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Research in Social and Administrative Pharmacy 10 (2014) 588–594

## Commentary

# Prescription drug coupons: Evolution and need for regulation in direct-to-consumer advertising

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#### Summary

Pharmaceutical marketing in the United States had undergone a shift from largely exclusively targeting physicians to considerable efforts in targeting patients through various forms of direct-to-consumer advertising ("DTCA"). This includes the use of DTCA in prescription drug coupons ("PDCs"), a new form of DTCA that offers discounts and rebates directly to consumers to lower costs of drug purchasing. Our examination of PDCs reveals that the use and types of PDC programs is expanding and includes promotion of the vast majority of top grossing pharmaceuticals. However, controversy regarding this emerging form of DTCA has given rise to health policy concerns about their overall impact on prescription drug expenditures for consumers, payers, and the health care system, and whether they lead to optimal long-term utilization of pharmaceuticals. In response to these concerns and the growing popularity of PDCs, what we propose here are clearer regulation and regulatory guidance for PDC DTCA use. This would include review for appropriate disclosure of marketing claims, increased transparency in PDC use for pharmaceutical pricing, and leveraging potential positive benefits of PDC use for vulnerable or underserved patient populations.

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Keywords: Direct to consumer advertising; Drug coupons; Drug expenditures; Health law; Health policy

#### Background

The practice of US pharmaceutical marketing has undergone significant changes since the 1990s when promotional spending focused primarily on detailing directly to physicians through pharmaceutical sales representatives.<sup>1–3</sup> This form of promotion focused on fostering physician–industry relationships and interactions, comprised of financial and non-financial transfers of payments and benefits such as pharmaceutical product detailing, provisioning of gifts and

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Competing interests: The authors declare no potential conflicts of interest, competing interests, or funding sources associated with this manuscript.

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entertainment, consulting arrangements, honorarium, free meals and travel, subsidizing of continuing medical education, and other forms of direct-to-physician marketing. <sup>1–5</sup>

However, increased scrutiny of physician-industry relationships and the potential conflicts of interests arising from these interactions coupled with record health care fraud and abuse settlements associated with illegal marketing, have resulted in new and emerging forms of pharmaceutical promotion aimed at consumers, not physicians. Similarly, the recent implementation of transparency and disclosure requirements for physician payments made by industry under the Patient Protection and Affordable Care Act sunshine provisions also may have an impact on direct-to-physician marketing, as manufacturers and physicians attempt to avoid public disclosure of these payments.

These development have led to an increased emphasis on direct-to-consumer advertising ("DTCA"), currently only permitted in the US and New Zealand in developed markets.<sup>7,8</sup> This form of promotion, which experienced a ~330% increase in expenditures from 1996 to 2005, has undergone its own changes and increases in utilization following the lifting of a US Food and Drug Administration ("FDA") voluntary moratorium in the 1980s and further permissive FDA guidance in 1997.8-10 However, DTCA has been criticized as having potential negative consequences, including leading to increased health care costs, inappropriate physician prescribing habits, marketing of unsafe drugs, and overemphasizing benefits over drug risks. 7,10-14

Like other forms of pharmaceutical promotion, DTCA recently has seen a decrease in spending, but unique to DTCA has been its emergence in new mediums, moving from early print and radio ads, followed by TV, and now increased growth and expenditure of online DTCA. <sup>10,14</sup> Indeed, US health care and pharmaceutical online advertisement spending is predicted to experience double-digit growth from 2010 to 2015, while consumers increasingly utilize the Internet for health information seeking and self-prescribing behavior. <sup>8,15,16</sup>

This "evolution" of DTCA has also recently included a move to the new medium of prescription drug coupons ("PDCs") that market cost-savings, discounts, and rebates on co-payments or out-of-pocket expenses direct to the consumer. <sup>17–19</sup> This relatively new form of DTCA has also come under scrutiny and debate regarding its potential impact on prescription drug utilization and expenditures necessitating further examination.

#### Expansion and forms of PDCs

PDCs, also known as prescription drug discount cards and prescription drug co-pay subsidy programs, are a relatively new and innovative phenomenon in pharmaceutical marketing. This form of DTCA advertises co-payment discounts to lower the cost of brand name drugs for patients with private insurance or those paying out-of-pocket. While PDCs often enable short-term savings for consumers on expensive brand name prescription drugs, a critical question is whether they represent an appropriate way to reduce overall prescription drug expenditures for consumers, payers or the health care system, and whether they lead to optimal long-term utilization of pharmaceuticals and health care resources.

PDCs are readily available in various mediums, including at physician offices in pamphlets, marketing inserts or other physical collateral, and are also available online as printable forms and even as eCoupons. 17,18,20 Increasingly, dedicated websites allow consumers to sign up for virtual drug discount cards and search and print PDCs online. 17,21 These third party non-manufacturer websites and related affiliate sites also actively promote PDCs and drug discount card services via social media DTCA, including use of You-Tube videos, Facebook promotional pages, and use of Twitter. DTCA of PDCs is also moving toward emerging mHealth platforms, including smartphone applications like "GoodRx", that allows consumers to search, shop for, and download coupons from their own mobile phone.<sup>22</sup>

Recently, health marketing company Physicians Interactive and wholesale pharmaceutical distributor McKesson Corporation also announced the launch of an eCoupon solution utilizing electronic health records and e-prescribing systems to automatically deliver PDCs directly to pharmacies.<sup>23</sup> The system aims to check PDC availability for medications selected by prescribers, check patient eligibility to qualify for PDC, and then automatically send the PDC to the pharmacy to enable the patient to redeem.<sup>23</sup> By leveraging electronic health record and prescribing systems and linking them with targeted DTCA at point-of-sale ("POS"), this innovative strategy has the potential to significantly increase PDC utilization.

Hence, use of DTCA for PDCs covers a broad scope of marketing mediums, and looks to continue to expand with emerging health-related technologies. A few examples of these PDC programs for blockbuster drugs are provided below.

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