Understanding Sample Usage and Sampling as a Promotion Tool

– State of Industry Practice and Current Research

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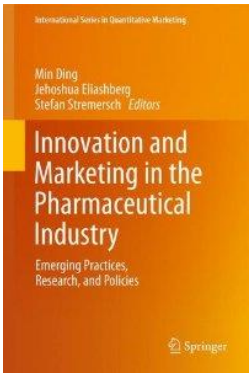

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Introduction

In the United States, the practice of dispensing drug samples is one of the most important tools adopted by the pharmaceutical industry. Industry studies have shown that sampling as a marketing practice accounts for a significant proportion of company marketing budgets. Drug sampling is effective in reaching physicians as evidenced in a survey by Henry J. Kaiser Family Foundation (2002) which showed that 92% of all doctors had accepted drug samples from pharmaceutical sales representatives. The U.S. pharmaceutical industry delivered an estimated $18.4 billion worth (in retail value) of free drug samples to doctors in 2005—more than all other marketing expenses combined (Donohue et al. 2007). Therefore it is important for pharmaceutical companies to understand how to distribute most efficiently these resources to targeted physicians.

Sampling is claimed to be "the most effective but most expensive way to introduce a new product or to create new excitement for an existing one." (Armstrong and Kotler 2009, page 433) Beyond the pharmaceutical industry, the practice of distributing free product samples has been adopted by companies in a wide range of industries such as consumer packaged goods, newspapers, etc. (Schultz et al. 1998). Compared to sample distribution practices in these other industries, pharmaceutical sampling is limited because drug samples cannot be legally dispensed directly from the manufacturers (the pharmaceutical companies) to consumers. This creates an environment in which doctors have ultimate control over what drug samples a patient can try. During this process, doctors play a "gatekeeper and decision maker" role in dispensing the billions of dollars' worth of free samples to patients. As a result, in order to assess the effectiveness of pharmaceutical sampling it is essential to understand what drives doctors' free sample dispensing decisions..

Pharmaceutical sampling has become one of the frequently debated topics in mass media due to the recent increase in public scrutiny regarding the soaring healthcare cost in the United States (e.g., Rabin 2007). In particular, the somewhat unexpected finding that poor, uninsured Americans are less likely than wealthy, insured Americans to receive free drugs samples in Cutrona et al. (2008) stirred a heated public discussion about whether free samples indeed play a "subsidy" role as claimed by the U.S. pharmaceutical industry and backed up by many doctors. Also, there is evidence showing that patients receiving free samples had higher out-of-pocket costs than those who did not, which may lead to discontinuity of treatment, especially for low-income patients (Chimonas and Kassirer 2009). Responding to these criticisms, some U.S. institutions, such as the University of Michigan Health System, have completely banned their doctors from dispensing free drug samples to patients, while others including the University of Pennsylvania and Stanford University medical schools have prohibited staff members from accepting free drug samples[2] (Rabin, 2007). Therefore, understanding the motivation for sampling in a physician's prescription decision is of interest to pharmaceutical companies both in designing an effective sampling strategy while maintaining healthy public relations. Results could also help policy makers decide whether sampling should be encouraged to the benefit of patient welfare.

Unlike other promotional tools employed in pharmaceutical marketing, the effects of sampling are not always one-sided. On the one hand, free drug samples can stimulate trial and improve sales. On the other hand, sampling might cannibalize sales from regular prescriptions. The extent of cannibalization could be severe, considering the over $18 billion retail value of drug

[2] Free drug samples can be provided to Stanford's pharmacy to be used in free clinics.

samples distributed in 2005 alone. Therefore it is important to consider both the positive and negative influence of pharmaceutical sampling when evaluating the profit impact on sales.

In this chapter, we first provide an overview of common practices in pharmaceutical sampling in the United States. Then we discuss various sources of data that can be used for drug sampling research. After that, we provide a literature review on the effects of samples on pharmaceutical sales from both the academic literature and the empirical studies in the industry. We close the chapter with suggestions for future research, for both practitioners and academic researchers.

Current Industry Practice of Pharmaceutical Sampling

In this section, we discuss industry practice of pharmaceutical sampling in the United States. Specifically, we focus on the following topics: (1) why samples are used; (2) the regulations governing pharmaceutical sampling; (3) sample decision support practice in pharmaceutical industry; (4) how drug samples are delivered to physicians; (5) how samples are consumed or dispensing pathway; (6) how samples are used in treating patients; and (7) the concept of "Source of Business" and how it is related to sample usage.

Why Samples are Used?

