creates conundrums that are hard to tackle. This commentary examines various dimensions of these relationships. In the end, a few suggestions are offered as a way forward.

Keywords

pharmaceutical sales representative, conflict of interest, gifts to physicians, physician-industry relationships, medical ethics, brand prescriptions, detailing, sun shine act, learned intermediary doctrine, independent physician heuristic

Introduction

Trust is considered to be a key component or a cornerstone while discussing provider-patient relationship.¹⁻⁴ Medical ethics is an imperative in the practice of health care for inculcating professionalism and building trust.⁵ However, providers being humans first, their vulnerability to conflict of interest is well documented in ancient⁶⁻⁸ as well as modern history.⁹

Drugs make a big part of modern therapeutics. Furthermore, drugs have become expensive and pharmaceutical companies stand to gain a lot if more of their brand drugs are sold. For most part, physicians are the agents who write prescriptions. Therefore, it serves pharmaceutical industry to persuade physicians to prescribe their brand drugs preferentially and in high volumes. One of the ways in which industry accomplishes this objective is via one-on-one marketing in the form of physician-pharmaceutical sales representative (PSR) interactions, also called as detailing. In detailing, PSRs try to convince the physicians how their company products are the best and need to be prescribed, although marketing their brand is not the sole objective or purpose of detailing. It is also meant to provide busy physicians up-to-date information about the pros and cons of using the promoted drugs and to keep them abreast with the cutting-edge advances in the field in general. The borderline between genuine recommendation and profitoriented persuasion is thin. Using smart marketing strategies and tactics such as offering gifts, friendship, and flattery, PSRs can influence physicians to prescribe their brand drugs in excess. While legitimate prescriptions are necessary and help patients, the profit incentives create an opportunity for

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Corresponding Author:

Avinash R. Patwardhan, Department of Global and Community Health, George Mason University, 4400 University Drive, Fairfax, VA 22030, USA. Email: apatward@gmu.edu

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¹George Mason University, Fairfax, VA, USA

misuse and conflict of interest leading to violation of medical ethics on the part of the physicians.

Lately, physician-pharmaceutical industry relationships have come under great scrutiny. While the old reasons for concern such as increased vulnerability to side effects and potential for being subjected to unnecessary ineffective treatment are still valid, what appears to be strongly driving the recent enhanced interest in the topic are the economic factors. In 2012 alone, pharmaceutical industry spent \$89.5 billion on detailing, accounting for 60% of the global sales and marketing spending.¹⁰ It is known that the brand prescriptions add to the cost of care, mostly at no added value.¹¹ When the increasing health care cost is becoming a global concern,¹² it is natural that the stakeholders would scrutinize physician-industry relationships related to excessive prescribing. Another cost-related factor could be an increase in the litigations due to adverse drug events following an increase in the brand or off label prescriptions. For example, between 2009 and 2010, 8 cases involving issues of drug safety were settled for \$8.6 billion.¹³

Following excesses in prescribing in 1980s, a report of the 1990 Senate Committee on Labor and Human Resources set forth the discussions, debates, and actions on this issue.¹⁴ However, as Mulinari says, there also appears to be cyclicality in the phenomenon.¹⁵ For example, in 2003, Katz et al mentioned that gifts of negligible value can influence the behavior of the recipient.¹⁴ Almost 13 years later, the same sentiment is echoed in an August 2016 article.¹⁶ In 2016 alone, there is a volley of articles on the topic of industry-sponsored gifts/payments and their impact on the prescribing patterns of the physicians, bringing perspectives from diverse fields such as public health, epidemiology, health policy, regulation, law, and from diverse geographies like Ethiopia and Pakistan.¹⁵⁻²⁴

As a caveat, it is noted here that other health professionals such as doctors of pharmacy, physician assistants, and nurse practitioners also carry prescribing authority. Although 2 publications from 2016, included in the citations, address the issues related to nonphysicians, data about them are currently inadequate. Therefore, for the sake of convenience, the article has used the word physician(s) throughout the narrative as the representative of the health professionals with prescribing authority. Similarly, though the physician-industry relationships are spread over diverse domains of activities ranging from big research projects involving a lot of money to small face-to-face interactions between an individual physician and a PSR, involving small token gifts such as sponsoring of meals, again for the sake of convenience and focus, the latter is treated as the topic of discussion.

