



November 22, 2010

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Re: Docket No. FDA-2010-N-0465 “Experimental Study: Effect of Promotional Offers in Direct-to-Consumer Prescription Drug Print Advertisements on Consumer Product Perceptions”**

Community Catalyst and its Prescription Access Litigation Project submit the following comments on the Food and Drug Administration’s Proposed Collection of Information referenced above.

The Prescription Access Litigation Project (PAL) is a national coalition of more than 130 consumer, health care, labor, legal services and human services organizations.<sup>1</sup> PAL is a project of Community Catalyst, a national non-profit advocacy organization that builds consumer and community participation in the shaping of our health system to ensure quality, affordable healthcare, including prescription drugs, for all.<sup>2</sup> PAL works to make prescription drugs more affordable for consumers by using class action litigation and public education to bring an end to illegal or deceptive pharmaceutical marketing practices.

As PAL testified at the FDA’s hearing on Direct to Consumer Advertising (DTCA) on November 2, 2005, we see deceptive marketing by pharmaceutical companies as one of the primary factors driving inappropriate use of prescription drugs in the United States. Coupons, as a form of DTCA, contribute to the negative effects of drug marketing. This study is of increasing importance, in light of recent news reports indicating the use of coupons, vouchers, and discount cards has risen by 258 percent in the last four years.<sup>3</sup>

We strongly support the FDA’s decision to investigate the effect of promotional offers in DTCA on consumer product perceptions. It is vital the public, the FDA and policymakers have a better understanding of how promotional offers can affect consumers’ perception of the risks and benefits of a particular drug. We predict the results of the study will show the promotional offers negatively impact the decision-making process of consumers by inflating the perceived benefits and diminishing concerns about risks. If this is the case, we support FDA action to ban the use of coupon promotions for prescription drugs.

In addition to the impact on the consumer’s decision-making process regarding drug safety and risks, we also oppose the use of promotional offers because of their negative impact on safety and health care costs. However, we want to state clearly that we do not consider valid Pharmaceutical Assistance Programs (PAPs) sponsored by manufacturers, pharmacy benefit

managers, insurers, non-profit organizations or others, that offer free or discounted prescription drugs to uninsured consumers based on income levels to have the same detrimental effects on the overall system, and we support the continued use of *bona fide* needs-based PAPs.

## **I. Improper Influence of Promotional Coupons on Consumers' Risk-Benefit Analysis**

Prescription drug coupons have multiple inappropriate and negative effects on consumer perception and behavior, as detailed below. The following sections highlight DTCA generally, consumers' risk-benefit determinations, the doctor-patient relationship, safety implications, and the federal Anti-Kickback Statute.

### **A. Direct to Consumer Advertising Background**

Prescription drugs require a physician or other medical professional with prescribing authority write a prescription and a licensed pharmacist fill the prescription. These requirements are imposed because we as a society have concluded that the safe and appropriate use of certain medications requires the participation and decision of a physician or other medical professional. There are many different reasons for this level of caution: the drug may be dangerous if taken incorrectly, the drug may be addictive, the condition and the choices regarding treatment may be complex, or the drug may not interact well with other drugs the person is taking. Regardless of the specific reason a drug is available by prescription only, we have ultimately entrusted the decision of whether to prescribe a drug and what drug to prescribe to highly-trained health care providers. The discussion between the physician and the patient concerning a prescription is an important part of the delicate doctor-patient relationship. We feel that DTCA, and coupons in particular, seriously interferes with that relationship by injecting the improper influence of self-interested pharmaceutical marketing.