Pharmaceutical samples are delivered by manufacturers or by third party distributors, dispensed by physicians and consumed by patients. These three parties share certain views on the roles of samples, while each member has its own reasons for using samples. Patients as consumers perceive samples as a quick access to treatment and a way to reduce their medication expense. Physicians use samples to provide better service for patients and improve their relationship with patients. Pharmaceutical companies use samples to promote drugs, and to gain access to customers.

The key decision maker regarding sample usage is the physician. Physicians use samples differently depending on the medical condition of the patient. Sawaya (2002) summarized the reasons why physicians use samples (Table 1) based on the result of a physician survey. These reasons reflect clinical, logistical as well as social issues faced by physicians on a daily basis.

Table 1 Reasons for Using Samples

To start therapy immediately
To convince a patient to start therapy, or to increase patient compliance
To encourage a patient to come back for a follow-up visit
To treat a medical problem that is of a limited nature (for short-term use)
To test efficacy before filling a prescription
To assess tolerability before filling a prescription
To help in switching a patient to a new medication
To gain first-hand experience with a drug
For dosage titration (increasing dosage temporarily)
On patient request or to increase patient satisfaction
For patient convenience (e.g., if the drug store is closed)
To preserve patient confidentiality
Because they are there
If samples are about to reach the expiration date
Because "it's common policy."
To teach and to demonstrate.
To taste-test the drug (this is mentioned quite often by pediatricians)
For personal use, for family use and for staff use

As there are many different reasons for physicians to dispense samples to patients, it would be a challenge to separately identify and quantify the factors that drive sample dispensation of a brand.

Government Regulations:

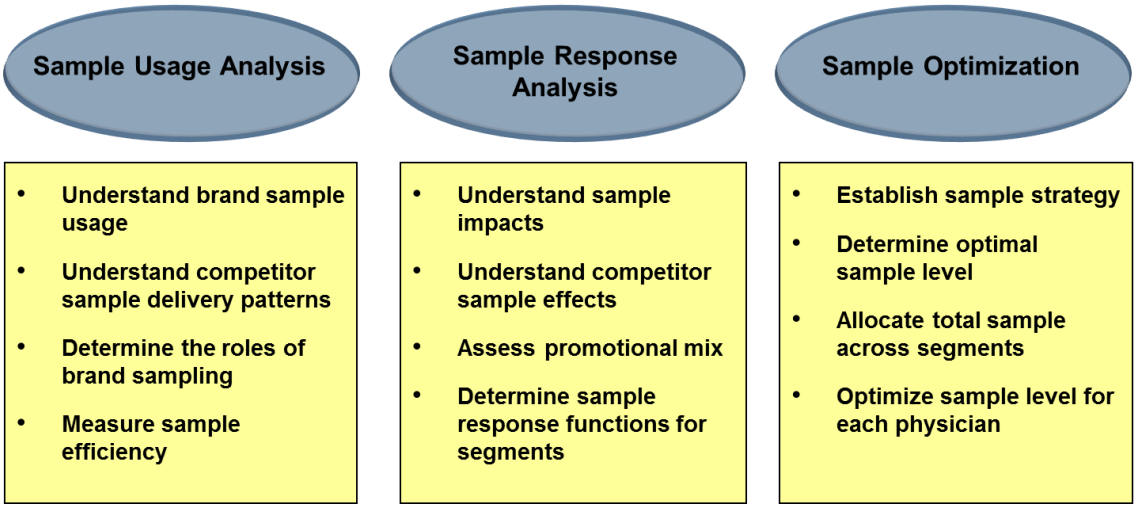
In the United States, the practice of pharmaceutical sampling is subject to detailed government regulations. According to “Prescription Drug Market Act” (PDMA) passed by the U.S. Federal Government in 1987, drug samples cannot be sold, traded, donated or supplied at a

reduced price to a third party, including charitable organizations. Drug samples can only be distributed to practitioners who are licensed to prescribe such drugs. PDMA requires distribution of drug samples only upon written request (called "sample signature" in the industry) by physicians with proper documentation. Sample distribution by mail or by sales representatives (sales reps) also requires a written receipt designated by the manufacturer or distributor acknowledging delivery and indicating name, address, and signature of practitioner or designee as well as the name, strength and quantity of drug samples received. According to PDMA, free drug samples must have a label that clearly denotes its status as a drug sample, such as "sample", "not for sale", "professional courtesy package". Manufacturers are required to keep detailed tracking data of sample distribution.

