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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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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.^{1–3} 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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entertainment, consulting arrangements, honorarium, free meals and travel, subsidizing of continuing medical education, and other forms of direct-to-physician marketing.^{1–5}

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.^{1,6,7} 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.⁶

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.^{7,8} 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.^{10,14} 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.^{8,15,16}

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.^{17–19} 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.¹⁸ 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 YouTube 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.²²

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.²³ 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.²³ 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.

Examples of PDCs

PDCs are typically used for top-selling branded drugs and may be associated with products with impending patent expiry that can enable continued sales following loss of market exclusivity. For example, in a simple online search using *Google* search engine conducted from Nov 2011–Nov 2012 using the keywords “prescription drug coupon” and a specific blockbuster drug name, we found nine of the top-10 selling drugs (90%) of 2010, which include Lipitor, Nexium, Plavix, Advair Diskus, Abilify, Seroquel, Singulair, Crestor, and Actos. All had PDCs available on their manufacturers’ websites. A majority (60%) of these drugs also had FDA “black box” warnings, indicating potential for serious injury or death (Table 1). Reflecting this increased PDC use, the number of PDC drug product programs has also proliferated rapidly, more than quadrupling from 86 in 2009 to 362 in 2012.²⁴ Ongoing access to PDCs are not always consistent, as some observed PDC programs were terminated during the time of review.

Common PDC characteristics include: (a) exclusion of patients covered by government programs (Medicare and Medicaid); (b) a single-digit advertised co-pay amount; and (c) maximum monthly and annual cost savings for participants. For example, the world’s historically best selling drug, Lipitor,^{25,26} uses a PDC program available online (see: <http://www.lipitor.com/patients/LipitorCoPayCardRegistration.aspx>). It prominently

advertises a “\$4 co-pay” card at participating pharmacy providers. Using the Lipitor PDC program, a consumer is able to have the manufacturer, Pfizer, cover the cost of their co-pay up to a maximum of \$100 per month with a maximum cost savings of \$1500 per year. In other words, if a consumer’s monthly co-pay from the insurer is \$104 per month or less, they only pay a total \$4 out-of-pocket for the branded product regardless of the cost to the payer. For those who exceed the \$104 co-pay or are uninsured, they receive a maximum discount of \$100 and pay the balance out-of-pocket.

Lipitor’s PDC program was launched in December 2010 and promoted using various forms of DTCA to retain market share in anticipation of patent expiry, loss of market exclusivity in November 2011, and as a strategy to attract new consumers.^{21,27} It began by offering a \$50 maximum discount when 2 generic versions (one manufactured by Ranbaxy Laboratories and one “authorized generic” sold by Watson Pharmaceuticals, Inc.) of Lipitor entered the market, but then raised the discount to \$75 and extended the term of the program in May 2012 in response to additional generic market entry that further pushed down Lipitor prices.^{18,21} The program currently offers a \$100 discount representing a 100% increase in the maximum rebate from its inception of the program in 2010, and now has an expiration date of December 2014. Although Lipitor has lost significant market share to generic manufacturers, its PDC program has signed up some

Table 1
Top 10 selling drugs and PDC availability

Top selling drugs	Sales in 2010 (\$BN)	Patent expiry state or expected patent expiry	Online PDC availability as of Nov 2011	Online PDC availability as of Nov 2012	Black box warning
Lipitor (atorvastatin)	7.2	Expired	Yes	Yes	No
Nexium (esomeprazole)	6.3	2014	Yes	Yes	No
Plavix (clopidogrel)	6.1	Expired	No	Yes	Yes
Advair Diskus (fluticasone/salmeterol inhaled)	4.7	Expired	Yes	Yes	Yes
Abilify (aripiprazole)	4.6	2015	Yes	Yes	Yes
Seroquel XR (quetiapine)	4.4	Expired	No	Yes	Yes
Singulair (montelukast)	4.1	2012	Yes	No	No
Crestor (rosuvastatin)	3.8	2016	Yes	Yes	No
Actos (pioglitazone)	3.5	2012	Yes	Yes	Yes
Epoen (epoetin alfa)	3.3	2015	No	No	Yes

Expected expiry date data from Medco https://host1.medcohealth.com/art/corporate/anticipatedfirsttime_generics.pdf.

Black box warnings data from Epocrates online.