DTCA induces consumers to ask their physicians for particular drugs by name. The pharmaceutical industry would not spend billions of dollars a year on DTCA if it did not believe DTCA to be effective. A Kaiser Family Foundation study found that each dollar invested in DTCA resulted in an increase in sales of \$4.20, a return on investment of over 400 percent.<sup>4</sup> Another Kaiser Family Foundation study found that nearly one-third (32 percent) of people who have seen drug ads say they have talked to a doctor about a medication as a result of seeing an ad.<sup>5</sup> Forty-four percent of those who spoke to their doctor after seeing an advertisement say their doctor gave them a prescription for the drug they asked about.<sup>6</sup> With respect to providers, a study in the Journal of the American Medical Association found that doctors were much more likely to prescribe a brand-name antidepressant to patients who requested the drug by name than to patients who did not, even when that antidepressant was not approved for the condition with which the patient presented.<sup>7</sup>

These studies overwhelmingly demonstrate that DTCA induces consumers to request particular prescription drugs from their physicians, and that such requests correlate with higher rates of prescribing of the requested drug, regardless of its appropriateness. Given that DTCA can cause such inducement based on advertising content alone, drug advertisements that are paired with or contain coupon promotions only serve to amplify this bias.

## **B. Interference with Risk-Benefit Determinations**

Coupons affect the perception of risk and benefit by introducing a financial consideration into the consumer's analysis of a drug. Consumers' perception of a drug's risks and benefits is not just a function of its efficacy and side effect profile but of the perceived economic value as well. Since DTCA almost never mentions price, it usually affects consumers' perceptions of risks and benefits through arguments concerning efficacy and side effects, as well as through the use of positive images. Coupons are often the only mention of price, or of anything monetary, in advertising for a particular drug. Given that non-drug coupons are shown to increase consumer perception of the value of a product, the same can be expected from drug coupons. Thus, by increasing the consumer's perception of the drug's overall value, drug coupons will diminish consumer's impression of the drug's risks and exaggerate their benefits.

## **C. Interference in the Doctor-Patient Relationship**

Coupons interfere with the doctor-patient relationship. By introducing a financial enticement into the patient interest in a drug, coupons increase the patient's desire to be prescribed a particular drug. If the physician refuses or recommends an alternate prescription (another drug or a generic version) or, alternatively no drug treatment, tension and mistrust between the physician and the patient can result. This could be particularly true if the consumer feels they stand to lose an item of value (the savings on a brand-name item that the coupon represents). By fostering the misperception that prescription drugs are equivalent to other consumer products, coupons diminish the importance of the doctor's role in counseling the patient and in acting as an intermediary between the consumer and the drug.

## **D. Impacts on Consumer Safety**

Drug companies issue coupons to promote the choice of their brand-name drugs in place of competing generic drug alternatives or equivalents. This can be a safety issue, since generic drugs or older brand name drugs have more established records regarding safety and side effects. In contrast, fewer people have used newer, brand-name drugs and less is known about their risks and long-term effects or if they have dangerous side effects. Thus, when consumers are incentivized to take new brand-name medications because of coupons and DTCA advertising, they may not be getting the safest and most effective treatment for their condition.

## **E. The Federal Anti-Kickback Statute**

The federal government has long been aware of the potential for rebates and coupons to influence purchasing behavior. For this reason, the federal Anti-Kickback Statute prohibits coupon use by beneficiaries of Medicaid, Medicare and other federal health care programs.<sup>8</sup> While many prescription drug coupons explicitly state that they are not valid for such beneficiaries of federal health care programs, the fact that such inducements are prohibited by the Anti-Kickback Statute underscores the dangers of such coupons even outside of the realm of federal health care programs.

## **II. Recommendations on Study Design**

We fully support the FDA's study and the overall study design. However, we recommend that the study sample be large enough to collect sufficient data to allow for robust analysis by population subgroups. The need for research on the impact of health care treatments, services and system design on priority populations and sub-groups was emphasized in the Federal Coordinating Council for Comparative Effectiveness Research in its 2009 Report to the President and Congress, which recommended that research address the needs of certain subpopulations, including racial and ethnic minorities, elderly Americans, individuals with disabilities, people of low socioeconomic status and others. We believe this attention to subpopulations should extend to research on the effects of pharmaceutical coupons. The effects of direct-to-consumer marketing on patient perception and primary sources of prescription drug information can vary significantly by ethnicity.<sup>9</sup> Market research has also shown that the use of coupons in particular varies by ethnicity.<sup>10</sup> Finally, the effects of required patient payment contributions on the utilization of prescription drugs differ by age, education and income.<sup>11</sup> This suggests there may also be disparities in the perceived value of drug coupons across patient subpopulations.