Sample Decision Support Practice in Pharmaceutical Industry:

As one of the most important promotion instruments, sampling has been studied extensively by pharmaceutical companies in order to gain competitive advantages in the market. The focus has been centered on understanding (A) how the sample is used, (B) prescription responses to sampling and (C) how to deploy samples effectively. The analytical process is illustrated in Figure 1. The foundation for fact-based decision making is to have good measurement of actual activities. The optimal sample strategy or decision needs to be based on an empirical sample response pattern, which depends on sample usage information. However, different from prescription dispensing that has been tracked by many different data sources; the record of sample dispensation is only available from limited data sources in the industry.

Figure 1 Core Sample Related Analyses in the Pharmaceutical Industry



Sampling decision remains to be a challenge for brand managers in practice because of data availability and the unique nature of sampling as a promotion tool. How many samples should be allocated to each brand, segment and physician? This question is one of the most critical and difficult marketing decisions faced by a pharmaceutical company. On the one hand, if a physician does not have enough samples for a particular drug, he may not start a new therapy or continue an existing therapy with that drug. Instead, he may start a new therapy using a competitor's drug for which samples are available. On the other hand, if the physician has too many samples available, the samples could cannibalize either new prescriptions or renewal prescriptions of the same brand.

Sample response models are difficult to build for several reasons. First, samples are frequently delivered during detailing encounters. In fact, on many occasions samples are physician access enablers. Without sample drops, many detailing encounters with physicians may not happen. This concurrency of sample drops and detailing creates a challenge to disentangle the effect of sampling from the effect of detailing. Second, a sample drop is recorded for delivery to a specific physician yet the delivered samples may be shared among several physicians from the same office. Therefore, the physicians who acknowledge the receipt of samples may be identified as

oversampled while other physicians within the same group practice may be identified as under-sampled. Third, unlike regular prescriptions that are tracked by standard pharmacy-based prescription audits such as IMS or NDC audits, prescriptions consisting of samples (except vouchers) do not go through a pharmacy and there is no good physician level audit on sample usage for each physician (with the exception of ImpactRx data for a limited size panel). All these factors make it difficult to build accurate sample response models. Consequently, the sampling-prescription response is more of a black box than a detailing-prescription response relationship.

Many pharmaceutical companies have personnel dedicated to sample analysis, planning, and operation management. Table 2 provides a list of sample related marketing research questions that frequently come up in the daily operation of pharmaceutical companies. Some of these questions may not be effectively addressed due to lack of data or methodology.

Table 2 Selected Sampling Related Measurement Issues Faced by Pharmaceutical Companies

Category	Selected Sampling Related Questions/Issues
Description of Sampling Activity	Are sales reps breaking up the boxes of samples into 1, 2, 3 or 4 SDOT (sample days of therapy)
	How many SDOT are the physicians giving away?
	What is the competition's sample configuration?
	How many of the competition's samples were given away?
	What are my competitors' sampling strategies?
	Are samples provided as treatment for the same patient diagnoses as scripts (i.e., contrast off-label usage for samples vs. scripts)?
	Do reps' sampling activities conform to the company's sample plan?
	To what extent does "counter sampling" occur (i.e., does the rep oversample physicians who have more competitor samples in their inventory)?
	Which products are physicians requesting samples for and are they receiving a sufficient amount of requested samples?
	How are samples used by different types of patients and by different sources of business?
Roles of Sampling	What are the roles of sampling?
	How do physicians see the value of samples?
	Are there any proper physician segmentations in terms of sample valuation or perception?

	Identify physicians who should not be sampled; i.e., are there physician, practice, third-party or patient characteristics that make sampling unproductive?
Mechanism between Sample Drop and Usage	What is the linkage between sample drop and sample usage?
	What are my reps doing in the sample closet?
	What channels are used to distribute samples for my brand?
Sampling Effect on Prescribing	What are the effects of my brand's sampling promotion?
	What are the effects of my competitors' sampling promotion?
	Does sampling increase physicians' prescribing activity or replace (reduce) prescribing activity?
	Is my brand oversampling?
	What are the sample effects on different types of source of business or different types of patients?
	What is the ROI of my brand's sample promotion?
	What is the long term effect of my brand's sampling promotion on physician prescribing?
Sampling Strategy and Tactics	What is the optimal sampling strategy?
	- Give away more or reduce samples?
	- Optimal sample packaging size or the ideal SDOT per box/unit?
	- Identify and design optimal sampling strategies according to product lifecycle (launch/growth/mature/decline).
	What is the optimal sample level for a targeted physician group practice?
	What sampling distribution strategy is actually implemented by the reps: e.g., random, opportunistic, to favored physicians, in proportion to prescribing to or appropriate patient populations, to physicians most responsive to sampling, etc.
	How is measuring effectiveness of sampling package designs used to induce "pull" by physician?
	How is measuring effectiveness of patient promotion and patient education materials integrated into the sample packaging to induce conversion to new prescription or to induce improved patient compliance and persistency (for refills)?