Attempts have been made to mitigate this challenge using different approaches. Numerous self-regulatory initiatives such as American Medical Association (1990) guidelines for gifts to physicians from industry, or "Pharmaceutical Research & Manufacturers of America" (2002) guidelines for ethical conduct of sales representatives have been

instituted.²⁵ Academic Medical Centers are increasingly restricting PSR access to their physicians.^{10,26} On the legal front, between 1993 and 2005, several US states adapted laws for transparency and disclosure of industry payments to physicians.²⁷ In addition, the 2007 Sunshine Act that required pharmaceutical and medical device makers to collect, track, and report financial relationships with physicians and teaching hospitals is now a part of the 2010 Patient Protection and Affordable Care Act in the United States.¹⁵ Furthermore, US Food and Drug Administration keeps a watch on the conduct of the industry using whistle-blower incentives.²⁸ Europe, Canada, and Australia have been equally engaged in addressing this issue, and in those countries equivalent self-regulatory and legislative regulatory checks and balances are in place.¹⁵ In emerging economies like India and China, however, the landscape appears to be murky.29

What stands out in this, about quarter of a century-long story regarding the conflict of interest generated by physician-industry financial relationships and the attempts to mitigate it, is that the problem still persists. Despite efforts to dissuade or restrict physician-PSR encounters that are accompanied by gifts to physicians, data show that these interactions are known. A study based on 2013 Medicare data found that 2% to 12% physicians received payments in the form of sponsored meals related to promotion of the target drugs.¹⁶ Two studies in Germany that sampled different groups of physicians in 2010 showed that 77% to 84% of the physicians saw PSRs at least once a week and they accepted gifts.^{30,31}

The physician-industry relationships, even if laden with the conflict of interest, cannot be simply wished away. There are arguments that these interactions add value and are good for the patients.^{32,33} Moreover, the law itself cannot eliminate physician-industry relationships due to the first amendment issue of freedom of commercial speech.²² In the current scenario, small gifts to physicians are allowed. One may think that reducing the limit on the gift amount still further might work, and there have been proposals for a total ban on the gifts.^{25,26,34} However, the issue appears to be nuanced. Though very small amounts of gift can sway the prescriber patterns of practice,^{14,16} it is not clear where the de minimis is or whether a total ban will work at all.¹⁴

The question is what more can be done? Is there a definitive doable solution? The best way forward might be to understand the perceptions, attitudes, and environments of the prescribers and the marketing strategies of the PSRs. In addition, the circumstances that create catch-22 situations will need a close examination. It is also important to become aware of the rapidly changing landscape of medical science and technology and that of the drug discovery. Without knowing these, optimum viable solutions might prove elusive. The article will take a high-level overview of these topics and then conclude by offering a few comments on the future directions.

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Prescribing Physicians: Perceptions and Attitudes

Studies related to the perception and attitudes of the physicians show that mostly physicians deny that they get influenced by the promotional pitches of the PSRs,^{32,35,36} although there is evidence that physicians admit that they get influenced.^{21,31} Paradoxically, many physicians believe that their peers get influenced by the marketing though they themselves are immune to it.^{30,37} Notwithstanding, studies have shown that many physicians are unable to discern between promotional evidence and scientific evidence.^{38,39} Social psychology theories have tried to explain this phenomenon.³³ Sah and Fugh-Berman have nicely elucidated how physicians easily believe biased information and suffer from cognitive dissonance, self-serving biases, and a sense of entitlement.⁴⁰

