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The Future of Prescription Samples, Vouchers, and Coupons: Stakeholder Perspectives

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I. Executive Summary

Changing market and political dynamics are forcing the pharmaceutical industry to reevaluate the practice of drug sampling. As a result, there is a growing interest in the use of coupons and vouchers, although the exact role they can play in the marketing mix remains unclear. Considering today's challenging and more regulated environment, it is critical to determine how coupons and vouchers can augment current sales and marketing efforts as a means toward improving patient outcomes. This research initiative was conducted to explore possible positioning of coupons and vouchers through the analysis of:

- Stakeholder perspectives
- Competitive trends
- Policy landscape

Stakeholder perspectives on coupons and vouchers are misaligned. From the physicians' perspective, they strongly prefer samples over coupons or vouchers due to convenience, familiarity, and the perception of value. On the opposite end of the continuum are the payers who prefer coupons over vouchers or samples since there is a lower potential for steering utilization and a greater opportunity to improve compliance (however, payers generally perceive all offerings from the pharmaceutical industry as negative). In the middle are patients and pharmacists who do not have very strong preferences. Although consumers tend to value a "risk-free" trial and/or financial assistance with samples, coupons, or vouchers somewhat similarly, they may prefer samples for new prescriptions and coupons for refills. Pharmacists believe that in comparison to samples, coupons and vouchers are more likely to facilitate medication counseling and to encourage patient compliance; however, their preferences are curbed by the negative experience of processing logistics, especially with coupons.

In general, all stakeholders have very limited experience with coupons and vouchers. In the physician practice setting, as reported by physicians and patients, coupons and vouchers are distributed to approximately 10-15% of patients for a very limited number of products (fewer than 10). In the retail setting on a weekly basis, pharmacists process coupons or vouchers for fewer than 30 prescriptions. Pharmacists are reporting a growing trend in the use of coupons and vouchers. Moreover, two-thirds of pharmacists report handing out coupons (for 6 products on average) and one-third of pharmacists report handing out vouchers (for 4 products on average). The use of coupons and vouchers was associated with a number of important consumer findings—of the 3 consumer groups surveyed, those who have received and used coupons and vouchers tend to receive, seek, and redeem them more frequently than other consumer segments studied, possibly because they tend to assign a higher value to these offerings.

Even though there are considerable differences in stakeholder perceptions, feedback on improving usability from physicians, pharmacists, and patients typically follows 3 general themes—simplify the process, improve distribution and visibility, and enhance value (Table I-1). Feedback indicates that there may be some opportunities to partner with payers on coupon programs that integrate with compliance/disease management programs or tier 2 pull-through initiatives.

Table I-1. Stakeholder Suggestions for Improvement

Theme	Physicians	Pharmacists	Patients
Simplify the process	• Less paperwork • No mail-in rebates • Product-specific offerings	• Simpler processing • Product-specific offerings	• Less paperwork and restrictions • No mail-in rebates
Improve distribution and visibility	• Distribution in pharmacies • No consumer channels • Attachments to sample packaging	• Distribution in pharmacies • Attachments to product packaging/behind-the-counter shelves	• Bundling with product information or starter kits
Enhance value	• ≥$20 coupons • Multi-use coupons • ≥1-month supply vouchers	• ≥$15 coupons • ≥2-week supply vouchers	• ≥$10 coupons • Multi-use coupons

Analysis of competitive trends demonstrated that two-thirds (25 out of 38) of heavily promoted products offer coupons or vouchers to consumers. Merck competitors equally use coupon and voucher programs but few offer both coupons and vouchers for a single product. In terms of economic value, most programs that were evaluated fall within the expectations of consumers and pharmacists. Approximately 50% of the evaluated programs also meet physician expectations; however, half of the coupon programs still use mail-in rebates and do not offer multi-use coupons.

Advocacy groups, legislators, and regulating authorities tend to align with the perspectives of the private payers. By and large, there is a negative perception of any program sponsored by the pharmaceutical industry due to the concerns of steering to inappropriate utilization. While there are very few current limitations on coupons and vouchers from a state or federal perspective, there is clearly a movement to add restrictions. Although the latest federal policy threat to include coupons and vouchers into average manufacturer price (AMP) and best price calculations has not been realized, it has raised concerns within the pharmaceutical industry about the viability of these programs in the future. Given the developing role of the federal government in prescription medications and the growing scrutiny of pharmaceutical practices by the states, it is likely that the pressure will grow and other restrictions will be advocated and possibly enacted. This illustrates the need to educate key stakeholders on the value of medications in seeking to improve the quality of life of patients as well as reducing overall medical expenses.

On the basis of these findings, the following recommendations are proposed:

- Sampling
    - Considering physician preference for samples and related implications for product loyalty, coupons and vouchers should be positioned with physicians as a supplement to samples (as opposed to an alternative)
    - Attaching coupons to samples may be an effective way to promote continued use of prescription products
- Positioning with physicians
    - Physician attitudes toward coupons and vouchers may gradually change if they understand that (1) coupons and vouchers can augment the value of samples, (2) consumers are interested in coupons that can apply to refills, and (3) an extra trip to the pharmacy for processing coupons or vouchers promotes patient safety and compliance; physicians may also benefit from an educational outreach program that emphasizes the benefits of coupons and vouchers to their patients, thereby highlighting the benefit of tracking such programs and their potential impact on compliance and persistence

- Use and distribution of coupons and vouchers
    - Consumer demand for coupons and vouchers may be directly related to the extent of their experience with these offerings; increased exposure to and distribution of coupons and vouchers may result in increased interest and use/redemption
    - Distribution of coupons in the pharmacies should be evaluated and possibly expanded to encourage compliance with refills
- Paperwork and processing
    - Reasonable efforts should be made to reduce paperwork, lessen restrictions, and simplify processing; for instance, the following may be considered:
        - Eliminate any steps requiring activation by physicians
        - Avoid mail-in rebates
        - Clearly communicate any restrictions to patients
        - Simplify processing for pharmacists
- Visibility and storage
    - In order to improve redemption of coupons and vouchers, efforts should be made to increase visibility for physicians, pharmacists, and patients; for instance, the following may be considered:
        - Attach coupons and vouchers to samples and product packaging
        - Create starter kits that include coupons and vouchers
        - Design coupons and vouchers to include tear-off product/disease information
        - Consider printing prescription pads with tear-off coupons and vouchers
        - Design storage devices that can be affixed to the shelf where samples in the sample closet or products in the pharmacy are located
        - Consider promoting coupons at the pharmacy counter
- Coupon/voucher value
    - Coupons should offer a discount of at least $10, preferably $20
    - Coupons should apply to more than one fill to encourage compliance
    - Vouchers should offer at least a 2-week supply of therapy, preferably a 1-month supply
    - Include coupon/voucher as part of the patient education brochure to promote appropriate medication use and disease management
- Policy
    - To ensure the future of coupons and vouchers, it may be of value to implement programs that can target compliance or disease management (in coordination with federal, state, and private payers)
    - Legislative and regulatory trends should be closely observed and monitored to understand implications for coupon and voucher programs
    - Educate key stakeholders on the role that samples, coupons, and vouchers play in seeking to improve the quality of life of patients as well as reducing overall medical expenses

- Other trends that may impact sampling, coupons, and vouchers include the following:
    - Evolving technologies that impact provider practice
        - E-prescribing
        - Electronic medical records
    - New practice settings
        - Convenient care clinics
    - Increasing patient involvement in healthcare decisions
        - Patient utilization of the Internet
        - Consumer-driven health care

Review of the Literature:

Drug Sampling: Overview

The distribution of samples to patients can be structured into 3 categories, the first consists of samples given to newly diagnosed patients with a prescription, the second is samples given to previously diagnosed patients with a prescription, and the third is samples given to patients with no prescription."[1]

During the first 6 months of 2004, Impact Rx collected longitudinal sample usage data from networks of more than 3000 high-volume prescribing primary care physicians and specialists to evaluate the distribution of samples by the 3 categories (Table II-1).[2] Findings reported that 60% of all samples are dispensed without an accompanying prescription; this is strong evidence to support the amount of the financial assistance that is provided by pharmaceutical manufacturers.

Table II-1:

Sample Distribution

THERAPEUTIC CLASS	% SAMPLES TO NEW PATIENTS WITH RX	% SAMPLES TO PREVIOUSLY DIAGNOSED PATIENTS WITH RX	% SAMPLES TO PATIENTS WITH NO RX
Osteoporosis	43%	27%	30%
Enlarged prostate	36%	14%	50%
Erectile dysfunction	34%	8%	58%
Migraine	30%	9%	61%
Allergic rhinitis	30%	6%	64%
Statins	29%	28%	43%
Alzheimer's	28%	13%	59%
Depression	27%	10%	63%
Asthma	26%	11%	63%
Proton pump inhibitors	26%	10%	64%
Oral solid antibiotics	24%	0%	76%
COX2 inhibitors	22%	6%	72%
Antipsychotic	21%	13%	66%
Oral anti-diabetics	20%	29%	51%
Angiotensin receptor blockers	19%	26%	55%
Hypertension	17%	26%	57%
Mean Across Classes	**27%**	**15%**	**58%**

SOURCE: ImpactRx

1. Lurker N, Caprara, B. The sampling subsidy. *Pharmaceutical Executive*. 2005.
2. Lurker N, Caprara, B. The sampling subsidy. *Pharmaceutical Executive*. 2005.

The retail value of samples distributed each year to physicians is one of the biggest promotional expenditures for a pharmaceutical manufacturer. According to IMS Health records, spending on samples has increased from $7.4 billion in 1997 to $18.4 billion in 2005.[3] This may, in part, be due to the increasing role that samples play in pharmaceutical representatives gaining access to physicians.

A growing number of medical centers, as well as some medical groups and solo practitioners, are banning or restricting the use of samples. The University of Michigan Health System has completely banned the use of free samples; however, a system of vouchers for a limited list of medications has been created to allow patients to receive free starter doses from the pharmacy of their choice. Only vouchers approved by the in-house formulary committee, for medications that have been identified as "preferred" because of their efficacy and cost, may be distributed.[4] University of Pennsylvania and Stanford University medical schools have also enforced a ban on samples. With several other health systems and medical centers considering similar restrictions, it is likely this list will continue to grow. The scrutiny on free samples is mainly due to the perceived impact of samples on prescribing practices; however, the growing concern about close ties between physicians and pharmaceutical manufacturers, rising prescription costs, and concern over expired samples also play a role.[5] The most vocal critics tend to cite studies such as the 2002 paper published in the *Annals of Family Medicine*. Findings from this study showed that the number of physicians who treated high blood pressure with first-line drugs recommended by national guidelines was low but significantly increased when samples were removed.[6] Other groups focus on a less harsh stance regarding samples and support "Taming the Sample Closet." This approach presented by Dr. Mitchell Cohen follows a few simple steps to allow physicians' offices to take control of samples before the samples take control of their offices.[7]

Health care payers are demonstrating an interest in generic drug sampling. Health plans encourage members to use generic drugs through reduced copayments. It is perceived that encouraging physicians to prescribe generic drugs continues to offer a cost-savings opportunity for plans without compromising safety or efficacy. At the end of 2006, Blue Cross Blue Shield of North Carolina joined with MedVantx to create an automated drug delivery network providing physician offices with kiosks that dispense free generic drug samples for both insured and uninsured patients.[8] A recent study published within the *Journal of Managed Care Pharmacy* showed that physician practices participating in the generic sampling program (2005-2006) demonstrated an increase in the average generic drug ratios compared with all other network physicians and that the direct drug cost savings after subtraction of all administrative costs associated with the generic sampling program were estimated at $1321 per physician in 2005, and $719 per physician in 2006. Members benefited from a $0 copay for the generic drug samples and from lower copayments for continued use of the generic drugs.[9]

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3. IMS Health Report. 2005.
4. Drug samples, drug reps, and beyond. *University of Michigan Health System*. 2006.
5. Drug samples, drug reps, and beyond. *University of Michigan Health System*. 2006.
6. Zweifler J, Hughes S, Schafer S, et al. Are sample medicines hurting the uninsured? *J Am Board Fam Pract.* 2002;15:361-366.
7. Cohen M. Taming the samples closet. *Family Practice Management*. 2006.
8. Kiosks dispense free drugs; Blue Cross gives away generics. *News & Observer*. 2006.
9. Scott A, Culley, E, O'Donnell J. Effects of a physician office generic drug sampling system on generic dispensing ratios and drug costs in a large managed care organization. *J Manag Care Pharm.* 2007;13(5):412.