How Samples Are Delivered to Physicians:

Traditionally, the majority of drug samples are physically delivered by sales reps either during detailing visits or on sample only visits. Some companies send the samples via mail, and have sales reps obtain signatures from physicians. Some pharmaceutical companies use independent sample distributors because of regulation compliance or cost and efficiency concerns. In addition to direct delivery to physicians, a voucher is another way of distributing samples, which

has become more popular in recent years, especially for generic drugs. Vouchers can be provided by pharmaceutical company sales reps or mailed by generic companies that intend to encourage the prescription of lower priced drugs. Vouchers are redeemable in pharmacies with the physician's approval. The pharmacies will get reimbursed for the vouchers they fill. Voucher activities are generally recorded by pharmacies as regular prescription scripts without co-payment by patients.

Recently, e-Sampling (i.e., electronic sampling) has emerged as a new trend in distributing samples to physicians. E-Sampling allows physicians to request samples through the internet and have the samples delivered by mail. The combination of E-Sampling with promotional websites has become a cost-effective way for pharmaceutical companies to reach "white space", i.e., non-detailed and "no-see" physicians. This new sample delivery method increases the importance of sampling due to its wide and easy access. However, it also raises new challenges in management of marketing channel integration between off-line and on-line channels for pharmaceutical companies.

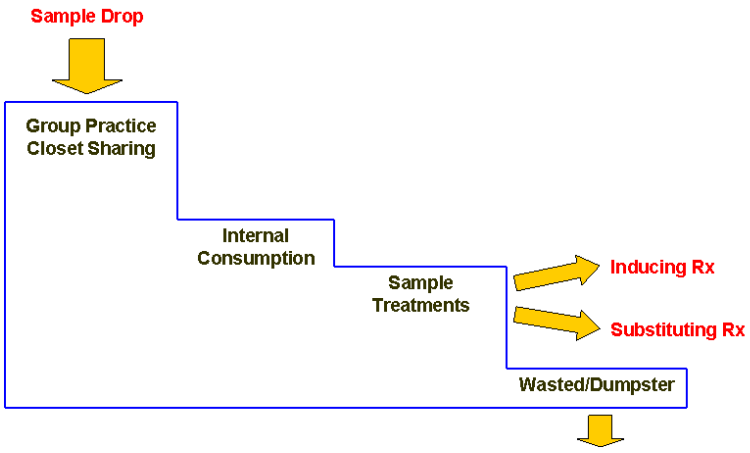
Sample Dispensation Pathway:

The pathway starting from the time when samples were dropped off by sales reps to samples being dispensed by physicians can be complicated and nontransparent. Samples dropped off by sales reps are normally only provided to a specific physician yet can be shared among physicians within the same group practice. This is because samples are typically stored in a sample closet which is accessible to all physicians in the same group. Although samples are typically dispensed to patients, surveys have shown that they can sometimes be consumed by physicians, their families and friends. For example, Westfall et al. (1997) conducted a physician and staff survey in a family practice residency, and they found that 66% of all respondents reported samples

being used for personal use, and 34% reported samples being used for their own family use. In addition, over supplied samples can expire and be thrown away.

Figure Figure 2 provides a graphical illustration of the dispensation pathway for a typical drug sample. Samples delivered to a physician belonging to a group practice will be shared, internally consumed and possibly discarded. The physician who receives the samples typically only dispenses a small portion of the samples delivered to her and she also dispenses other drug samples received by other physicians in the same group practice. Because of these organizational reasons, sample delivery does not correspond to sample dispensing at the physician level. This unobserved step in the pathway makes sample planning and allocation even more challenging.

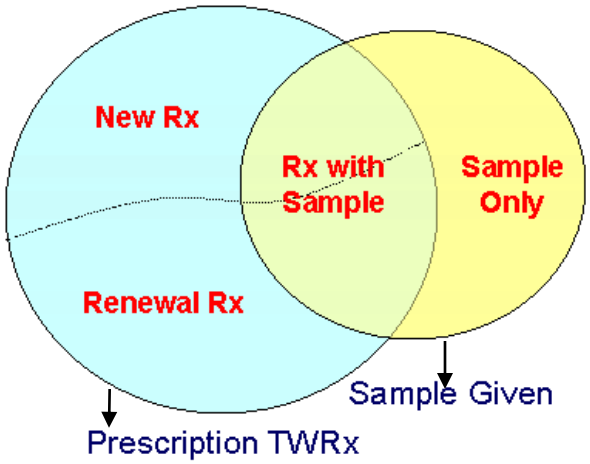
Figure 2 Illustrations of Physical Sample Dispensation Pathways



Sample Dispensing Patterns:

Typically, a physician has three options when prescribing a drug to a patient, as illustrated in Figure : prescription treatment (either new or renewal), sample only treatment or prescription treatment with sample.