PSRs Use Social Psychology Techniques in Their Marketing Strategies

Behind a PSR trying to influence a physician's prescribing pattern stands a huge industry that he or she serves and represents. Complex analyses and planning in the backend precede the PSR-physician meetings. These include details such as the expected role practice, physician's broad background, or time management.¹⁰ During the meetings, PSRs usually resorts to adaptive selling behavior and alter and adjust the sales behaviors based on the perceived nature of the situation.⁴¹ Principles of reciprocation, commitment, social proof, liking, authority, and scarcity, as delineated in social and psychological sciences, are routinely used by the PSRs to influence the minds of physicians at subconscious level.^{40,42,43} Fugh-Berman and Ahari in their article conclude that "physicians are susceptible to influence because they are overworked, overwhelmed . . . and feel underappreciated . . . bearing food and gifts, drug reps provide respite and sympathy . . . "³⁷ Katz et al remark that food flattery and friendship are powerful tools of persuasion, more so when they are combined.¹⁴ However, providing respite and sympathy is only half of the job. Studies show that PSRs downplay the information about safety and side effects and exaggerate benefits regarding their products.^{43,44} The 2-pronged strategy brings about the desired effects.

Paradoxes and Dilemmas

Physicians and Cognitive Dissonance

On a closer look, it appears that cognitive dissonance is a necessary, inevitable, and unavoidable part of a physician's persona. Absence of cognitive dissonance can overwhelm a physician and make the practice of clinical medicine impossible. Probably in recognition of this paradoxical anomaly, courts have consistently applied the "learned intermediary doctrine" and used the "independent physician heuristic" in the trials involving pharmaceutical litigations.⁴⁵ Therefore, education and awareness can assuage the problem, but a residue of dissonance will always remain.

Pharmaceutical Sales Representatives

It is impossible to totally delegitimize the profit-driven business strategies, tactics, and maneuvering of the pharmaceutical industries unless the government owns the industries. Such a socialistic solution is a far cry, but the argument elucidates the daunting nature of the challenge of regulating the pharmaceutical marketing. If the industry uses social psychology to manipulate physicians, then that is what its shareholders' dictated job is. Managers are paid to think creatively to increase business.¹⁰ It is conceivable that if a zero-dollar limit on the gifts is imposed,²⁶ the industry might start offering goodwill gesture free services instead to the physicians in their daily personal lives. As Katz et al wistfully suggest, industry will find out a way to go around the law.¹⁴

Changing Landscape of Pharmaceutical and Health care Field

Discussions about the conflict of interest concerning prescribers do not highlight adequately the dramatic changes in the field of health sciences and technologies. The days of blockbuster drugs are over.⁴⁶ Specialty drugs and personalized medicine domains are already highly monitored and regulated. One wonders if the current topic might lose relevance in 25 years in the futuristic world of telemedicine and medical robotics.

Future Directions

It seems that it is practically impossible to eliminate altogether the conflict of interest in health care. It is also uncertain if public disclosure of physician-industry relationships data in itself will make a major difference in the outcomes, though morally it is the right thing to do. It is suggested that more attention should be given to understanding those problems of the physicians where PSRs are adding value, albeit in exchange of favors. Probably the mid-career physicians suffer the most. They are in scarcity of ready-made up-to-date current usable information. They are neither fresh from the academy to know it all, nor well settled in practice yet to afford the luxury of time to acquire knowledge on their own. A popular article calls doctors as cheap dates for the industry because they get influenced with even small gifts.⁴⁷ Reality might be subtler. The castigated gift might be the face of the currently undetected issues that bother physicians. While the other measures might be pursued enthusiastically, the best approach today seems to be, as Grande suggests, having

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public-funded academic detailing programs to replace industry-driven detailing.²⁵