For more than 30 years, sampling has been a standard practice for pharmaceutical manufacturers; however, over the last few years newer technologies and approaches have started to replace office-based sampling with electronic/paper coupons and vouchers. In 2001, *Pharmaceutical Executive* published a piece entitled, "Vouchers: More Data, Fewer Dollars." In this piece, survey results indicated 50% of physicians (surveyed) preferred coupons and vouchers to product samples. Reasons included decreasing liability, ease of management, and proper labeling. As for the physicians who preferred samples, patient interaction and the ability to observe patients after they take their medications were cited as reasons.[10]

Drug Sampling: Pros

Key Points:

- Help drive patients to physicians for assessment
- Improve manufacturer–physician–patient relationships
- Provide needed therapy for low-income patients
- Heighten product awareness within practice settings

Drug sampling has many benefits, one of which includes face-to-face interactions with patients and physicians.[11] Drug sampling, similar to direct-to-consumer advertising, is a way to get the patient into the doctor's office for proper assessment and treatment. Sampling can also assist in enhancing the relationship between drug manufacturers, physicians, and patients. When a physician is able to better serve the patient by reducing costs, the patient is pleased; therefore, physicians tend to express a high degree of gratitude to the industry for providing their patients with samples.[12] Sampling provides physicians the ability to test the efficacy and tolerability of a drug and allows for dose adjustment before writing a prescription, and it allows patients the opportunity to immediately begin the course of therapy.[13] Drug samples play a role in providing therapy to patients who cannot afford it, although over half of the physicians surveyed did not ask about prescription coverage. There are physicians who even refuse to give samples to patients with prescription drug coverage, preferring to save those samples for patients without it.[14] Providers who are not familiar with a given sample available to patients are less likely to prescribe this drug. According to a study conducted by Adair and Holmgren (2005), access to drug samples in clinics influences resident prescribing decisions.[15]

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10. Singer, S. Vouchers: more data, fewer dollars. *Pharmaceutical Executive*. 2001.
11. Tsang J, Rudycher I. The sample equation. *Medical Marketing & Media*. 2006.
12. Lurker N, Caprara B. The sampling subsidy. *Pharmaceutical Executive*. 2005.
13. Zweifler J, Hughes S, Schafer S, et al. Are sample medicines hurting the uninsured? *J Am Board Fam Pract.* 2002;15:361-366.
14. Lurker N, Caprara, B. The sampling subsidy. *Pharmaceutical Executive*. 2005.
15. Adair RF, Holmgren LR. Do drug samples influence resident prescribing behavior? A randomized trial. *Am J Med.* 2005;118(8)881-884.

Drug Sampling: Cons

Key Points:

- Unable to provide continued coverage
- Eliminate pharmacist involvement in medication oversight
- Limitations in sampling supply chain
- Extensive regulatory requirements
- Unintended waste of samples
- Perception that it may encourage use of inappropriate medications

Physicians rely on drug samples as a way to provide for the patients who are uninsured or for those who cannot afford the out-of-pocket costs, although over half of the physicians surveyed did not ask about prescription coverage; however, this is a short-term solution, and the larger problem still remains after the trial period is over—people who cannot afford medications will still not be able to afford them after they receive their free samples.[16]

According to a study conducted by Chew (2000), physicians are motivated to dispense samples in order "to avoid burden of cost to the patient." The study also indicates that samples may deprive many patients from pharmacist counseling.[17] With sampling, the pharmacist is often not counseled, which is potentially risky as it is the pharmacist's role to monitor potential drug interactions.[18]

Studies indicate that 71% of surveyed physicians reported that availability of sample packets from drug makers impacts their prescribing decisions. Of these, 38% indicated they do not receive enough samples through traditional delivery methods and 22% of physicians complain the supply of drug samples is too unpredictable.[19]

Over the last few years, sampling has come under increased scrutiny, with regulations specific to sampling listed under the Prescription Drug Marketing Act (PDMA). PDMA requires pharmaceutical companies to establish written policies and procedures for distributing samples, maintaining secure sample inventories, training and auditing sales reps, and preventing fraud and errors, and it requires physicians who distribute drug samples to meet requirements similar to those of retail pharmacy dispensing practices.[20]

According to research completed by Impact Rx, accounts from physicians indicate that significant quantities of samples are ultimately being discarded. This is wasted money to the company, which could be prevented if samples were filled at pharmacies.[21]

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16. Coupons for prescription drugs; why drug companies are offering coupons, and where you can get them. Available at: About.com. 2007.
17. Chew L, O'Young T, Hazlet T, Bradley K, Maynard C, Lessier D. A physician survey of the effect of drug sample availability on physicians' behavior. *J Gen Intern Med*. 2000;15:478-483.
18. Gebhart F. Pharmacists welcome vouchers in place of drug samples. *Drug Topics*. 2002.
19. Drug reps must embrace technology to avoid missing sales opportunities. *Pharmaceutical Business Review Online*. 2006.
20. Gebhart F. Pharmacists welcome vouchers in place of drug samples. *Drug Topics*. 2002.
21. Lurker N, Caprara, B. The sampling subsidy. *Pharmaceutical Executive*. 2005.

Critics of drug sampling argue that such waste has the potential to increase healthcare costs by encouraging the use of brand name drugs instead of less expensive generic equivalents. Not only is there potential for increased healthcare costs, the use of coupons may discount the ability of generic companies to compete in the marketplace.[22]

Drug Coupons and Vouchers: Overview

According to the literature, coupons and vouchers are most often offered for[23]-[24]:

- Advair HFA, Avandia, Avodart, Flonase, Imitrex, Wellbutrin XL, (GlaxoSmithKline)
- Glucophage XR (Bristol-Myers Squibb)
- Diovan, Elidel, Enablex, Lamisil, Lotrel, Miacalcin, Zelnorm (Novartis)
- Detrol LA, Liptor, Viagra, Zoloft, Zyrtec (Pfizer)
- Crestor, Nexium (AstraZeneca)
- Clarinex, Nasonex (Schering-Plough)
- Cialis (Lilly)
- Ortho Evra (Ortho-McNeil Pharmaceutical)
- Prevacid (Tap Pharmaceutical Products Inc.)
- Xenical (Roche)
- Omnicef (Abbott)
- Adderall XR (Shire)
- Ambien (Sanofi-Aventis)

Drug Coupons and Vouchers: Pros

Key Points:

- Drive patients to physician offices
- Allow the patient to interact with a pharmacist
- Effective in building brand loyalty among patients (high satisfaction with savings)
- Successful in driving physician prescribing habits through the reduction in time spent by physician staff on management of cumbersome sampling process
- Alleviate the need to manage time spent conforming to PDMA regulations
- Provide savings to manufacturers over sampling process
- Provide opportunity for data collection

Coupons and vouchers, which resemble direct-to-consumer advertising, are a way to get the patient into the doctor's office for proper assessment and treatment. Coupons/vouchers have many benefits; one important benefit to highlight is the added interaction with pharmacists, one that traditional sampling does not allow. The pharmacist plays a critical role in minimizing drug interactions and provides the patient with information regarding dosage, side effects, and proper storage.[25] A survey by the Kansas Pharmacists

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22. Drug coupons may be no bargain. *Boston Globe*. 2006.
23. Drug makers offer coupons for free prescriptions–but patients still have to get their physician's approval, and most don't pay for pills. *Wall Street Journal*. 2002.
24. Coupons for prescription drugs; why drug companies are offering coupons, and where you can get them. Available at: About.com. 2007.
25 Gebhart F. Pharmacists welcome vouchers in a place of drug samples.(2002) *Drug Topics*

Association showed that "81% of pharmacists surveyed said they are seeing an increase in sample coupons." They hope coupons will continue to increase, mostly because this brings the pharmacists back into the loop.[26]

It has been shown that coupons and vouchers equally motivate new and current users; therefore, coupon discounts can motivate patients to try a new brand. The previous PDI study indicated that, on average, new or lapsed users of the product generated 53% of FSI coupon's redemptions, which could help to build a consumer base.[27]

Because of the high satisfaction with savings, coupons and vouchers can assist pharmaceutical manufacturers in building brand loyalty. Building loyalty within certain patient populations is easier than others. For example, because patients on a "lifestyle" medication (eg, Viagra) take their medications sporadically for extended periods of time and typically pay a higher copayment, they are more likely to continue use of the medication if they receive coupons and discounts.[28]

With the use of vouchers, physicians can stock coupons instead of actual samples. There are numerous benefits to using coupons and vouchers for a physician, including reduced liability, ease of management, and proper labeling practices.[29]

The use of coupons and vouchers allows tracking data on where, when, and how they are used as well as whom they are used by. Important data, such as sample size, dosage, patient information, and the authorizing physician, are readily available and accessible. These data provide valuable information to pharmaceutical manufacturers for targeting key demographics and enhancing marketing efforts for branded products.[30] In addition, these data provide health plans with information to assist in making formulary decisions, marketing efforts, and other heathcare services.[31]

According to the 2004 Impact Rx study, less than half of the $10 billion dollars worth of prescription samples are generating any revenue. The reason for this is unknown; however, coupons and vouchers can aid in decreasing such a loss through the ability to keep and track records.[32] In addition, coupon/vouchers allow manufacturers to save money, reduce costs spent on wasted expired products, save costs of shipping and stocking samples, and decrease the amount of time sales reps spend stocking samples for physicians.[33]

Coupons and vouchers help alleviate several of the problems that are involved with samples. By increasing the number of sample vouchers, physicians can step aside from the PDMA, which requires physicians who distribute samples to meet specific requirements similar to those of retail pharmacy dispensing practices.[34]

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26 Gebhart F. Pharmacists welcome vouchers in a place of drug samples.(2002) *Drug Topics*
27. Studies indicate coupons are an effective promotional tool. *Santella & Associates*. 1998.
28. Coupons for prescription drugs; why drug companies are offering coupons, and where you can get them. Available at: About.com. 2007.
29. Singer S. Vouchers: more data, fewer dollars. *Pharmaceutical Executive*. 2001.
30. Drug firms seek profit in giveaway. *The Boston Globe*. 2005.
31. Singer S. Vouchers: more data, fewer dollars. *Pharmaceutical Executive*. 2001.
32. Lurker N, Caprara B. The sampling subsidy. *Pharmaceutical Executive*. 2005.
33. Buta P, Smith S. Clipping coupons. *Pharmaceutical Executive*. 2004.
34. Gebhart F. Pharmacists welcome vouchers in place of drug samples. *Drug Topics*. 2002.

