

April 6, 2006

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

Re: Docket No. 2006N-0029, "Impact of Coupons on Consumer Perceptions of Products"

To Whom it May Concern:

The Prescription Access Litigation Project and the undersigned organizations submit the following comments on the Food and Drug Administration's (FDA) Proposed Collection of Information referenced above.

The Prescription Access Litigation Project (PAL), is a coalition of 118 organizations representing consumers, health care advocates, seniors, labor unions, nonprofit health plans, legal services organizations, and others. PAL is a project of Community Catalyst, a national advocacy organization that builds consumer and community participation in the shaping of our health system to ensure quality, affordable healthcare for all. PAL works to make prescription drugs more affordable for consumers by using class action litigation and public education to bring an end to illegal pharmaceutical price inflation.

As we testified at the FDA's hearing on Direct to Consumer Advertising (DTCA) on November 2, 2005¹, we see deceptive marketing by pharmaceutical companies as one of the primary factors driving up the cost and inappropriate use of prescription drugs in the United States. Coupons, as a type of DTCA, contribute to the negative effects of drug marketing and represent one of its crassest forms.

In our November 2005 testimony, we called for coupons for prescription drugs to be banned, and we reiterate that call now. We understand that the FDA's Request for Comments solicited comments specifically on a proposed study of the impact of coupons on consumer perceptions of drug risks and benefits. Our comments below do contain a number of recommendations regarding the design of the study. Nonetheless, we also felt it important to restate our position that coupon promotions for prescription drugs are inappropriate and should not be permitted. We anticipate that the FDA's proposed study will demonstrate that coupons inappropriately inflate consumers' perception of benefit while reducing their perception of risks. We expect and hope that if and when the FDA's study produces such

¹ This testimony is available at www.prescriptionaccess.org/resource.php?wv_edit=1&wv_int=1&base_id=978

findings, the FDA will take regulatory action to address that harm, and **our recommendation would be a prohibition on the use of coupon promotions for prescription drugs.**

Types of Prescription Drug Coupons

We use the term “coupons” here to refer to any program or offer by or behalf of a manufacturer of prescription drugs that does any of the following:

- Reduces the cost of a course of the medication in question at the point of sale (a traditional “coupon”), either for a fixed amount (e.g. “\$10 off”) or as a percentage (e.g. 20% off);
- Reduces the cost after purchase upon submission of documentation (a “rebate”);
- Offers a “free trial” or sample for any amount or duration of the medication (not including samples provided in a doctor’s office);
- Offers a free refill or course of the medication after a certain number of refills or filled prescriptions (e.g. “buy six get one free”); or
- Offers any item of value, either product or service, as a premium for filling or refilling a prescription (e.g. free online music downloads, consumers products or discounts on other consumer products).

We do not consider valid Pharmaceutical Assistance Programs (PAPs) sponsored by manufacturers, pharmacy benefit managers, insurers, nonprofit organizations or others, which offer free or discounted prescription drugs to uninsured consumers based on income levels to be coupons.

Drug Coupons in the Context of DTCA Overall

Coupons are a promotional vehicle normally associated with traditional consumer products. Prescription drugs are not such a consumer product. Unlike shampoo, breakfast cereal and dishwashing liquid, a consumer cannot just enter a store and purchase a prescription drug. Prescription drugs require that a physician or other medical professional with prescribing authority write a prescription and that a licensed pharmacist fill the prescription.

These requirements are imposed because we as a society have concluded that the use of certain medications requires the participation and decision of a physician or other medical professional. There are different reasons for these requirements for different drugs – the drug may be dangerous if taken incorrectly, the drug may be addictive, the condition and the choices of treatment for it may be complex or the drug may not interact well with other drugs the person is taking. Regardless of the specific reason, we have ultimately entrusted the decision of whether to prescribe a drug and what drug to prescribe to the physician.² 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.**

² Although other medical professionals have prescribing authority (such as Nurse Practitioners), we are going to refer to “physicians” for convenience’s sake.