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References

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- 1. Thom DH, Kravitz RL, Bell RA, Krupat E, Azari R. Patient trust in the physician: relationship to patient requests. *Fam Pract*. 2002;19:476-483.
- Gille F, Smith S, Mays N. Why public trust in health care systems matters and deserves greater research attention. *J Health Serv Res Policy*. 2015;20(1):62-64.
- 3. Mechanic D. Changing medical organization and the erosion of trust. *Milbank Q.* 1996;74:171-189.
- Rowe R, Calnan M. Trust relations in health care—the new agenda. Eur J Public Health. 2006;16:4-6.
- Carrese JA, Malek J, Watson K, et al. The essential role of medical ethics education in achieving professionalism: the Romanell Report. *Acad Med.* 2015;90(6):744-752.
- Hulkower R. The history of the Hippocratic Oath: outdated, inauthentic, and yet still relevant. *Einstein J Biol Med*. 2016;25(1):41-44.
- Jayasundar R. Healthcare the Ayurvedic way. *Indian J Med Ethics*. 2012;9(3):177-179.
- Fu-Chang D. Ancient Chinese medical ethics and the four principles of biomedical ethics. *J Med Ethics*. 1999;25:315-321.
- 9. Shaw B. *The Doctor's Dilemma: A Tragedy*. Baltimore, MD: Penguin Books; 1954.
- Chressanthis GA, Sfekas A, Khedkar P, Jain N, Poddar P. Determinants of pharmaceutical sales representative access limits to physicians [published online ahead of print April 29, 2015]. *J Med Mark*. doi:10.1177/1745790415583866.
- Jackevicius CA, Chou MM, Ross JS, Shah ND, Krumholz HM. Generic atorvastatin and health care costs. *N Engl J Med*. 2012;366(3):201-204.
- Keehan SP, Cuckler GA, Sisko AM, et al. National health expenditure projections, 2014-24: spending growth faster than recent trends. *Health Aff (Millwood)*. 2015;34(8):1407-1417.
- KPMG International. "Rising costs of litigation in pharmaceuticals industry." *Issues Monitor-Pharmaceuticals*. 2011;9(14):1-3. https://www.kpmg.com/Global/en/IssuesAndInsights/Articles Publications/Issues-monitor-pharmaceuticals/Documents/issuesmonitor-pharmaceuticals-june-2011.pdf (accessed August 12, 2016).

- Katz D, Caplan AL, Merz JF. All gifts large and small: toward an understanding of the ethics of pharmaceutical industry giftgiving. *Am J Bioeth*. 2010;10(10):11-17.
- Mulinari S. Unhealthy marketing of pharmaceutical products: an international public health concern. *J Public Health Policy*. 2016;37(2):149-159.
- DeJong C, Aguilar T, Tseng CW, Lin GA, Boscardin WJ, Dudley RA. Pharmaceutical industry–sponsored meals and physician prescribing patterns for Medicare beneficiaries. *JAMA Intern Med.* 2016;176(8):1114.
- Yeh JS, Franklin JM, Avorn J, Landon J, Kesselheim AS. Association of industry payments to physicians with the prescribing of brand-name statins in Massachusetts. *JAMA Intern Med.* 2016;176(6):763-768.
- Steinbrook R. Industry payments to physicians and prescribing of brand-name drugs. *JAMA Intern Med.* 2016;176(8):1123. doi:10.1001/jamainternmed.2016.2959.
- Shalowitz DI, Spillman MA, Morgan MA. Interactions with industry under the Sunshine Act: an example from gynecologic oncology. *Am J Obstet Gynecol*. 2016;214(6):703-707.
- Ladd E, Hoyt A. Shedding light on nurse practitioner prescribing. J Nurse Pract. 2016;12(3):166-173.
- Workneh BD, Gebrehiwot MG, Bayo TA, et al. Influence of medical representatives on prescribing practices in Mekelle, Northern Ethiopia. *PLoS One*. 2016;11(6):e0156795.
- 22. Orentlicher D. Off-label drug marketing, the first amendment, and federalism. *Wash Univ J Law Policy*. 2016;50(1):4
- 23. Khan N, Naqvi AA, Ahmad R, et al. Perceptions and attitudes of medical sales representatives (MSRs) and prescribers regarding pharmaceutical sales promotion and prescribing practices in Pakistan. *J Young Pharm.* 2016;8(3):244-250.
- Grundy Q, Bero L, Malone R. Interactions between non-physician clinicians and industry: a systematic review. *PLoS Med.* 2013;10(11):e1001561.
- Grande D. Limiting the influence of pharmaceutical industry gifts on physicians: self-regulation or government intervention? J Gen Intern Med. 2010;25(1):79-83.
- Brennan TA, Rothman DJ, Blank L, et al. Health industry practices that create conflicts of interest: a policy proposal for academic medical centers. *JAMA*. 2006;295(4): 429-433.
- Ross JS, Lackner JE, Lurie P, Gross CP, Wolfe S, Krumholz HM. Pharmaceutical company payments to physicians: early experiences with disclosure laws in Vermont and Minnesota. *JAMA*. 2007;297(11):1216-1223.
- Kesselheim AS, Mello MM, Studdert DM. Strategies and practices in off-label marketing of pharmaceuticals: a retrospective analysis of whistleblower complaints. *PLoS Med.* 2011;8(4):e1000431.
- 29. Francer J, Izquierdo JZ, Music T, et al. Ethical pharmaceutical promotion and communications worldwide: codes and regulations. *Philos Ethics Humanit Med.* 2014;9(1):7.
- Lieb K, Brandtönies S. A survey of German physicians in private practice about contacts with pharmaceutical sales representatives. *Dtsch Arztebl Int*. 2010;107(22):392-398.
- Lieb K, Scheurich A. Contact between doctors and the pharmaceutical industry, their perceptions, and the effects on prescribing habits. *PLoS One*. 2014;9(10):e110130.