750,000 users and has expanded to five other drugs.²¹

Similar to Lipitor's PDC program, AstraZeneca's Nexium PDC site advertises an \$18 per month savings card that has a maximum discount of \$50 for a one-month supply (see: <https://www.purplepill.com/purple-plus-savings-card.aspx>). Nexium's patent is set to expire in 2014. Other PDC programs have some variation but similar terms. As an example, Otsuka America Pharmaceutical, Inc.'s Abilify PDC site promotes a PDC Savings Card program that combines a 30-day free trial of the drug followed by promotion of a \$25 co-pay that has a maximum discount of \$150 for a one-month supply (see: <https://www.abilifyassistprogram.com/>). Both of these programs have expiration dates associated with their PDC programs indicating that discounts may not be accessible to patients on later dates.

Controversy regarding PDC DTCA

PDCs may have the potential to provide substantial discounts directly and conveniently to patients to offset co-pays and out-of-pocket expenses, reduce financial burden of prescription drug expenditures, and even improve medication adherence, especially for newer pharmaceuticals with no other therapeutic alternative or generic formulation.^{18,19} However, a key health policy concern regarding PDCs is whether they will materialize into actual short-term or long-term cost savings for individuals and whether they will lead to increased aggregate health care expenditures which could lead to higher indirect costs (i.e., increased insurance premiums).¹⁸ For example, the Pharmaceutical Care Management Association, a trade association of pharmacy benefit managers, has claimed that PDC programs will increase prescription drug costs by \$32 billion for commercially insured patients in the next decade.^{20,24} With an estimated 19 million Americans now using coupons to save money on prescription medications, appropriate assessment of this form of DTCA is critical.²⁸

From the perspective of the patient/consumer, DTCA utilized for PDCs may have an impact on consumer attitudes or behavior that may influence perceptions or receptiveness regarding risks and benefits and subsequent purchase of a branded pharmaceutical product.²⁹ A study conducted by Bhutada et al found that consumers exposed to fictional PDC DTCA had significantly more favorable and positive attitudes toward pharmaceutical

advertisements and brands and were also more likely to ask a physician about the advertised PDC drug.¹⁹ This is despite the risk that consumers may not take all the necessary steps to redeem the rebate.³⁰ Indeed, consumers may have optimistic perceptions of following through with redemption, but research has shown that similar types of rebate programs can result in very low redemption rates, meaning benefits may not inure to the consumer.³⁰ As an example, market research studies have estimated that online coupon redemption rates are only between 5 and 20%.³¹

PDCs also prominently use statements such as "pay as low as \$X co-pay per month" or "[BRAND] \$X Co-Pay Card" advertising the lowest cost possible to the consumer. However, the actual cost to the prospective patient/consumer can be higher than what is marketed due to limits on savings, eligibility requirements, prescription size limitations, and limited time of offers with details often provided in obscure fine print not easily accessible to consumers.²⁸

For example, uninsured consumers (if eligible) or those without prescription drug coverage paying out-of-pocket for drugs are limited to a maximum disbursement that can significantly reduce expected savings. When the authors examined Lipitor's PDC program in 2012, an out-of-pocket paying patient purchasing brand name Lipitor from healthwarehouse.com, a popular and accredited National Association of Boards of Pharmacy Verified Internet Pharmacy Practice Site online retail mail-order pharmacy, would pay a listed price of \$168.30 (40 mg/1-month supply) and would receive a PDC credit (\$75) totaling a net cost of \$93.30 (\$1119.60/year). In comparison, the generic equivalent to Lipitor under the International Nonproprietary Name, Atorvastatin, is available from the same online retailer at the same dosage and quantity for the price of \$16.00 per month without a coupon (\$192.00/year). This represents a cost savings of \$77.30/month (\$927.60/year) for the consumer who chooses to purchase the generic equivalent.

Similarly, a study funded through a multistate prescription drug consumer fraud settlement by the state Attorney General Consumer and Prescriber Education Grant program issued by Consumer Reports, examined a number of PDCs in 2012.²⁸ It found that even though free trials and discounts on prescription drugs might be available, alternative therapeutic options or generic equivalents may represent better and more cost-effective treatment options.²⁸ Tiered prescription pricing

for insured patients using PDCs may also result in higher costs if using branded products when generics equivalents are available.²⁰ In these cases, patients may be responsible for any difference between the generic price and the branded price in commercial health plans, which can be 4–6 times higher than generic co-pays.³²

Consumers also may be faced with price increases if a manufacturer decides to have a limited term on PDC eligibility or otherwise discontinues a PDC program.¹⁸ When such changes abruptly occur, consumers may experience significant co-pay and/or other cost increases if they do not take necessary steps to ensure continued savings or switch to generic equivalent if clinically appropriate.²⁸ As an example, the PDC program for Crestor only applies to the first 12 prescriptions filled during a 14-month term, following this period, consumers are no longer eligible for discounts.²⁸