Drug Coupons/Vouchers: Cons

Key Points:

- Perception that it contributes to overutilization of expensive brand-name drugs without a benefit
- Inflate prescription drug value
- Supercede physician recommendations

Payers with a negative opinion of coupons and vouchers note their potential to contribute to overutilization of expensive, brand-name drugs instead of equally effective and much cheaper generics. A 2004 study demonstrated that employers and health plans alone could have saved nearly $20 billion a year through the use of generics in only 6 therapeutic classes."[35] Coupons/vouchers may hide the true cost of prescription medicines and lead patients to think they are getting a great deal, but in fact, the small, often one-time discount from a coupon does little to offset the dramatically higher costs of brand-name drugs. When compared, there is more savings from utilizing a generic drug then a one-time $10 coupon; this is particularly true in the case of long-term maintenance drugs.[36]

According to a study conducted by Monroe (1987), by increasing the patients' perception of a product's value you are inflating a prescription drug's value, which can be extremely detrimental to the patient. When patients inflate the value of a drug, they may also overlook the drug's side effect profile and the underlying illness.[37] The patient's desire for certain medications is, in most cases, based on price when it should primarily be based on whether that prescription drug is the right choice for them. This is why some people feel that the use of coupons prevents both physicians and patients from making the best medical decisions.[38]

Some proponents believe coupons and vouchers can cause a physician's medical knowledge and experience to be overlooked by patients as many are making their own decisions before even entering the physician's office. In other words, "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."[39]

Next, we draw upon Merck's internal experience with samples, coupons, and vouchers to identify themes, using the information to design our stakeholder research.

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35. Coupons, INC. 2004.
36. PAL: Prescription Access Litigation.
37. Monroe, Kent, and Chapman. Framing effects on buyers' subjective product evaluations.
38. Is the bargain worth the price? *Eye on the FDA*. 2006.
39. PAL: Prescription Access Litigation.

Overview of Merck's Experience:

To evaluate internal perceptions of samples, coupons, and vouchers, 18 qualitative interviews were conducted with key Merck personnel. Of those interviewed, 14 have direct experience with coupons and vouchers. Table II-2 provides a complete list of those interviewed.

Table II-2. List of Merck Interviewees

Mike Kelly, Executive Director, Federal Healthcare Affairs	Joseph A. Kozlowski, Senior Director, Customer Fulfillment
Elvin Knight, Associate Director, Customer Resource & Planning Development	Jane Horvath, Senior Director, Public Policy
Leo Mendez, Executive Director, Hospital National Accounts	Bob Gianetti, Associate Director, Managed Care Market Research
Kim Gwiadzinski, Senior Director, HMS	Chuck Grezlak, Vice President, Government Affairs and Policy
Dennis O'Brian, Senior Director, Managed Care Marketing	John Duardo, Director of Customer Fulfillment
Mark Stejbach, Vice President, Managed Care, Pharmaceutical Marketing	Bruce Hartman, Counsel Legal USHH
Dr. Paul Snyderman, Executive Director, Scope/Market Development	Bob Hunter, Executive Director, Government Affairs and Policy
Rob Shepherd, Executive Director, Managed Care Marketing MSP	Tyrone Edwards, Senior Vice President, Primary Care Sales
Charlotte McKines, Vice President, Marketing Communications	Kevin Paris

Interviews were conducted to assess the current gaps in knowledge and synthesize the findings of past market research projects before initiating this project. During the course of the interviews, several themes among perceptions emerged:

- Coupons offset out-of-pocket expenses
- Coupons and vouchers often get lost in physician offices and are merely a promotional tool
- Redemption rates are very low
- Vouchers are well received by physicians, but samples are still preferred
- Coupons and vouchers help with access by minimizing the financial burden to the patient and help with adherence and persistence
- Confusion exists around best price implications
- Restrictions on use of coupons in Part D patients may soon apply to all

In addition, respondents were asked to shift focus to the future of samples; when asked if samples will still be used in 5 years, the majority (14 of 18) replied with a definite yes. Of the remaining responses, 2 felt that changes in legislation would prevent the use of samples, and 2 did not know what the future holds. Elaborating on their thoughts, respondents shared that samples may be eliminated due to legislation

in 10 years, but that it would take legislation for such a change to occur in the industry. Other trends they foresee include increased use of vouchers, rebates, and starter kits.

After sharing their perceptions of and experiences with coupons and vouchers, the respondents were asked to formulate key unanswered questions they have regarding samples, coupons, and vouchers; responses are categorized below by stakeholder segment.

*Physician and Pharmacist-Focused Questions:**

- What are physician perceptions of coupons and vouchers?
- What is the perceived value?
- What is the acceptance level of coupons and vouchers?
- How are sample vouchers used in the in-patient setting?
- Do physicians screen patients for Medicare/Medicaid participation before distributing a coupon?
- What characteristics of coupons and vouchers are cumbersome?
- How do coupons and vouchers impact compliance and adherence?

** During the interview process, one major physician research study was shared, a Sample Alternative study conducted by The Robinson Group. Through this study, physician perceptions of samples, coupons, and vouchers were initially assessed. The key finding was that physicians prefer using samples, especially for new-start or low-income patients; however, they are open to using coupons and vouchers as long as they are simple, intended for multiple use, and offer a certain level of value. This research provided our team a baseline understanding of physician perceptions, which were used in designing questions to validate these findings and to explore additional themes with this audience.*

Consumer-Focused Questions:

- What are patient perceptions of coupons and vouchers?
- Can coupons and vouchers impact compliance/adherence?
- What is the minimum value threshold associated with coupons and vouchers?
- Do coupons and vouchers inspire loyalty to the product, physician, or pharmacist?
- What role does the Internet play in consumer use of coupons and vouchers?
- What are the characteristics of consumers who use coupons and/or vouchers?

Payer-Focused Questions:

- What is the perceived value?
- Do managed care organizations (MCOs) prefer to mail coupons to their population or do they prefer distribution by physicians?
- How do MCOs feel about the impact of coupons and vouchers on physicians?
- How do they feel about coupons for third-tier products?
- How do they feel about coupons to off set out-of-pocket costs in order to increase adherence?

The following general questions were raised regarding use of coupons and vouchers:

- What is the ROI of coupons and vouchers?
- What are the legislative developments?

Information and responses derived from the internal interviews were used to aid design of the overall project. Findings in the Stakeholder Perspectives section reflect many of the questions internal interview respondents shared. The Coupon and Voucher Trends section highlights competitive practices regarding coupons and vouchers. The Relevant Health Law and Policy Section briefly reviews current and proposed legislation that has the potential to affect the future of samples as well as coupon and voucher use within the pharmaceutical industry.

III. Stakeholder Perspectives

For this project, Kurkowski Market Research (KMR) was contracted to conduct a comprehensive market research study on perceptions and use of samples, coupons, and vouchers. The study was designed to obtain the perspective of 4 audiences: physicians, patients, pharmacists, and payers.

Methodology:

Three of the audiences—physicians, patients, and pharmacists—were investigated through a quantitative survey as well as qualitative interviews. The 3 surveys were designed through a joint effort of KMR and the ACI team. The fourth audience—payers—participated in qualitative interviews only.

In all 3 surveys, qualitative interviews were utilized to refine and validate the survey instrument before it was administered in the field. Then, after completion of the quantitative portion, qualitative interviews were used to gain further insight into the results. The sample sizes for the 4 audiences are summarized in Table III-1.

Table III-1. Stakeholder Interview Samples

Audience	"Pre" Interviews	Quantitative Survey	"Post" Interviews
Physicians	8 physicians	75 participants • 45 PCPs • 15 CARDs • 15 ENDOs	7 physicians
Patients	5 patients	600 participants • 200 received and used coupons and vouchers • 200 received, but never used, coupons and vouchers • 200 had no experience with coupons and vouchers	9 patients
Pharmacists	11 pharmacists	75 pharmacists • 55 chain • 20 independent	4 pharmacists
Payers	5 payers		5 payers

Participants from each of the audiences were screened according to criteria specific to this study. The major components of this screening are outlined below:

Physicians:

- Qualitative telephone interviews
  - Private, office-based practice
  - See at least 10 patients per week in the hospital setting
  - Between 1 and 30 years in practice
  - Accept coupons and vouchers from pharmaceutical companies for prescription medications
  - Self-report a rating of 2-5 with regards to the frequency with which they provide their patients with coupons or vouchers for prescription medications (on a scale of 1-5 with 1=never and 5=most of the time)

- Quantitative Web surveys [differences in screener]
    - Between 2 and 28 years in practice
    - Permitted to receive samples from pharmaceutical companies

Patients:

- Sample included the following 3 patient types:
    - Patients who have received and used coupons and vouchers
    - Patients who have received, but not used, coupons and vouchers
    - Patients with no experience with coupons and vouchers
- 18-75 years of age
- Not working in related industry
- Have not participated in related research in the last 3 months
- Mixture of educational backgrounds and incomes

Pharmacists:

- Included both chain and independent pharmacists in urban, suburban, and rural settings
- Between 2 and 28 years in practice
- Work in retail pharmacy, no less than 30 hours per week
- Personally prepare or dispense medications
- Accept and process coupons or vouchers for prescription medications
- Self reported as either "very familiar" or "somewhat familiar" with the processing of coupons or vouchers

Payers:

- Managed care medical or pharmacy directors
- Had familiarity with coupons and vouchers offered by pharmaceutical companies

Details about the samples are included in the appropriate sections of the report.
The "pre" and "post" qualitative interviews generally lasted 30-45 minutes and were conducted via telephone. The interviews were conducted via conference call service to permit monitoring by the research team. The surveys were administered and completed online. The client reviewed and approved the online questionnaires. Participants were awarded an appropriate honorarium to encourage a high rate of participation.

The interviews and questionnaires were completed according to the schedule outlined in Table III-2. Sample screeners and surveys are available in the Appendices section.

Table III-2. Stakeholder Interview Schedule

"Pre" Interviews	Quantitative Survey	"Post" Interviews
July 23-August 9, 2007	August 14-27, 2007	September 5-18, 2007

Physician Perspectives:

Demographics:

A total of 75 physician responders represented experienced physicians who practice in various outpatient settings throughout the United States (Table III-3). The sample included 45 primary care providers, 15 cardiologists, and 15 endocrinologists.

Table III-3. Physician Demographics

Physician Characteristics	PCPs (n=45)	CARDs (n=15)	ENDOs (n=15)	All (n=75)
Experience in practice, mean years	14	9	10	12
Region, number of respondents				
Northeast	4	2	4	10
Mid-Atlantic	7	4	2	13
South	9	3	2	14
Southwest	3	3	2	8
Midwest	11	1	4	16
West	11	2	1	14
Practice setting, % of respondents				
Multi-specialty group practice	31%	13%	53%	32%
Single-specialty group practice	13%	73%	33%	29%
Group family practice	40%	0%	0%	24%
Solo specialty practice	4%	13%	13%	8%
Solo family practice	11%	0%	0%	7%
Patient volume, mean number of prescriptions per week				
Inpatients	17	47	12	22
Outpatients	135	73	82	112
Prescription type, mean % of prescriptions per week				
New starts	39%	31%	24%	34%
Ongoing therapy	61%	69%	76%	66%

Key Findings:

Perceptions and Attitudes:

Extensive experience with drug samples has significantly shaped physician perceptions. They remain most receptive to samples, followed by vouchers, and then coupons (Table III-4). Survey responses reveal that cardiologists may be more receptive to coupons than vouchers; however, interpretation of this finding is limited by the small sample size (15 cardiologists).