The proposed study should be designed to detect effects within subgroups of racial and ethnic minorities, persons of lower socioeconomic status, and persons of lower literacy and education levels. Researchers have asserted that exploratory subgroup analyses in randomized clinical trials often produce spurious results.<sup>12</sup> It is therefore essential that FDA's study be designed such that analyses are sufficiently powered to detect effects in the above subgroups. This is especially relevant in this study, as effects may vary by both type of advertisement and population subgroup.

## **III. Conclusion**

In sum, we believe prescription drug coupons have negative effects on consumers because they skew their perceptions of risks and benefits, interfere with the doctor-patient relationship, and compromise patient safety. It is these negative effects that lead us to support the proposed FDA study, and also to recommend prescription drug coupons be prohibited.

In addition, we must comment on the impact of promotional coupons in the greater context of health care cost containment. While the FDA does not have the authority to regulate the pricing of prescription drugs, the study will shed light on the impact of marketing, including promotional offers, on the consumer behavior and market decisions. President Obama's administration and the Department of Health and Human Services are heavily invested in the success of health care reform and health care cost containment, and as consumer organizations, we share this commitment. Therefore, we offer this additional analysis of the effect of promotional coupons' effect on health care costs.

The rate of inflation in medical costs is unsustainable. According to the actuarial firm Milliman, medical costs for a typical American family of four are now \$18,074, up 7.8 percent from 2009, with the average employee share at \$7,297.<sup>13</sup> This compares to the total consumer price index increase for all items (less food and energy), which was only 0.6 percent (Oct. 2009-Oct. 2010) according to the Bureau of Labor Statistics.<sup>14</sup> Pharmaceuticals accounted for 15 percent of

overall medical costs in 2010, with an annual increase of 6.1 percent. This reflects utilization (17 percent) and average unit cost increases (83 percent), with the latter driven by the mix of drugs dispensed, generic vs. brand name drugs, and the introduction of new therapies. Thus, marketing strategies, including the use of coupons, that result in consumer demand for more and higher cost drugs contribute to overall medical cost inflation.

Generic drugs cost on average \$90 less per month than brand-name medications.<sup>15</sup> A study by Express Scripts reported that in 2009, \$51 billion was wasted when Americans chose more expensive brand-name medications over generics.<sup>16</sup> Additionally, the average cost of generics went down 9 percent in 2008 while the average cost of brand-name medications increased by 7.4 percent.<sup>17</sup> Drug companies, driven by profit incentives, use coupons to promote sales and market share for brand-name drugs. Generic manufacturers generally do not issue coupons since there is no way to ensure a prescription would be filled with a particular manufacturer's version of the generic drug.

In an effort to control costs by changing consumer behavior, the trend in recent years has been for health plans to tier prescription drug benefits to incentivize use of generic drugs. Specifically, health plans often place less expensive generic drugs on a lower 'tier' with a lower co-payment, while brand-name drugs are on a higher tier with a higher co-payment. This saves the health plan money, which has the potential to lead to lower premiums without a reduction in benefits.<sup>18</sup> Brand-name drug manufacturers then offer coupons to consumers to cancel-out the increase in co-pay cost, and recent news reports indicate that the use of coupons, vouchers, and discount cards has risen by 258 percent in the last four years.<sup>19</sup> Using this strategy, companies selling brand-name prescription medications can restructure the consumer's perception of value.

However, the consumer may not be cognizant of the long-term effect of their coupon use. They pay less at the pharmacy today, but their costs go up when the coupon is no longer available. Premiums and out-of-pocket costs may rise as a result of the cost to the insurer of paying for the name-brand drug instead of the generic drug. Ironically, these costs probably contribute to the consumer's price-consciousness at the pharmacy, making coupons even more attractive.