DTCA induces consumers to ask their physicians for particular drugs by name. The pharmaceutical industry would not spend in excess of \$4 billion a year on DTCA if they did not believe it 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%.³ Another Kaiser Family Foundation study found that one-quarter (26%) of people who have seen drug ads say they have talked to a doctor about a medication as a result of seeing an ad. More than half of these people said the doctor prescribed the medication that they requested.⁴ Another 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 that drug by name than to patients who did not, even when that antidepressant was not approved for the condition with which they presented.⁵

Studies such as these and others demonstrate that DTCA does indeed induce consumers to request particular prescription drugs from their physicians, and that such requests do correlate with higher rates of prescribing of the requested drug, regardless of 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 that inducement.

Effects of Coupons on Consumer Perceptions of Value Generally

There is a large body of research showing that coupons do induce consumers to purchase the product being promoted. In addition, studies show that coupons enhance purchasers' perception of a product's value.⁶ Studies further show that reducing a product's cost through a coupon is a more effective marketing tool than simply reducing the usual price of that product.⁷ Ironically, a flat reduction in a product's price can have the effect of lowering the consumer's perception of the value of a product, whereas a coupon promotion can actually increase the consumer's perception of that product's value.⁸

What is true of coupon promotions generally is likely to be true of prescription drug coupons as well. In fact, it is possible that coupons have an even greater inducement effect in the purchase of prescription drugs than in consumer products. Prescription drugs are often necessary purchases, particularly in the case of chronic conditions, whereas most other consumer products for which coupons are offered are discretionary. Thus, an offer to save

³ 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 (accessed March 30, 2006).

⁴ Kaiser Public Opinion Spotlight, "Views On Prescription Drugs And The Pharmaceutical Industry," (February 2005) <http://www.kff.org/spotlight/rxdrugs/index.cfm> (accessed March 29, 2006).

⁵ *Journal of the American Medical Association*, *Influence of Patients' Requests for Direct-to-Consumer Advertised Antidepressants*, April 27, 2005 (Vol 293:1995-2002).

⁶ Kent B. Monroe, and Joseph D. Chapman, *Framing Effects on Buyers' Subjective Product Evaluations*, *Advances in Consumer Research*, Vol. 14, pp 193-197 (1987).

⁷ Emin Babakus, Peter Tat & William Cunningham, *Coupon Redemption: A Motivational Perspective*, *The Journal of Consumer Marketing*, Vol. 5, No. 2 p. 39 (Spring 1988).

⁸ Shih-Fen S. Chen, Kent B. Monroe and Yung-Chien Lou, *The Effects of Framing Price Promotion Messages on Consumers' Perceptions and Purchase Intentions*, *Journal of Retailing*, Vol. 74(3), pp. 353-372 (1998).

money on a product that a consumer needs, or believes that he or she needs, is likely to have a greater appeal (and thus a greater effect on behavior) than on a product that is not necessary.

Negative Effects of Prescription Drug Coupons

We see prescription drug coupons as having a number of inappropriate and negative effects on both consumer perception and behavior, which are detailed below:

- **Coupons interfere with the doctor-patient relationship:** By injecting a financial enticement into the patient's visit to a doctor, coupons increase the patient's desire to be prescribed a particular drug. If the physician refuses or recommends an alternate prescription or treatment, tension and mistrust between the physician and the patient can result, particularly if the consumer feels that they stand to lose an item of value (the savings that the coupon represents). Coupons foster the notion that prescription drugs are just another consumer product, diminishing the importance of the doctor's role in counseling the patient and in acting as an intermediary between the consumer and the drug.
- **Coupons foster overuse of brand-name drugs at the expense of generic drugs:** Prescription drug coupons are used to build sales and market share for brand-name drugs, usually in therapeutic classes with stiff competition (e.g. those that treat gastric reflux, cholesterol, erectile dysfunction, insomnia, etc). They are most often used for newer (and thus more expensive) drugs. They are generally not used for generic drugs, since there is no way to ensure that a prescription would be filled with a particular manufacturer's version of the generic drug.