Legal considerations

Federal government programs ban PDC usage because they regard these remuneration schemes to be in potential violation of the federal Anti-Kickback statute. Similarly, Massachusetts was the only state that specifically banned PDC usage; however, recently Massachusetts passed legislation amending its state anti-kickback law allowing PDC programs to be used by consumers only in circumstances where there is no generic equivalent medication available.³³

Yet, despite legal prohibitions, PDCs may be utilized by patients covered under government prescription drug plans, even though this most likely constitutes a violation of applicable fraud and abuse laws and may lead to additional costs for federal and state health care programs. In fact, a 2012 survey found that 6% of seniors utilized PDCs for drug benefits available through Medicare Part D or Medicare Advantage.³⁴ Nearly all respondents stated they were unaware that Medicare imposes restrictions on the use of PDCs.³⁴

Payers are also increasingly concerned about PDCs and their impact on cost-containment efforts. In March 2012, lawsuits were filed against seven drug manufacturers using PDC programs by a consumer coalition alleging that they were illegal and fraudulent under federal antitrust law.²⁴ Insurers have also unsuccessfully challenged manufacturer drug co-payment subsidy programs through litigation under the Racketeer Influenced and Corrupt Organizations Act and the Robinson–Patman Act for commercial bribery

that have largely been dismissed by US District Courts in New York and New Jersey.³⁵

Policy reform

The growing popularity and increasing presence of DTCA-based PDCs in various physical and digital mediums requires careful consideration regarding potential benefits and negative impacts on health policy and prescription drug expenditures. Though PDC programs may enable cost savings to individual consumers, consumers may nevertheless not be fully cognizant of the true cost of purchasing branded drugs through PDC programs when other clinically appropriate options are available.

In response, the FDA in partnership with the Federal Trade Commission (“FTC”) should be more proactive in review of physical and digital forms of DTCA promotion of PDC programs by manufacturers and other third parties. This should include requiring pre-submission and review of proposed PDC DTCA material under the existing FDA Office of Prescription Drug Promotion. While the FDA is currently engaged in exploratory studies examining the impact of DTCA coupons and other promotional offers on consumer perceptions regarding pharmaceutical product risk and benefit, PDC programs are already active and proliferating, requiring more immediate regulatory action.²⁹

At a minimum, the FDA and FTC should begin the process of reviewing existing PDC DTCA to ensure that it is not false or misleading, that information presented is truthful, balanced, and accurately communicated, and that the cost associated with use of PDCs in comparison to other available clinically appropriate alternatives is provided to consumers in a transparent and easily understandable manner. This would include development of industry guidance on appropriate use of advertising claims such as “\$X co-pay programs,” with requirements to explicitly disclose to consumers that they are mail-in rebate programs and may impose limits and conditions on maximum cost savings. This information should be prominently disclosed in all DTCA marketing communications to consumers to ensure balanced information regarding potential cost and benefits.

Additionally, PDC programs should include dynamic and transparent disclosure of expected pricing of advertised products based on examples of typical insurance status or lack thereof,

information on alternative treatment options (including availability of generic equivalents if applicable), explanation of higher costs that may be incurred with different health plan pricing arrangements, and the potential cost to the consumer if the PDC is terminated. If PDC benefits are only available at specified pharmacies, they should be disclosed to customers in an up-to-date listing with associated pricing.

Ideally, PDCs should originate only from licensed and authorized manufacturers of an advertised drug to ensure quality and accuracy of information and to ensure patient safety. Another alternative is adopting policy similar to the state of Massachusetts to only permit PDC DTCA in cases when no clear generic equivalent is available for consumption. However, policymakers also can explore programs that leverage the potential benefits of PDC programs for patients. This could include exploration of targeted PDC use for prescription drugs or patient populations that are underserved (such as for orphan drugs or rare disease populations as proposed in previous studies),³⁶ for patients who are economically disadvantaged, or for pharmaceuticals with low treatment adherence rates.

It would behoove physicians to be aware of the potential risks and benefits of PDCs and carefully partner with their patients to make informed decisions about possible use given that they may represent one of the primary sources of dispensing PDCs to patients.³⁴ With provider oversight, the use of clinically-equivalent generics and no-cost/low-cost drug programs should be considered to ensure appropriate treatment at cost-effective pricing.

Conclusion

PDCs represent a new and emerging form of DTCA that has yet to be adequately studied or assessed for potential impact on consumer perception and influence, prescription drug utilization, or effect on overall health care related expenditures. However, researchers, consumer advocacy groups, and insurers have already expressed concern over this form of DTCA that may incentivize consumers to purchase expensive drugs. Health care professionals, regulators and policymakers must partner to appropriately address this form of pharmaceutical promotion while remaining sensitive to the cost concerns of patients to best advocate for responsible use of PDCs and their potential benefits.

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