Table III-4. Physician Receptiveness to Samples, Vouchers, and Coupons*

	PCPs (n=45)	CARDs (n=15)	ENDOs (n=15)	All (n=75)
Samples	4.4	4.5	4.6	4.4
Vouchers	3.6	3.9	3.9	3.7
Coupons	3.3	4.1	3.5	3.5

*Rated on a 5-point scale: 5=strongly positive, 3=neutral, 1=strongly negative.

Physicians believe that samples provide the best means for ensuring a risk-free trial (eg, tolerance, titration, bridging), as motivation for patient compliance and for assisting patients financially. A detailed analysis of physician attitudes shows that coupons and vouchers are considered less desirable than samples, primarily due to the following negative perceptions:

- Coupons and vouchers require a trip to the pharmacy
- Coupons and vouchers offer relatively low value
- Coupons and vouchers are cumbersome to use/store

Even when asked to identify situations in which coupons or vouchers are more useful than samples, physicians frequently respond that samples are generally more useful than coupons (27 out of 67 open-ended responses) or vouchers (20 out of 61 open-ended responses). Table III-5 lists positive features that were perceived by physicians to be attributed more to coupons or vouchers than to samples. Interestingly, physicians tend to discriminate against coupons and vouchers despite recognizing their benefits in reference to storage, inventory, and organization. In addition, it is important to note that physicians believe that coupons and vouchers reinforce patients to fill prescriptions at the pharmacy.

Table III-5. Positive Features Attributed by Physicians to Coupons or Vouchers*

	Applies to Samples	Applies to Coupons	Applies to Vouchers	Applies to None of These
Take up more shelf space	89%	4%	5%	8%
Require documentation and inventory management	81%	9%	13%	17%
Good for scheduled agents, such as sleep aids or narcotics	9%	27%	40%	52%
Best for continuing-therapy patients	36%	56%	35%	23%
Easy for the patient to carry	29%	79%	80%	11%
Good for getting patients to fill a new prescription	40%	49%	73%	11%
Good for getting patients to refill their prescription	21%	65%	55%	20%
Difficult or time-consuming to organize	47%	39%	37%	32%

* Physicians indicated whether a series of statements applied to samples, coupons, vouchers, or none of these.

Experience and Use:

Physician experience with coupons and vouchers is rather limited. Surveyed physicians reported having coupons or vouchers for a relatively small number of products. On average, physicians have coupons and vouchers for 7 and 6 products, respectively. Primary care providers may have a greater variety of coupons and vouchers on hand than the specialists. Furthermore, physicians often forget to use coupons or vouchers. Less than 15% of the respondents' patients receive coupons or vouchers. Although physicians tend to use samples primarily for new starts, there are no significant differences in the use of coupons or vouchers for new starts or patients who are continuing therapy (Table III-6).

Table III-6. Distribution of Samples, Coupons, and Vouchers for New Starts or Continuing Therapy

	New Starts	Continuing Therapy
A sample with or without a prescription	42%	21%
A coupon and a prescription	6%	7%
A voucher and a prescription	6%	5%
A sample, voucher, and a prescription	3%	-
Nothing, just a prescription	43%	68%

Vouchers and coupons are often used for patients without prescription coverage, almost as frequently as samples. However, a greater proportion of coupons than vouchers or samples are used to offset high out-of-pocket costs for patients with prescription coverage (Table III-7). Despite restrictions on the use of coupons for Medicare or Medicaid beneficiaries, only 43% of physicians screen patients for coverage before handing out coupons. In addition, it was reported that vouchers and coupons are rarely used in the in-patient setting despite the benefit in ensuring improved adherence with discharge medications. In 90%

of instances, physicians rarely or never use coupons in the institutional setting, which again represents a lost opportunity.

Table III-7. Distribution of Samples, Coupons, and Vouches by Patient Attributes

	Samples	Coupons	Vouchers
Patients without insurance	42%	34%	41%
Patients with insurance, but high copay	17%	30%	20%
Any patient	15%	14%	15%
Patients who request samples	11%	10%	10%
Patients with a history of low tolerance	8%	6%	8%
Patients with adequate insurance who may not comply	7%	6%	7%

No specific "winning" or "losing" coupon/voucher programs were identified by physicians. Reflective of their limited experience with coupons and vouchers, the majority of responses (31 to 46 responses) simply stated "I don't know." Merck and GSK were the top 2 companies mentioned to have the best coupon/voucher programs (8 responses each).

Preferences and Opportunities:

Physician preference for samples affects their prescribing behavior. Almost 70% of physicians stated that, when faced with a choice of clinically similar products, they would prefer using a product with samples.

More than 50% of physicians prefer vouchers over coupons primarily because they view them as the closest alternative to samples; however, in cases of continuing therapy, physicians may prefer using coupons over samples or vouchers especially if patients have prescription coverage.

When physicians were asked about opportunities to make coupons and vouchers friendlier/more usable, the following themes emerged:

- Require less paperwork for coupons and vouchers
    - 36% of respondents preferred a plastic card format for coupons and vouchers
    - All respondents stated a coupon should be redeemed at the pharmacy at the point of sale
    - Interestingly, electronic prescribing is not seen as an opportunity to reduce paperwork; almost 60% of electronic prescribers (23% of respondents) still prefer printing coupons and vouchers in their offices
- Improve methods for distributing coupons and vouchers
    - Respondents suggested distributing coupons and vouchers at the pharmacy; it should be noted that 72% of physicians oppose distribution through consumer channels
    - To improve visibility in the office, it was suggested to attach coupons and vouchers to samples (73% of physicians keep coupons and vouchers in the samples closet)
- Increase the value of coupons and vouchers (greater discount or longer duration of use)
    - 80% of respondents suggested that a coupon should provide a discount of at least $20 or the cost of prescription copay
    - 88% of respondents prefer coupons, which can be applied to multiple refills
    - 61% of respondents suggested that a voucher should provide at least 1-month supply of therapy

Physicians prefer to receive coupons and vouchers through their sales representatives (52%). The majority of respondents were not receptive to manufacturer-sponsored storing/tracking systems or company-specific coupon/voucher programs.

Patient Perspectives:

Demographics:

A total of 600 patients participated in the survey. They were stratified into 3 equal groups based on their experience with and use of coupons or vouchers. The respondents were mostly between the ages of 18 and 65 years old, 65% were male, and 43% were Caucasian (Table III-8).

Table III-8. Patient Demographics

Patient Characteristics	Received and Used (n=200)	Received, Not Used (n=200)	No Experience (n=200)	All (n=600)
Age, % of respondents				
18-34	34%	37%	41%	37%
35-49	44%	40%	38%	40%
50-65	21%	21%	19%	20%
66-80	1%	3%	3%	2%
81 or older	1%	0%	0%	<1%
Gender, % of respondents				
Male	57%	73%	67%	65%
Female	44%	28%	33%	35%
Ethnic background, % of respondents				
Caucasian	46%	41%	41%	43%
Hispanic, Latino	26%	21%	29%	25%
African-American	14%	25%	14%	18%
Asian	13%	10%	11%	11%
Other*	2%	4%	6%	4%

*Other ethnic backgrounds included multi-racial and Native American respondents.

On average, the responders were taking 2.6 prescription medications at the time of the survey (Table III-9). Coupon and voucher users tended to use more medications with a mean of 3.4. In addition, they reported having more medical conditions than the rest of the sample. Overall, the top conditions mentioned by the responders included allergy/asthma (28%), high blood pressure (25%), anxiety/depression (20%), and high cholesterol (17%). Almost half of the responders have been hospitalized in the past 5 years, and patients who have received coupons or vouchers in the past tended to search for product information on the Internet more frequently than those who had no previous experience with these offerings.

Table III-9. Medication Use and Related Patient Behavior

Patient Characteristics	Received and Used (n=200)	Received, Not Used (n=200)	No Experience (n=200)	All (n=600)
Number of current prescription medications, mean	3.4	2.3	2.1	2.6
Current conditions treated with prescription medications, % of respondents				
None	7%	23%	27%	19%
Allergy/asthma	39%	27%	17%	28%
Blood pressure	31%	23%	23%	25%
Anxiety/depression	25%	20%	17%	20%
High cholesterol	24%	13%	15%	17%
Chronic pain	17%	16%	9%	14%
Sleep disorder	20%	8%	5%	11%
Other*	9%	6%	5%	7%
Place of prescription redemption, % of respondents				
Pharmacy only	71%	82%	84%	79%
Pharmacy and mail order	28%	16%	13%	18%
Mail order only	3%	3%	4%	3%
Use of Internet for prescription product information, % of respondents				
Often	68%	59%	41%	56%
Rarely	28%	35%	43%	35%
Never	5%	7%	17%	9%
Use of toll-free numbers for prescription product information, % of respondents				
Often	20%	7%	4%	10%
Rarely	37%	26%	27%	30%
Never	44%	68%	70%	60%
Hospitalization in the past 5 years, % of respondents				
No	51%	54%	55%	54%
Yes	49%	46%	45%	46%

* Other conditions included birth control, migraine, diabetes, arthritis, infection (antibiotics), hormone disorders, gastric disorders, heart disease, erectile dysfunction, thyroid, and osteoporosis.

The participants were evenly distributed in terms of household income (Table III-10). More than 70% of responders received prescription coverage through commercial insurers. The sample also included 17% of responders without prescription coverage. In addition, 20% of participants have received free medication through indigent patient assistance programs. In comparison to the other 2 groups, coupon and voucher users included more people who reported having high prescription copayments.

Table III-10. Patient Income and Prescription Coverage

Patient Characteristics	Received and Used (n=200)	Received, Not Used (n=200)	No Experience (n=200)	All (n=600)
Household income, % of respondents				
<$25,000	12%	13%	15%	13%
$25,000-$39,999	17%	26%	24%	22%
$40,000-$54,999	16%	18%	20%	18%
$55,000-$69,999	12%	17%	19%	16%
$70,000-$84,999	13%	10%	9%	10%
$85,000-$99,999	10%	7%	5%	7%
$100,000 or more	20%	11%	10%	13%
Level of prescription coverage, % of respondents				
Good prescription coverage	25%	32%	38%	31%
Adequate coverage, copay too high	51%	42%	35%	42%
Enrolled in Medicare	7%	7%	5%	6%
Enrolled in Medicaid	4%	5%	3%	4%
No prescription coverage	14%	16%	21%	17%
History of participation in prescription patients assistance program, % of respondents				
Yes	28%	21%	13%	20%
No	72%	79%	87%	80%

Key Findings:

Perceptions and Attitudes:

Unlike physicians, experienced consumers value samples, coupons, and vouchers similarly (Table III-11). In the case of prescription refills, coupons are considered nearly as valuable as samples. Consumers' perception of value is primarily linked to financial assistance and opportunity for a "risk-free" trial. It was also found that users may assign a higher value to coupons or vouchers than consumers who have received, but have not used, these offerings. For instance, on a 5-point scale with 5 representing high value, coupons with new-start therapy received a rating of 4.3 by users and a rating of 3.0 by nonusers. In addition, brochures are also deemed valuable since patients are interested in materials with product information.