Generic drugs cost on average \$60 less per month than brand-name drugs.⁹ In many therapeutic classes where generics are available, more expensive brand-name drugs are heavily overutilized, even when the generics are of equal clinical value. This is overwhelmingly a consequence of aggressive marketing by brand-name manufacturers. A study by ExpressScripts Inc. showed that consumers, employers and health plans could have saved \$20 billion in 2004 through greater use of generics in just six therapeutic classes.¹⁰ Not surprisingly, these six classes are ones in which DTCA and coupons are often utilized: gastrointestinal drugs, cholesterol-lowering drugs, calcium channel blockers, antihypertensives, NSAIDs and antidepressants.

As described above, consumers often place greater value on a price reduction through a coupon than through a lower overall price. A coupon creates the perception that the consumer is getting a "deal," whereas, somewhat counterintuitively, a lower price can

⁹ Emily Cox, PhD, Andy Behm, PharmD, Doug Mager, Steve Miller, MD, "2004 Generic Drug Usage Report," Express Scripts, www.express-scripts.com/ourcompany/news/outcomesresearch/onlinepublications/study/gdur.pdf (accessed March 30, 2006).

¹⁰ Id.

give the consumer the impression that the product is of lower value. One study showed that 30 percent of consumers who used coupons assumed that they were getting the lowest price by using the coupon without first having compared prices.¹¹ Thus, it is likely that many consumers assume that by using a prescription drug coupon, they are getting the lowest price possible, when in many cases an unadvertised generic would have been equally effective and cheaper. This has a particularly negative effect on low-income consumers and consumers who lack prescription drug coverage. Coupons may introduce them to a drug that they can later not afford when they do not have a coupon. As patients tend to continue using particular drugs once they have begun using them and found them effective, this may lead low-income consumers to struggle to continue to pay for an expensive brand-name drug, rather than use a cheaper and equally effective generic drug.

- **Coupons inevitably affect the perception of risk and benefit:** Consumers' perception of a drug's risks and benefits is a function not just of efficacy and side effect profile but of the perception of 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, music and the like (what we refer to as the "fields of flowers" effect, for the frequent images in drug ads of happy people frolicking through fields of flowers). Coupons are often the only mention of price, or of anything monetary, in advertising for a particular drug. Given that coupons are shown to increase consumer perception of the value of a product, it is axiomatic that drug coupons increase the consumer perception of the value of a drug. Thus, it is inevitable that drug coupons, by increasing the consumer's perception of the drug's value overall, will dampen their impression of the drug's risks and exaggerate their impression of the drug's benefits.
- **For consumers with government prescription coverage, coupons can constitute an illegal kickback:** The federal Anti-Kickback Statute¹² prohibits the offer or payment of any "remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person to purchase...any good...or item for which payment maybe made in whole or in part under a Federal health care program." This definition encompasses prescription drug coupons used by beneficiaries of Medicaid, Medicare and other Federal health care programs, since a coupon is the offer or payment of remuneration in cash or in kind to induce beneficiaries to purchase drugs.

While many prescription drug coupons explicitly state that they are not valid for such beneficiaries¹³ of federal health care programs, the fact that such inducements are

¹¹ Jerry N. Conover, *The Influence of Cents-Off Coupons on Brand Choice Decisions at the Point of Purchase*, *Advances in Consumer Research*, Vol 16, 443-446 (1989).

¹² 42 U.S.C. § 1320a-7b(b).

¹³ See, e.g., "Answers to your Frequently Asked Questions about Allegra Extras," www.allegra.com/allegraSavings/allegraExtras.do (accessed March 30, 2006) ("Offer not valid for prescriptions reimbursed or paid under Medicare, Medicaid or any similar federal or state health care program, including any state medical or pharmaceutical assistance programs.")

prohibited by the Anti-Kickback Statute underscores the dangers of such coupons even outside of the realm of federal health care programs. For the majority of American consumers who have prescription drug coverage in which a third party pays for most of the cost of a prescription (less a copayment or co-insurance), coupons amount to a form of bribe or kickback, to the detriment of the third party paying the lion's share of the actual price. Since coupons induce consumers to use more expensive, brand-name medications, they contribute to the escalating cost of health care in the United States and to prescription drug cost burden under which health plans and employers are struggling.