- Fischer MA, Keough ME, Baril JL, et al. Prescribers and pharmaceutical representatives: why are we still meeting? *J Gen Intern Med.* 2009;24(7):795-801.
- Chimonas S, Brennan TA, Rothman DJ. Physicians and drug representatives: exploring the dynamics of the relationship. J Gen Intern Med. 2007;22(2):184-190.
- Greenland P. Time for the medical profession to act: new policies needed now on interactions between pharmaceutical companies and physicians. *Arch Intern Med.* 2009;169(9):829-831.
- 35. Breen KJ. The medical profession and the pharmaceutical industry: when will we open our eyes? *Med J Aust.* 2004;180(8):409-410.
- 36. Wazana A. Physicians and the pharmaceutical industry: is a gift ever just a gift? *JAMA*. 2000;283(3):373-380.
- Fugh-Berman A, Ahari S. Following the script: how drug reps make friends and influence doctors. In: Sismondo S, Greene JA, eds. *The Pharmaceutical Studies Reader*. New York, NY: John Wiley; 2015:123-134.
- Molloy W, Strang D, Guyatt G, et al. Assessing the quality of drug detailing. *J Clin Epidemiol*. 2002;55(8):825-832.
- Avorn J, Chen M, Hartley R. Scientific versus commercial sources of influence on the prescribing behavior of physicians. *Am J Med.* 1982;73(1):4-8.
- 40. Sah S, Fugh-Berman A. Physicians under the influence: social psychology and industry marketing strategies. *J Law Med Ethics*. 2013;41(3):665-672.

- Kara A, Andaleeb SS, Turan M, Cabuk S. An examination of the effects of adaptive selling behavior and customer orientation on performance of pharmaceutical salespeople in an emerging market. *J Med Mark.* 2013;13(2): 102-114.
- Kenrick DT, Goldstein NJ, Braver SL, ed. Six Degrees of Social Influence: Science, Application, and the Psychology of Robert Cialdini. New York, NY: Oxford University Press; 2012.
- Vukadin KT. Failure-to-warn: facing up to the real impact of pharmaceutical marketing on the physician's decision to prescribe. *Tulsa L. Rev.* 2014;50:75-113.
- 44. Mintzes B, Lexchin J, Sutherland JM, et al. Pharmaceutical sales representatives and patient safety: a comparative prospective study of information quality in Canada, France and the United States. *J Gen Intern Med.* 2013;28(10):1368-1375.
- Greenwood K. Physician conflicts of interest in court: beyond the independent physician litigation heuristic. *Ga. St. UL Rev.* 2013;30:759.
- Lines SA. Drug patent expirations and the "patent cliff." US Pharm. 2012;37(6):12-20.
- Mount I. A cheap lunch from a pharma rep can influence doctors' prescriptions. *Fortune*. http://fortune.com/2016/06/21/ doctors-cheaper-drug-prescriptions/. Published June 2016. Accessed August 11, 2016.