Table III-11. Value Assigned by Consumers to Samples, Vouchers, Coupons, and Patient Brochures*

	Received and Used	Received, Not Used	No Experience	**All**
New Start				
Sample	4.6	4.6	4.6	4.6
Voucher	4.4	3.9	-	4.3
Coupon	4.3	3.0	-	4.2
Patient brochure	4.2	4.1	4.1	4.1
Continuing therapy, all				
Sample	4.5	4.3	4.7	4.5
Coupon	4.4	4.0	-	4.3
Patient brochure	4.1	3.3	3.7	3.9

*Value rated on a 5-point scale; 5=high, 1=low.

Experiences and Uses:

With new therapy, patients are considerably more likely to receive samples than coupons or vouchers (Table III-12). In most conditions, those who were offered coupons or vouchers with new treatment also received patient brochures; however, when it came to refills, coupons were used almost as frequently as samples.

Table III-12. Receipt of Samples, Patient Brochures, Coupons, or Vouchers in Selected Conditions

	New Start				Continuing Therapy			
	Received and Used	Received, Not Used	No Experience	All	Received and Used	Received, Not Used	No Experience	All
Allergy/asthma	(n=78)	(n=54)	(n=34)	(n=166)	(n=78)	(n=54)	(n=34)	(n=166)
Nothing	9%	22%	44%	20%	55%	78%	94%	70%
Sample	81%	74%	50%	72%	26%	15%	3%	17%
Patient brochure	33%	15%	12%	23%	14%	4%	3%	8%
Coupon	36%	0%	0%	17%	27%	4%	0%	14%
Voucher	23%	2%	0%	11%	-	-	-	-
High blood pressure	(n=60)	(n=45)	(n=45)	(n=150)	(n=61)	(n=44)	(n=45)	(n=150)
Nothing	33%	42%	60%	44%	57%	84%	96%	77%
Sample	55%	42%	38%	46%	16%	11%	2%	11%
Patient brochure	23%	20%	7%	17%	11%	4%	2%	7%
Coupon	22%	4%	0%	10%	23%	2%	0%	10%
Voucher	17%	4%	0%	8%	-	-	-	-
High cholesterol	(n=48)	(n=26)	(n=30)	(n=104)	(n=47)	(n=26)	(n=30)	(n=103)
Nothing	31%	46%	63%	44%	56%	85%	93%	74%
Sample	58%	42%	27%	45%	23%	12%	3%	14%
Patient brochure	21%	19%	10%	17%	13%	8%	3%	9%
Coupon	21%	0%	0%	10%	29%	0%	0%	13%
Voucher	27%	0%	0%	13%	-	-	-	-
Diabetes	(n=29)	(n=15)	(n=17)	(n=61)	(n=28)	(n=15)	(n=17)	(n=60)
Nothing	24%	47%	76%	44%	48%	87%	82%	67%
Sample	59%	33%	18%	41%	28%	0%	12%	16%
Patient brochure	41%	33%	6%	30%	24%	0%	6%	13%
Coupon	24%	7%	0%	13%	10%	13%	0%	8%
Voucher	21%	0%	0%	10%	-	-	-	-

The likelihood of receiving coupons or vouchers appears to correlate with the general use of these offerings. Approximately 15-30% of users and only 4-10% of nonusers received coupons or vouchers (Table III-12). Furthermore, in comparison to the rest of the sample, users are more likely to receive or seek coupons and vouchers outside of physician offices (Table III-13).

Table III-13. Access to Coupons or Vouchers Outside of Physician Offices

	Received and Used	Received, Not Used	No Experience	All
Received in the in-patient setting	(n=97)	(n=91)	(n=89)	(n=277)
Yes	34%	8%	0%	14%
No	66%	92%	100%	86%
Received from the health plan	(n=200)	(n=200)	(n=200)	(n=600)
Often	25%	6%	3%	11%
Rarely	28%	24%	20%	24%
Never	47%	71%	78%	65%
Sought on the Internet	(n=200)	(n=200)	(n=200)	(n=600)
Often	48%	15%	14%	26%
Rarely	35%	45%	33%	38%
Never	17%	41%	53%	37%

Coupon or voucher users also have relatively high redemption rates. Specifically, 72% of them report using coupons and vouchers most of the time. Those who tend not to redeem their coupons and vouchers (both users and nonusers) frequently forget about them (Table III-14). In addition, perception of low value can also lead to nonredemption, especially among users of coupons and vouchers.

Table III-14. Reasons Cited for Nonredemption

	Received and Used (n=57)*	Received, Not Used (n=200)	All (n=257)
Forget or lose it	48%	72%	67%
Not worth it/not enough value	39%	16%	21%
Other	11%	13%	11%

* Includes users of coupons and vouchers who have indicated redeeming them "sometimes," "rarely," or "never."

Preferences and Opportunities:

Patient perceptions toward samples, coupons, and vouchers are not as skewed as those of physicians. Roughly 60% of consumers tend to think that samples are better than vouchers or coupons. In addition, 49% of consumers consider vouchers better than coupons; however, 1 in every 3consumers does not express a preference for either of these offerings, regardless of their previous experience (Table III-15). Lack of clear preferences is also reflected in patient attitudes and behavior. Samples motivate 65-75% of patients to fill/refill a prescription and to have positive feelings about the physician and the product. Coupons and vouchers have a similar effect in 55-60% of patients.

Table III-15. Patient Preferences for Samples, Coupons, and Vouchers

	Received and Used (n=200)	Received, Not Used (n=200)	No Experience (n=200)	All (n=600)
"A sample is better than a voucher"				
Agree	59%	60%	53%	57%
Neutral	27%	27%	35%	29%
Disagree	15%	15%	13%	14%
"A coupon is better than a sample"				
Agree	24%	10%	13%	15%
Neutral	32%	27%	36%	31%
Disagree	46%	64%	53%	54%
"A voucher is better than a coupon"				
Agree	56%	52%	39%	49%
Neutral	33%	35%	49%	39%
Disagree	12%	15%	13%	13%

Patient preferences tend to vary somewhat depending on the treatment situation. With new starts, 55% of patients prefer samples, 10-16% prefer coupons or vouchers, and 20% of patients have no specific preferences (Table III-16); however, with refills, 46% of patients prefer coupons, 23% prefer samples, and 31% have no specific preferences. These findings again support the notion that discounts on recurrent out-of-pocket expenses with refills are valued by consumers.

Table III-16. Patient Preferences by Treatment Situation

	New Start		Refill
	Chronic Therapy	Acute Therapy	Chronic Therapy
A sample	55%	56%	23%
A coupon	10%	12%	46%
A voucher	16%	13%	-
No preference	20%	19%	31%

When patients were asked about general preferences and opportunities to make coupons and vouchers friendlier/more usable, the following themes emerged:

- Require less paperwork and ease restrictions for coupons and vouchers
    - Patients cited reducing paperwork and easing restrictions as the primary suggestion for improvement
    - 79% of respondents preferred to redeem coupons in the pharmacy at the point of sale
    - Surprisingly, 61% of patients did not have a preference for format (ie, paper or plastic)
- Offer recurring discounts that apply to refills
    - The majority of patients stated that increasing coupon value and making them reusable would increase their value; interestingly, however, 64% of patients indicated that a coupon should offer at least a $5-10 value
    - 84% of patients stated that they would like a coupon or voucher that covers refills as well as the first prescription

    - 48% of patients prefer a $15 coupon with every refill over a sample or voucher
- Link/bundle with other offerings
    - A substantial number of patients suggested adding drug information to coupons, vouchers, or samples
    - 86% of patients were open to a starter kit that would include samples, vouchers, coupons, and product information; the majority felt that such a starter kit would improve compliance
    - 68% were also open to coupons for over-the-counter products in the related therapeutic area

Pharmacist Perspectives:

Demographics:

A total of 75 pharmacists participated in the survey (Table III-17). The sample included 55 pharmacists from chain pharmacies, which are primarily located in the urban and suburban areas (83%). Walgreen's (15 pharmacists) and CVS (11 pharmacists) were best represented in this subset of the sample. In addition, 20 responders practice in independent community pharmacies, 45% of which are located in rural areas.

Table III-17. Pharmacist Demographics

Pharmacist Characteristics	Chain (n=55)	Independent (n=20)	All (n=75)
Region, number of respondents			
Northeast	3	1	4
Mid-Atlantic	9	7	16
South	11	2	13
Southwest	7	1	8
Midwest	15	6	21
West	10	3	13
Geographic area, % of respondents			
Urban	45%	30%	41%
Suburban	38%	25%	35%
Rural	16%	45%	24%
Daily prescription volume, mean	265	191	245

Findings:

Perceptions and Attitudes:

Pharmacists have mixed perceptions on drug samples. Virtually all pharmacists (94%) think that samples provide a good way for patients to try a product; however, 78% believe that samples encourage physicians to prescribe more expensive products. Most importantly, lack of adequate counseling was identified by pharmacists as the major issue with samples.

Generally, pharmacists are quite receptive to coupons and vouchers; most believe that they are better for the pharmacy's bottom line than samples. Most importantly, pharmacists think that coupons and vouchers are more likely to facilitate medication counseling and to encourage patient compliance (Table III-18). Reduction in patient's out-of-pocket costs is identified as the greatest benefit associated with coupons, while risk-free trial is seen as the greatest benefit associated with vouchers; however, since both offerings involve special processing, a substantial percentage of pharmacists (50-60%) find them cumbersome to process at the point of sale. Qualitative interviews also reveal that since voucher processing bypasses third-party adjudication, patients may try a product before understanding coverage and possible out-of-pocket costs. In addition, processing of coupons and vouchers involves a number of different restrictions. Common restrictions include federal program exclusions, one-time use, expiration dates, limits on dosages, etc. Finally, more than a half of responders reported that patients tend to lose coupons and vouchers.

Table III-18. Pharmacist Perceptions Associated With Counseling, Compliance, and Patient Satisfaction*

	Samples	Coupons	Vouchers	None
Good for patient counseling	13%	59%	64%	27%
Good for encouraging patients to fill a new prescription	27%	79%	96%	3%
Good for encouraging patients to refill their prescription	9%	84%	61%	11%
Enhance patient satisfaction	57%	76%	81%	11%

* Responders were asked to select statements that applied to samples, vouchers, coupons, or none of these (more than one option could be selected).

Experiences and Uses:

Although pharmacist experience with coupons and vouchers is currently limited, there is a growing trend in the use of these offerings (Table III-19). It appears that suburban pharmacists are encountering a greater volume of prescriptions that are accompanied by coupons or vouchers than pharmacists in other areas. Patients receive coupons from physicians or through the Internet. More than 70% of pharmacists report seeing coupons downloaded from the Web. Moreover, pharmacists are actively involved in distributing coupons, especially in suburban and rural areas (Table III-19). Two-thirds of pharmacists report handing out coupons for 6 products on average (range: 4-9). In-pharmacy distribution of vouchers occurs to a much lower extent; only one-third of pharmacists report handing out vouchers for 4 products on average (range: 2-6).