In sum, we believe prescription drug coupons have negative effects on consumers, on their perceptions of risks and benefits, on the doctor-patient relationship, on the overutilization of brand-name drugs at the expense of cheaper generics, and on the rising cost of prescription drugs and health care generally. It is these negative effects that lead us to recommend that prescription drug coupons be prohibited by regulation.

Recommendations on Coupons Generally

As stated at the beginning of these comments, we recommend that the FDA promulgate regulations and/or guidances prohibiting the use of coupons (as defined above) for any drug for which a prescription is required under 21 U.S.C. §353(b). Such a ban could be implemented in stages, beginning with a ban on the use of coupons for drugs for which such promotions have the greatest negative effect. For example, we feel that the drugs for which coupons are most inappropriate, and for which a ban on coupons is most urgent are:

1. Any drug with a **“black box”** warning
2. Any drug which the FDA has designated as **Pregnancy Category C, D or X.**

If the FDA decides not to ban coupons, we recommend that the FDA promulgate a guidance or regulation that **prohibits the inclusion of a coupon in a “reminder advertisement,”** i.e. an advertisement which contains the name of a drug but nothing about its indication. Because prescription drug coupons materially affect the consumer's perception of a drug's effectiveness, we feel that the inclusion of a coupon in any advertisement constitutes a statement that falls within the requirements of the “brief summary” as defined in 21 CFR §202.1(e)(1). Thus, we recommend that the FDA find that the inclusion of a coupon renders an advertisement ineligible to be considered a “reminder advertisement” under 21 CFR §202.1(e)(2). The FDA should require that advertisements with coupons contain either the full brief summary, or, in the case of broadcast advertisements, the major statement and adequate provision.¹⁴

Recommendations on the Study to be Conducted

- **Include consumers who do not suffer from insomnia:** The Federal Register Notice announcing the study states that “Consumers will be screened and recruited by the contractor to be currently diagnosed with insomnia or at risk of developing insomnia.” We feel that this improperly narrows the study population. One effect of DTCA, including

¹⁴ 21 U.S.C. 352(n)

coupons, is to give otherwise healthy people the impression that normal features of human experience (such as occasional insomnia) are medical conditions requiring treatment with prescription drugs. Insomnia medications are one of the most widely-advertised classes of drug today, and such advertisements are promoting significant overuse and abuse of sleep medications. We recommend that the FDA include consumers in the study who do not currently suffer from insomnia nor who are risk of developing it. Such consumers should be included both because DTCA and coupons may induce them to seek such medications, and because they can function as a “control group” against whose responses the consumers with insomnia can be compared.

- **Include consumers with a range of reading abilities and English-speaking abilities:** The notice states that “Because the task presumes basic reading abilities, all participants will have English as their primary language.” We believe that both of these criteria inappropriately narrow the study participants. Consumers who have either limited reading ability or limited English proficiency can still be and are in fact influenced by both DTCA and coupons. In fact, they are more likely to be improperly influenced by prescription drug coupons than other consumers – a coupon stating “**\$10 off!**” can be understood by most consumers, even those with limited literacy or English abilities, whereas the risk and benefit information required in the brief summary cannot. Thus, the inclusion of a coupon can overstate the benefits and effectiveness of a drug in the eyes of such consumers while not being balanced by the risk and side effect information contained in the brief summary. Because of these effects on consumers with limited literacy and English-speaking abilities, we feel that such consumers should be included in the study, perhaps as a separate sub-group for whom a specific evaluation is done.
- **Drug coupon promotions targeting children should be studied:** We laud the FDA for undertaking this study and hope it will lead to agency action to curb the negative effects of drug coupon marketing. There is a disturbing and growing trend towards coupon-style marketing for prescription drugs which targets children. We recommend that the FDA undertake a study specifically on the effects of coupon marketing on children, and that the FDA take action to ban or severely restrict such promotions targeting children. An appendix showing two examples of such promotions immediately follows these comments.