Once again, thank you for undertaking this study of the effects of promotional coupons on consumers' perceptions of drug risks and benefits, and thank you for the opportunity to comment. We hope our additional analysis of health care cost containment is accepted in the spirit it is offered: not to influence decisions around this particular study, but to provide a background picture of policy implications.

Sincerely,

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<sup>1</sup> Prescription Access Litigation website: <http://www.prescriptionaccess.org/>

<sup>2</sup> Community Catalyst website: <http://www.communitycatalyst.org/>

<sup>3</sup> Edney, Anna, "Drug Coupon Use Soars, Prompting Safety and Spending Concerns." Bloomberg News: Oct. 28, 2010.

<sup>4</sup> Kaiser Family Foundation, "Demand Effects of Recent Changes in Prescription Drug Promotion," June 2003. [www.kff.org/rxdrugs/upload/Demand-Effects-of-Recent-Changes-in-Prescription-Drug-Promotion-Report.pdf](http://www.kff.org/rxdrugs/upload/Demand-Effects-of-Recent-Changes-in-Prescription-Drug-Promotion-Report.pdf) (accessed November 20, 2010).

<sup>5</sup> Kaiser Public Opinion Spotlight, "Public and Physician Views of Direct-to-Consumer Prescription Drug Advertising," (April 2008) <http://www.kff.org/spotlight/rxdrugsconsumer/index.cfm> (accessed November 21, 2010).

<sup>6</sup> *Id.*

<sup>7</sup> Journal of the American Medical Association, "Influence of Patients' Requests for Direct-to-Consumer Advertised Antidepressants," April 27, 2005 (Vol 293:1995-2002).

<sup>8</sup> See 42 USC Sec. 1320a-7b(b).

<sup>9</sup> DeLorme D, Huh J, Reid LN. Evaluation, use, and usefulness of prescription drug information sources among Anglo and Hispanic Americans. *Journal of Health Communication* 2010;15(1):18-38.

<sup>10</sup> Kaufman CJ and Hernandez SA. Barriers to coupon use: a view from the bodega. *Journal of Advertising Research* 1990;30(5):18-2.

<sup>11</sup> Lundberg L, Johannesson M, Isacson DG, Borgquist L: Effects of user charges on the use of prescription medicines in different socio-economic groups. *Health Policy* 1998;44(2):123-134.

<sup>12</sup> Brookes ST, Whitely E, Egger M, Smith GD, Mulheran PA, Peters T. "Subgroup analyses in randomized trials: risks of subgroup-specific analyses; power and sample size for the interaction test." *J Clin Epidemiol* 2004;57:229-236.

<sup>13</sup> 2010 Milliman Medical Index, May, 2010. Milliman, Inc.

<http://publications.milliman.com/periodicals/mmi/pdfs/milliman-medical-index-2010.pdf>

<sup>14</sup> Bureau of Labor Statistics, "Economic News Release: Consumer Price Index Summary," November 17, 2010. <http://www.bls.gov/news.release/cpi.nr0.htm> (accessed November 19, 2010).

<sup>15</sup> Express Scripts, "A Plan Design Check-Up," April 2010.

<http://www.express-scripts.com/research/studies/whitepapers/> (accessed November 21, 2010).

<sup>16</sup> Steve Miller, MD, *et al.* "2009 Drug Trend Report: Solving for America's \$163 Billion in Pharmacy-Related Waste," Express Scripts, April 2010. <http://www.express-scripts.com/research/studies/drugtrendreport/> (accessed November 20, 2010).

<sup>17</sup> Express Scripts, "A Plan Design Check-Up," April 2010.

<http://www.express-scripts.com/research/studies/whitepapers/> (accessed November 21, 2010).

<sup>18</sup> We are aware that not all health plans have historically used savings/profits one year to reduce premium or out of pocket costs for consumers in subsequent years. However, the newly imposed Medical Loss Ratios should contribute to a more causal relationship between health care expenditures and premium costs in the coming years.

<sup>19</sup> Edney, Anna, "Drug Coupon Use Soars, Prompting Safety and Spending Concerns." Bloomberg News: Oct. 28, 2010.