Table III-19. Pharmacist Experience With Coupons and Vouchers

	Coupons	Vouchers
Average number of prescriptions accompanied by a coupon per week		
Urban	13	10
Suburban	23	14
Rural	11	8
All	16	11
% of responders reporting a growing trend in the past year		
Urban	68%	71%
Suburban	81%	77%
Rural	94%	83%
All	79%	76%
% of responders distributing in the pharmacy (frequently to sometimes)		
Urban	54%	22%
Suburban	69%	27%
Rural	73%	33%
All	64%	27%

No clear "winning" or "losing" coupon/voucher programs were mentioned by pharmacists. Two-thirds of the pharmacist sample could not identify a program that they especially liked or disliked; however, qualitative data revealed that features that are conducive to quick and simple processing are key to winning the pharmacists. For instance, pharmacists especially favor coupons or vouchers, which either can be processed as checks (don't require adjudication) or have clear instructions for processing. Interestingly, pharmacists expressed frustration with multi-use cards due to difficulty in processing or simply forgetting. Among the products that were named as examples of winning or losing programs, Merck products were not listed.

Preferences and Opportunities:

When it comes to new prescriptions, 44% of pharmacists have no preference for coupons or vouchers (Table III-20). Another 41% of pharmacists prefer vouchers for new prescriptions primarily because they are easier to process. Pharmacists who practice in independent community stores are much more likely to prefer vouchers with new prescriptions. In the case of chronic medications, a substantial percentage of pharmacists (44%) believe that coupons may have a greater potential to encourage patient compliance than vouchers or samples.

Table III-20. Pharmacist Preferences With New Prescriptions

	Chain (n=55)	Independent (n=20)	All (n=75)
Voucher	35%	70%	44%
Coupon	18%	5%	15%
No preference	47%	25%	41%

When pharmacists were asked about general preferences and opportunities to make coupons and vouchers friendlier/more usable, the following themes emerged:

- Simplify processing
  - Pharmacists' preferences are mainly driven by the desire to work with coupons and vouchers, which require minimum time for processing and no workflow interruption
  - There is no clear preference for format (55% prefer plastic while 45% prefer paper; 89% would process coupons attached to electronic prescriptions)
  - 59% of pharmacists prefer single-use programs, most likely because of processing issues with multi-use coupons
  - 73% prefer product-specific over company-specific coupons or vouchers
- Distribute coupons and vouchers through pharmacies
  - 83% of responders are interested in distributing coupons and vouchers to their patients
  - 40% of pharmacists are open to having a manufacturer offer a better system for storing or accessing coupons and vouchers (typically coupons are being stored on the shelf next to the product); suggested improvements included attachments to product packaging, storage devices on the shelf, on-demand fax-back systems, integration with pharmacy software so that coupons and vouchers are printed with the label, etc
- Offer adequate value
  - Although pharmacists did not specifically state that coupons and vouchers offer low value, the large majority chose upper limits as the perceived minimum value
    - 59% of pharmacists stated that a coupon should provide a discount of at least $15 or the cost of prescription copay
    - 66% of pharmacists stated that a voucher should provide at least a 2-week or 1-month supply of treatment

Payer Perspectives:

Demographics:

Ten individuals representing managed care organizations participated in qualitative phone interviews. The sample included 4 pharmacy directors and 6 medical directors. On average, participants have spent 5 years in their current position (range: 3-11 years).

Findings:

Perceptions and Attitudes:

Payers have strong reactions to drug samples. They understand that samples provide a convenient risk-free means of trying a product; however, they are greatly concerned that samples affect provider and patient behavior by shifting utilization toward high-cost branded products without a perceived benefit. Also, inability to track samples as a part of resource utilization is associated with negative perceptions. The following responses exemplify these sentiments:

- "*I think it can be a wonderful thing if it's used to facilitate the selection of the appropriate drug…. What I think samples are being used for now is convenience, almost like a perk to the patient. 'We will give you this medication to try. It may be the Rolls Royce of hypertensive meds, but I have a drawer full of samples and we'll get you started on this.' Once you get a patient started on it, it gets very expensive. Nobody has enough samples to keep a patient covered indefinitely*." [Respondent #6, Payer]"
- "*If they give enough samples, they can cut down our costs by providing a fairly large number of samples, and, of course, that reduces our costs, too…. Sampling can encourage people to go for the tier 3 products, when maybe a generic or tier 2 would do the same thing.*" [Respondent #3, Payer]
- "*The drawback, from a managed care company perspective, is that we can't capture those claims. When we do retrospective reviews, we don't know whether a member is actually adherent to the medication. If there's a gap, it may be because they have samples.*" [Respondent #5, Payer]

Generally, payer attitudes toward samples spill over to coupons and vouchers. The primary concerns from their perspective are that these programs promote utilization of tier 3 products and that utilization cannot be tracked by the payers:

- "*A potential negative is that people are not giving out coupons for generic drugs. So, basically, it's going to get the patient on a branded product that they have to continue to pay for. Maybe the patient has a fixed copay that doesn't vary significantly, but it's more expensive to the organization. If you practice appropriately, it's not going to affect it at all. For example, if a patient fails on available generic products, and I wanted to try a branded product using coupons or samples, then it's simply a way of saving the patient some money*." [Respondent #1, Payer]
- "*If a manufacturer decides to send out coupons for ABC drug, we probably wouldn't hear about it, and given that we have such a large membership, I'm not sure that it would be an impact that would show up. I've never seen that couponing has really made that much difference to us, positive or negative.*" [Respondent #7, Payer]
- "*I don't know that it makes that much difference from the health plan's perspective. They all lead to the same potentially negative result, which is either deviation from the formulary altogether or*

steer the patient to a product at a higher co-pay when a lower cost alternative is available. I think, as we move forward, consumers will become more and more sensitive to that kind of thing and make value-based decisions." [Respondent #9, Payer]

Experience and Use:

Payer experience with samples, coupons, and vouchers is mostly limited to promotion of generic/OTC products. Examples include OTC Prilosec (to counter Nexium) and generic Claritin and Allegra (to counter Clarinex). The Prilosec program reportedly saved one plan $1.2 million:

- "*We have contracted with a particular sampling company that does generic sampling in physicians' offices, such as the generic antibiotics, SSRIs, and NSAIDs. There are about 20 different meds. In those cases, we do see the claim, but when it comes to branded agents from the pharmaceutical company, there's no way to ascertain whether or not they're getting samples.*" [Respondent #5, Payer]
- "*In order to promote generics, we will give patients a voucher for the first month's generic copay. We will send it to you, and then you send that back, and it will get redeemed. It's not linked to any specific drug, so it's just a brand to generic. So it's not like we're promoting a drug— the message is generic. Once we get people to make that move, it's highly unlikely they'll move back…. We've used coupons in a very selective fashion with a very positive effect. One of our most effective initiatives ever was when Prilosec went OTC; we worked directly with Procter & Gamble and sent out hundreds of thousands of coupons. Procter & Gamble told us that this was the highest redemption rate in the history of their company. Their typical redemption rate is in the 1-2% range, and a really effective coupon is in the 4-5% range. We were talking in the 15-16% redemption range.*" [Respondent #7, Payer]
- "*If we did something, we would do direct targeting to the members. Our idea, in terms of coupons, that we have discussed was not primarily compliance-based, but giving an incentive to switch from a statin like Lipitor to a generic product like Zocor. The goal would be that we spend some money on the coupons, but the plan would save significant costs by switching patients to a lower cost product. It's something that, ultimately, we don't think will harm the patient; we think it's going to better the plan financially*." [Respondent #1, Payer]

Preferences and Opportunities:

Some payers prefer coupons over vouchers for the following reasons:

- Prescriptions with coupons are adjudicated by the payer
- Coupons for refills may encourage patient adherence/compliance (it should be noted that the majority of participants preferred coupons that permit multiple uses for refills of a chronic medication)
- With coupons, patients still share financial responsibility (lesser moral hazard effect, "still some skin in the game")

Payers are suspicious of any pharmaceutical manufacturer programs that encourage use of expensive drugs over generics. As such, they may not be generally interested in partnering with a specific manufacturer in implementing coupons or voucher programs, although some like the State of Florida as well as some Medicare demonstration projects have operated some innovative pharmaceutical pay for performance programs:

- *"I would say, from our organization's perspective, we don't generally partner with pharmaceutical companies because we want to be independent, not tied to a pharmaceutical company because that raises some suspicion."* [Respondent #5, Payer]
- "*I don't want to say that we're hands off, but we try to maintain a respectful distance between the pharmaceutical companies and the plan in terms of co-marketing. I mean we've always had discussions when we use some materials for a program like a "Stop Smoking" program. We're always concerned about what type of branding or labeling there is. It's one thing for it just to be on literature, but I think that anything more than that would be problematic for us.*" [Respondent #1, Payer]
- *"We don't do [joint programs with a pharmaceutical company]. We used to, but I think everybody has cut down because of the new regulations. I think, in general, health plans are trying to keep an eye on and some distance from pharmaceutical companies.*" [Respondent #9, Payer]

However, some payers may be open to programs that promote tier 2 products or encourage appropriate utilization as a part of a disease management or compliance program.

- "*If it becomes tier 2, we do allow the manufacturers' representatives to use our logo informing the doctors that this drug is on our formulary tier 2. Diovan is tier 2, and we did have coupons for that, so if it's a tier 2, we're very much in favor of it. We primarily put them in the hands of the social worker. We'd have them send them out.*" [Respondent #3, Payer]
- *"From our standpoint, we want compliance; we want to keep patients out of the hospital. If the compliance is better, hospital costs go down and the patient ends up better off…. Anything that would lower our costs would be a win-win. That's all there is to it—lower our costs and improve our insurant compliance. This is what we're looking for."* ***[Respondent #3, Payer]***
- *"I would love to partner with a company through a coupon or voucher program. It would have to be where I actually want to see increased utilization of a particular drug that's being underutilized and everybody widely acknowledges that it's a benefit to a given population. Asthma is the one that comes to mind most readily."* ***[Respondent #6, Payer]***
- *"Maybe something in the commercial population for smoking. Chantix, the new Pfizer medication—we're getting a lot of use on that med and from what I understand, it has been helping…. If you target high volume providers and get them to move market share to one of our preferred drugs that would probably be the only real advantage."* ***[Respondent #5, Payer]***

IV. Coupon and Voucher Program Trends

Methodology:

Coupon and voucher programs offered by other pharmaceutical companies were evaluated through an online search in order to assess competitive trends. A sample of 38 branded prescription drugs was selected based on the following characteristics:

- Top 200 drugs in retail sales in 2006[40]
- Top 25 drugs in direct-to-consumer (DTC) spending in 2006[41]
- Therapeutic areas that overlap with Merck products

The search strategy was primarily focused on the product Web sites. In addition, the following consumer coupon Web sites were cross-referenced:

- www.internetdrugcoupons.com
- www.reduceprescriptioncosts.com
- www.grocerycouponguide.com

40. Verispan, VONA. Available at: www.drugs.com/top200.html.2007.
41. Nielsen Monitor-Plus. *DTC Perspectives*. 2007.

Findings:

The analysis revealed that 25 out of 38 products (66%) offered a coupon and/or a voucher (Table IV-1). However, only 3 of them (8%), Advair, Lipitor, and Nasonex, offered both a coupon and a voucher (see Appendix A for examples).