Conclusion

We are glad that the FDA is undertaking this study. We hope that this indicates that the FDA is following up on the recommendations of PAL and other consumer advocates at the FDA’s Hearings on Direct-to-Consumer Advertising in November 2005. We hope that this study is an indication of new initiative at the FDA to curb the worst excesses of DTCA and to step up oversight and enforcement at the Division of Drug Marketing, Advertising, and Communications (DDMAC). We think that the negative effects of prescription drug coupons are already evident, and that the FDA’s study will bear that out. We urge the FDA to follow up the study with regulatory action and/or guidances to prohibit the use of coupons in prescription drug advertisements, beginning with prohibiting coupons for drugs with black

box warnings, drugs that are in Pregnancy Categories C, D, or X, and for reminder advertisements. Thank you for the opportunity to submit these comments.

Sincerely,

Alex Sugerman-Brozan
Director, Prescription Access Litigation Project
Community Catalyst, Boston, MA

Also on behalf of:

Action Alliance of Senior Citizens
Philadelphia, PA

American Federation of State, County and
Municipal Employees (AFSCME)
Washington, DC

The Annie Appleseed Project
Delray Beach, FL

Congress of California Seniors
Sacramento, CA

Connecticut Citizen Action Group
Hartford, CT

Consumers for Affordable Health Care
Coalition
Augusta, ME

Consumers Union
Washington, DC

Gray Panthers California
Sacramento, CA

Health Care for All
Boston, MA

Health Care for All Coalition
Hartford, CT

JPAC for Older Adults
New York, NY

Long Island Health Access Monitoring Project
Great Neck, NY

Massachusetts Breast Cancer Coalition
Quincy, MA

Massachusetts Senior Action Council
Boston, MA

MassPIRG
Boston, MA

Metro New York Health Care for All Campaign
New York, NY

Minnesota Senior Federation
St. Paul, MN

New York Statewide Senior Action Council
Albany, NY

Tennessee Health Care Campaign
Nashville, TN

United Senior Action of Indiana
Indianapolis, IN

Utica/Central New York Citizens in Action
Utica, NY

U.S. PIRG
Washington, DC

Wisconsin Citizen Action
Madison, WI

APPENDIX: DRUG COUPON PROMOTIONS TARGETTING CHILDREN

Home | For Healthcare Professionals | GALDERMA

About Acne | About Differin® | Skin Care | Ask Your Doctor | Special Offers

Music Program | Rebate | Adults | Teens | Parents

About Acne
About Differin®
Before and After Photos
Skin Care
Special Offers
Emotional Impact of Acne

Get Free Music. Fight Acne. Stay Cool.

Get free music downloads from Differin® and RealPlayer Music Store - every time you fight acne with Differin®. RealPlayer Music Store has all the hit music you love, from rock to rap, from country to pop. It's ready and waiting.

[Sign up now](#) to download free music and receive tips and ideas for keeping your skin looking great.

Note to registered users: Do you need to print your proof of purchase form? [Do it here.](#)

| Level | Requirement | #of Free Music Downloads |
|-------|-------------------------------------|--------------------------|
| 1 | Sign Up | 2 |
| 2 | Get and Fill Differin® Prescription | 7 |
| 3 | Refill Differin® Prescription | 10 |

Note: There is a limit of one set of music codes per household per pharmacy receipt.

Sign up Tell a friend

RETIN-A MICRO®
tretinoin gel microspheres, 0.04% / 0.1%
from OrthoNeutrogena

If you've been prescribed RETIN-A MICRO®...
It's time to get unplugged™

A FREE email series guiding you to clearer skin

- Teen acne and skincare info and tools
- Skincare coupons and rebates
- Rewards—and more!

[To preview *Unplugged™*, click here.](#)

Get rewards when you get *Unplugged...*
As you progress through treatment, you'll enjoy various rewards—including skincare product samples, savings, and more!

To get *Unplugged* tell us where you stand:

(Select One)

> Continue