Table IV-1. Products with Coupon and/or Voucher Offerings

Brand	Retail Sales Rank	DTC Rank	Therapeutic Area	Coupon Offering	Voucher Offering
Actonel	48	Not rated	Osteoporosis		√
Actos	14	Not rated	Diabetes	√	
Advair	4	7	Asthma	√	√
Ambien CR	67	2	Insomnia		√
Atacand	181	Not rated	Hypertension		√
Avodart	146	13	BPH		√
Boniva	119	12	Osteoporosis		√
Clarinex	106	Not rated	Allergy	√	
Crestor	37	3	Lipids		√
Cymbalta	35	5	Depression/pain		√
Flonase	117	Not rated	Asthma	√	
Imitrex	43	21	Migraine	√	
Lipitor	1	9	Lipids	√	√
Lumigan	142	Not rated	Glaucoma	√	
Lunesta	61	1	Insomnia		√
Nasacort	112	Not rated	Allergy	√	
Nasonex	45	11	Allergy	√	√
Nexium	2	4	GI		√
Requip	122	15	Parkinson's/RLS		√
Rhinocort Aqua	124	Not rated	Allergy	√	
Rozerem	Not rated	10	Insomnia	√	
Tricor	40	Not rated	Lipids	√	
Zomig	192	Not rated	Migraine	√	
Zyrtec	29	Not rated	Allergy	√	

*Coupon/voucher offered to consumer upon registration for newsletter; without subscription, details could not be obtained.

A total of 13 products were not included in coupon or voucher programs (Table IV-2). Most of these products (12 out of 13) have been available on the market for at least 4 years and were not considered as top DTC spenders in 2006 (11 out of 13). Although Diovan and Diovan HCT were included in the list of products that did not provide a coupon or a voucher, these products did offer a money-back guarantee based on the ability to reach blood pressure treatment targets (see Appendix A for details).

Table IV-2. Products Without Coupon or Voucher Offerings

Therapeutic Area	Retail Sales Rank	DTC Rank	Brand
Asthma	117	Not rated	Flovent
Asthma	73	Not rated	Pulmicort
Cancer/GSF	Not rated	17	Neulasta
CINV	53	Not rated	Zofran
Diabetes	199	Not rated	Avandamet
Diabetes	17	Not rated	Avandia
Diabetes	97	Not rated	Byetta
Diabetes	38	Not rated	Lantus
Glaucoma	189	Not rated	Travatan
Hypertension	50	Not rated	Altace
Hypertension	39	Not rated	Diovan*
Hypertension	42	Not rated	Diovan HCT*
Stroke/PAD prevention	7	6	Plavix

*Money-back guarantee program available.

Fourteen products that provided coupons to consumers are listed in Table IV-3. A large majority of these products (13 out of 14) offered coupons that were ≥$10 in value; 9 offered a discount of ≥$15; and 7 offered a discount of ≥$20. The highest coupon amount was offered by Actos—up to $50. Only one product, Lipitor, offered a variable discount ($10-15), depending on the out-of-pocket cost (eg, <$35 vs ≥$35). A total of 50% of the coupon programs (7 out of 14) offered a discount through a mail-in rebate. The other 50% provided a discount at the point of sale, some through a co-pay card (see Appendix A for examples). In addition, 50% of the offered coupons (7 out of 14) could be applied to multiple refills, up to 12 refills with Flonase, Lipitor, and Nasacort (see Appendix A for examples).

Table IV-3. Products That Participate in Coupon Programs

Therapeutic Area	Brand	Coupon Value	Mail-In Rebate	Limits on Use
Allergy	Clarinex	≤$25[‡]	√	Unspecified
Allergy	Flonase	$5 (up to $60)	√	12 times[†]
Allergy	Nasacort	$20 (up to $240/year)	√	12 times/year
Allergy	Nasonex	$10		1 coupon/purchase, up to 10 purchases[*]
Allergy	Rhinocort Aqua	≤$20		1 time only[* †]
Allergy	Zyrtec	$10 (up to $40)	√	4 times[* †]
Asthma	Advair	$10		[†]
Diabetes	Actos	≤$50		1 coupon per purchase[* †]
Glaucoma	Lumigan	$20	√	Unspecified
Insomnia	Rozerem	≤$20	√	1 time only[* †]
Lipids	Lipitor	$10-15		Up to 12 times per year[†]
Lipids	Tricor	$15		Unspecified
Migraine	Imitrex	$10 (up to $60)	√	6 times[†]
Migraine	Zomig	≤$35		6 times in 12 consecutive months

[*]Offer expires in 2007.
[†]Not applicable if prescription is paid by federal/state program, Medicare/Medicaid, or where prohibited by state.

Thirteen products that provided vouchers to consumers are listed in Table IV-4; 6 out of 13 vouchers offered at least a 2-week supply of therapy, and 6 products offered a 1-month supply of therapy (see Appendix A for examples).

Table IV-4. Products That Participate in Voucher Programs

Therapeutic Area	Brand	Voucher Day Supply	Limits on Use
Allergy	Nasonex	30 days	1 time only
Asthma	Advair	30 days	1 time only[†]
BPH	Avodart	30 days	1 voucher per Rx
Depression	Cymbalta	14 days	1 time only, valued up to $25
GI	Nexium	7 days	Unspecified
Hypertension	Atacand	14 days	1 time only; no mail order[†]
Insomnia	Ambien CR	7 days	Unspecified
Insomnia	Lunesta	7 days	Unspecified
Lipids	Crestor	15 days	Unspecified
Lipids	Lipitor	30 days	[†]
Osteoporosis	Actonel	28 days	1 time/12 months
Osteoporosis	Boniva	30 days	Unspecified
Parkinson's/RLS	Requip	14 days	Unspecified

[*]Offer expires in 2007.

[†]Not applicable if prescription is paid by federal/state program, Medicare/Medicaid, or where prohibited by state.

V. Relevant Health Law and Policy

State Laws:

The regulations from the state government in the area of pharmaceutical couponing focus mainly on the practice of pharmacy whereas the federal regulations focus on pharmaceutical companies and physicians. A review of the state laws governing couponing and sampling reveals that, while most states are silent on the issues, a growing number of states are setting restrictions in place. For example, Massachusetts prevents coupons and vouchers from being used to reduce the out-of-pocket expense for those who have insurance. This is a trend we anticipate will grow as additional federal regulations are introduced.

Federal Laws and Policy Movements:

While there currently are very few limitations on pharmaceutical couponing from a state or federal perspective, there is clearly a movement to add restrictions. CMS is very interested in promoting appropriate care, including improving adherence and preventing inappropriate utilization; inappropriate utilization is defined as a situation where a patient is encouraged to take a more expensive medication and/or less effective medication. Given the developing role of the federal government in prescription medications, it is likely that the pressure will grow and the addition of restrictions will be put into place. Regulators will focus on areas that inappropriately influence prescribers into writing more costly medications when less expense alternatives exist (ie, brand over generic), calling current couponing/voucher programs into question. Since pharmaceutical manufacturers rely heavily on couponing/voucher programs to promote branded products, it will be critical to coordinate efforts with all payers (eg, federal, state, private) to develop programs that promote appropriate treatment options to the appropriate patients.

In 2006, 24 patient advocacy groups requested that the FDA ban couponing based on their fear that coupons inappropriately influence the prescription the physician recommends for the patient. This is based on the primary principle for patient advocates that nothing should come between the patient and physician in care decisions.[42] This is a slightly different philosophical belief but is similar to that of the federal government. As stated by Scott Gottlieb, deputy commissioner of the FDA from 2005-2007 who stated in a *Wall Street Journal* commentary that "inside the federal agencies that oversee parts of the healthcare system, there is a palpable view that doctors can no longer be trusted to do the right thing."[43]

The common thread among patient advocacy groups and the federal government is that physicians need guidance to ensure appropriate prescribing because, if left on their own, they would be unduly influenced. Now that the federal government, through Medicare Part D, is one of the most significant payers for prescription drugs, anything that increases the use of inappropriate medications is viewed by the federal government as a practice that must be stopped.

Perhaps more out of accounting difficulty than a policy statement in July 2007 CMS published a final rule with comment period that implements sections of the Deficit Reduction Act of 2005 (DRA) regarding

42. Eye on FDA. Available at: www.eyeonfda.com/eye_on_fda/2006/05/is_the_bargain_.html. Accessed August 27, 2007.
43. Gottlieb S. Prescription for trouble. Available at: online.wsj.com/article/SB117314968751527893.html. Accessed August 28, 2007.

Medicaid drug pricing and reimbursement.[44] The final rule addresses a broad range of issues related to the determination of average manufacturer price (AMP), determination of best price, treatment of authorized generics, and new reporting requirements for manufacturers. The regulation took effect on October 1, 2007. The final rule excludes manufacturer coupons from both AMP and best price provided that the full value of the coupon is passed on to the consumer and that the receiving pharmacy, agent, or other entity does not receive any price concession. The preamble to the final rule, however, sets forth slightly different criteria with respect to AMP. It states that coupons (and vouchers for free products) are excluded from AMP if: (1) the coupon is not contingent on any purchase requirement; (2) the manufacturer establishes the coupon's benefit amount without any negotiation with a third party; (3) the entire amount of the coupon's value is made available to the individual patient without an opportunity for a third party to reduce the benefit amount or take a portion of it; and (4) the pharmacy collects no additional payment other than the benefit amount and a bona fide service fee. In addition, patient assistance programs, including copayment assistance programs and manufacturer-sponsored drug discount programs, are excluded from AMP if: (1) they are focused on extending free products or financial assistance not contingent on any purchase requirement to low-income individuals; (2) the manufacturer establishes the subsidy amount without any negotiation with a third party; (3) the entire amount of the free product or assistance is made available to the individual patient without an opportunity for a third party to reduce the benefit amount or take a portion of it; and (4) the pharmacy collects no additional payment other than the benefit amount and a bona fide service fee.

It is important to remember that the federal government is looking to ensure that it is not paying more for medications because of some potential gaming of the reimbursement system.

There are steps manufacturers can take to ensure compliance:

- Begin cataloging coupon and voucher programs in order to identify the following:
    - How the program works
    - Who benefits
    - Where in the organization is the program implemented
    - How transactions are recorded and files maintained
- Conduct a legal review of the programs comparing the requirements outlined in the final rule to determine the application of these transactions within the AMP calculation
- Evaluate pharmacy service fees and ensure that the information is documented and the fair-market value is calculated

44. Available at: www.cms.hhs.gov/DeficitReductionAct/Downloads/MASTER%20CMS-2238-FC_070507%200406pm.pdf.

VI. Conclusions and Recommendations

Findings gathered through this research lead to the following conclusions:

- Stakeholder perspectives on coupons and vouchers are misaligned
    - Physicians strongly prefer samples over coupons or vouchers due to convenience, familiarity, and the perception of value
    - Patients and pharmacists do not have very strong preferences; their preferences are driven by specific circumstances
    - Payers would prefer coupons over vouchers or samples since there is a lower potential for steering inappropriate utilization and a greater opportunity to improve compliance and the data can be captured
- Coupons are in a unique position to target refills that cannot be addressed through sampling
- Physicians and patients do not value processing of prescriptions with coupons and vouchers in the pharmacy as an advantage over samples
- Patients value and seek consumer product information
- Stakeholders have very limited experience with coupons and vouchers, but the trend is growing
    - Consumers who have used coupons or vouchers tend to receive, seek, and redeem them more frequently than the other consumer segments possibly because they tend to assign a higher value to these offerings
- Recommendations for improving usability of coupons and vouchers falls into 3 general themes – simplify the process, improve distribution and visibility, and enhance value
- Use of coupons and vouchers is popular among heavily promoted products; however, these programs are not always aligned with stakeholder expectations
- While there are very few current limitations on coupons and vouchers from a state or federal perspective, there is clearly a movement to add restrictions

On the basis of these findings, the following recommendations are proposed:

- Sampling
    - Considering physician preference for samples and related implications for product loyalty, coupons and vouchers should be positioned with physicians as a supplement to samples (as opposed to an alternative)
    - Attaching coupons to samples may be an effective way to promote continued use of prescription products
- Positioning with physicians
    - Physician attitudes toward coupons and vouchers may gradually change if they understand that (1) coupons and vouchers can augment the value of samples, (2) consumers are interested in coupons that can apply to refills, and (3) an extra trip to the pharmacy for processing coupons or vouchers promotes patient safety and compliance; physicians may also benefit from an educational outreach program that emphasizes the benefits of coupons and vouchers to their patients, highlighting the benefit of tracking such programs and their potential impact on compliance and persistence

- Use and distribution of coupons and vouchers
    - Consumer demand for coupons and vouchers may be directly related to the extent of their experience with these offerings; increased exposure to and distribution of coupons and vouchers may result in increased interest and use/redemption
    - Distribution of coupons in the pharmacies should be evaluated and possibly expanded to encourage compliance with refills

- Paperwork and processing
    - Reasonable efforts should be made to reduce paperwork, lessen restrictions, and simplify processing; for instance, the following may be considered:
        - Eliminate any steps requiring activation by physicians
        - Avoid mail-in rebates
        - Clearly communicate any restrictions to patients
        - Simplify processing for pharmacists
- Visibility and storage
    - In order to improve redemption of coupons and vouchers, efforts should be made to increase visibility for physicians, pharmacists, and patients; for instance, the following may be considered:
        - Attach coupons and vouchers to samples and product packaging
        - Create starter kits that include coupons and vouchers
        - Design coupons and vouchers to include tear-off product/disease information
        - Consider printing prescription pads with tear-off coupons and vouchers
        - Design storage devices that can be affixed to the shelf where samples in the samples closet or products in the pharmacy are located
        - Consider promoting coupons at the pharmacy counter
- Coupon/voucher value
    - Coupons should offer a discount of at least $10, preferably $20
    - Coupons should apply to more than one fill to encourage compliance
    - Vouchers should offer at least a 2-week supply of therapy, preferably a 1-month supply
    - Include coupon/voucher as part of patient education brochure to promote appropriate medication use and disease management
- Policy
    - To ensure the future of coupons and vouchers, it may be of value to implement programs that can target compliance or disease management (in coordination with federal, state, and private payers)
    - Legislative and regulatory trends should be closely observed and monitored to understand implications for coupon and voucher programs
    - Educate key stakeholders on the role that samples, coupons, and vouchers play in seeking to improve the quality of life of patients as well as reducing overall medical expenses

- Other trends that may impact sampling, coupons, and vouchers include the following:
    - Evolving technologies that impact provider practice
        - E-prescribing
        - Electronic medical records
    - New practice settings
        - Convenient care clinics
    - Increasing patient involvement in healthcare decisions
        - Patient utilization of the Internet
        - Consumer-driven health care

VII. Study Limitations

There are certain limitations, which include:

- Limited availability of Medicare beneficiaries in the survey
- Lack of experience of physicians with E-prescribing

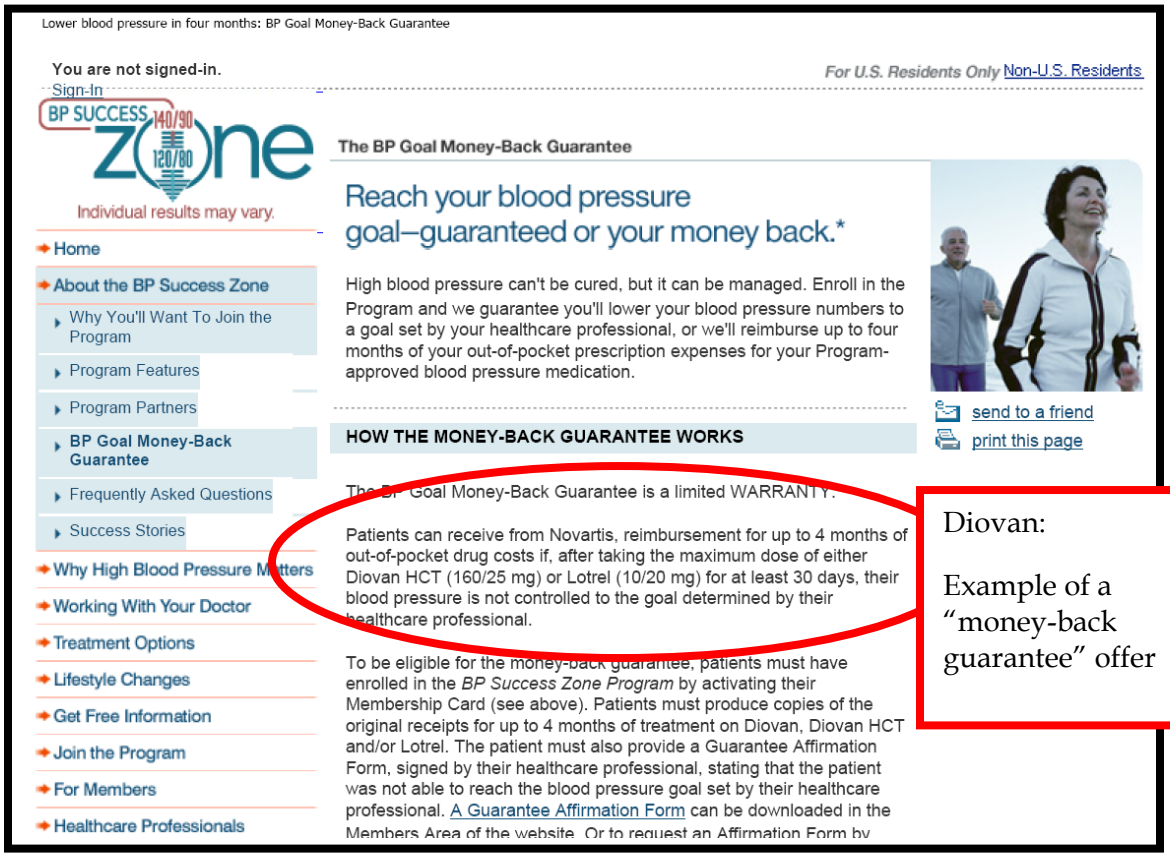
The limited availability of Medicare beneficiaries is important to note when considering the effect of sampling, couponing, and vouchering for certain classes of medications. For example, the antidementia agents are utilized over 90% of the time in the Medicare population.

The increasing push by the federal government and other payers for E-prescribing is likely to have a major impact on sampling, couponing, and vouchering. For example, while over half of physicians surveyed stated that they did not screen patients for participation in Medicare or Medicaid before giving out a coupon, E-prescribing will automatically inform prescribers of patient prescription drug coverage. This information, in addition to immediate notification of what is the plan-preferred medication plus the ability to know of available coupons and vouchers, is likely to have a tremendous impact on what is prescribed.

The availability of E-prescribing is likely to increase the efficiency in which couponing and vouchering programs work. In addition, E-prescribing presents additional opportunities for pharmaceutical companies to develop programs with payers that are based on improved outcomes through focused disease state management programs.

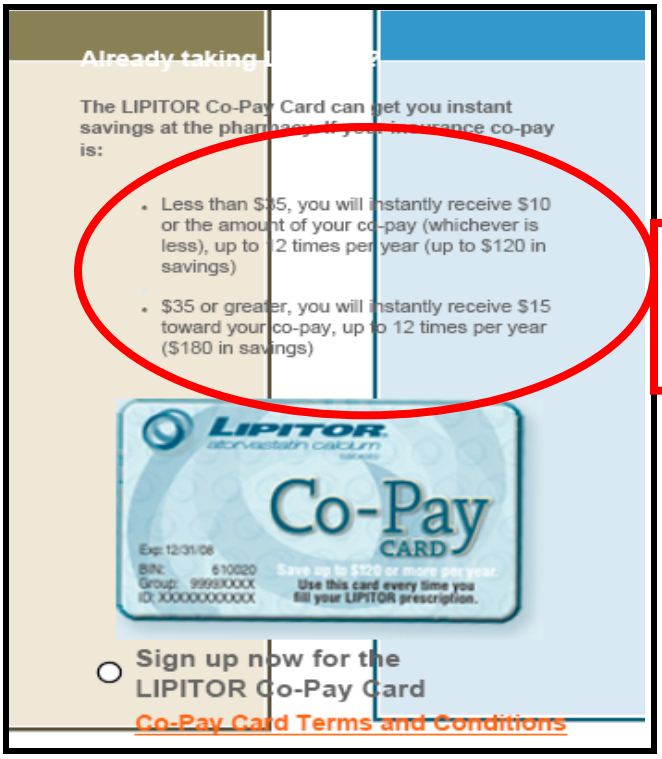
VIII. Appendices

APPENDIX A: Select Competitive Product Offerings



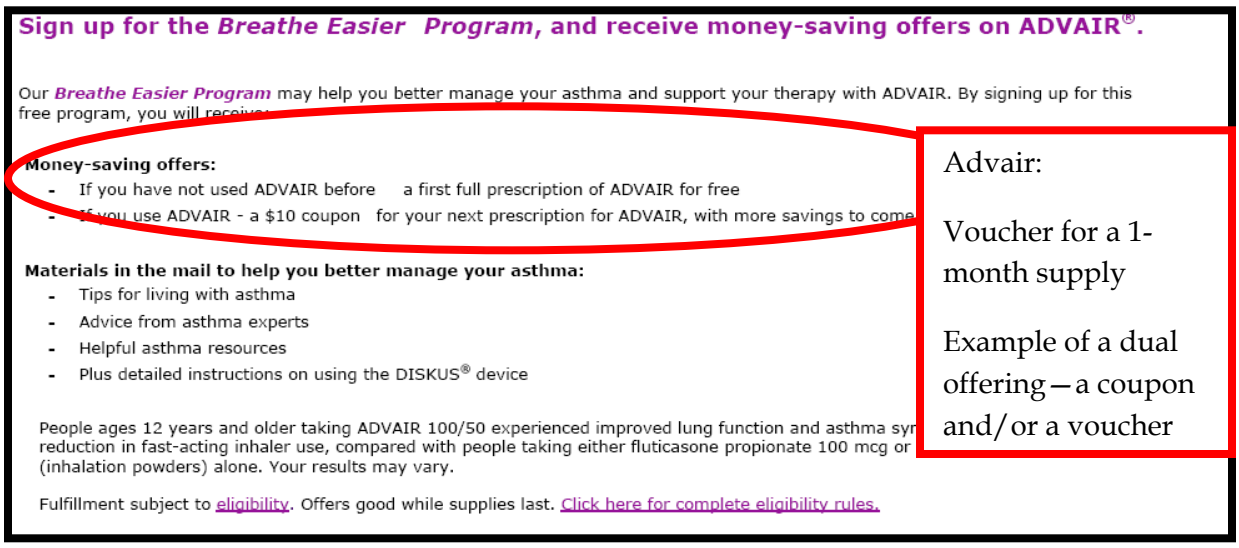
Diovan:

Example of a "money-back guarantee" offer



Lipitor:

Coupon value depends on the out-of-pocket cost.



Advair:

Voucher for a 1-month supply

Example of a dual offering—a coupon and/or a voucher

APPENDIX B: Background Materials

Enclosed in the enclosed CD-ROM are copies of the following reference materials:

- Reference and supporting articles
- Internal interview notes from sessions with Merck employees
- Screener questions used to identify and qualify market research respondents
- Copies of final survey tools
- Final survey data, by segment