Figure 3 Illustration of Sample Dispensation



- As a concrete illustration of sample dispensation patterns, we provide a descriptive analysis of the top 150 most promoted (based on detailing volume) brands that primary care physicians prescribed in the United States. The data comes from the ImpactRx sample treatment audit and was for the year 2010. There are several basic data notions to be explained here. TWRx stands for Total Written prescriptions, which is the sum of new prescriptions and renewal prescriptions written[3] by physicians. Similarly, NWRx stands for Newly Written prescriptions, which are new prescriptions written by physicians. We constructed the following metrics at brand level to measure sample usage and provided the summary statistics of these metrics for 150 brands in

  Table 3.

- *Sample Given/TWRx*: This ratio measures the number of treatments with free samples relative to the number of total written prescription treatments for each brand. Sample given (SG) includes both sample only (SO) treatment and prescription treatment with samples.

- *Sample Only/TWRx*: This ratio measures the number of sample only treatments relative to the number of total written prescription treatments for each brand.

- *NWRx with Sample/NWRx*: This ratio measures the percentage of newly written prescriptions which are prescribed with samples out of the total number of newly written prescription treatments for each brand.

- *RWRx with Sample/RWRx:* This ratio measures the percentage of renewal written prescription treatments which are prescribed together with samples out of the total number of renewal written prescription treatments for each brand.

[3] . The ImpactRx data is collected from its physician panel, therefore the prescriptions are "written" by physicians but may not be "dispensed" through pharmacies which have certain degree of prescription switching power. To distinguish from the normally used "dispensed" prescription data obtained from pharmacy audit, ImpactRx uses "written" prescription measure.

- *Sample Only/Sample Given*: This ratio measures the percentage of free sample treatments without prescription out of the total number of treatments with free samples for each brand.
- *Sample Only/NWRx*: This ratio measures the number of the percentage of free sample only treatments relative to the number of newly written prescription treatments for each brand.

Table 3 Summary Statistics of Selected Sample Usage Measures for Top 150 Brands

Descriptive Statistics	Sample Given / TWRx	SO / TWRx	NWRx with Sample / NWRx	RWRx with Sample / RWRx	Sample Only / Sample Given	Sample Only / NWRx
Mean	0.28	0.14	22%	7%	42%	0.31
Median	0.19	0.08	22%	6%	45%	0.28
Standard Deviation	0.24	0.15	12%	6%	17%	0.24
Maximum	1.31	0.84	55%	42%	76%	1.26
Minimum	0.00	0.00	0%	0%	0%	0.00

Note that above statistics are based on a sample of 150 brands. It provides some insights regarding how samples are used in the most promoted products among primary care physicians. Here are some observations based on these statistics. First of all, samples are widely used among primary care physicians. Of all the 150 brands considered, 137 brands (91.3%) have instances where NWRx were prescribed with samples at the same time, and 143 (95.3%) have sample only treatments.

Secondly, sample usage intensity varies widely across brands, as indicated by the standard deviation of the ratio of Sample Given/TWRx. The average of this ratio across all brands is 0.28 and the median value is 0.19. The brands having the lowest "Sample Given/TWRx" ratio are OXYCONTIN, VYVANSE, ANDROGEL, NUCYNTA and RECLAST. The brands having the highest "Sample Given/TWRx" ratio are PENNSAID and DULERA, both of which are at their launch phases in the data period. Overall, about 73% of the 150 brands have "Sample

Given/TWRx" ratio at 10% or higher. This indicates that sample promotion is commonly used by a majority of the most promoted products in the U.S.

Thirdly, the average percentage of new prescription treatments prescribed with samples is 22%, and this ratio is only 7% for renewal prescription treatments. In other words, sample usage with new therapies is more than three times of sample usage with continued therapies. This indicates that samples are used more frequently by primary care physicians to initiate new therapies than to ensure continuation of existing therapies.

Lastly, sample only treatment without prescription is a common practice and accounts for a majority of how samples were dispensed to patients. On average, the ratio of "Sample Only" to "Sample Given" for all 150 brands is 42%, and the median is 45%. Fifteen brands have two-thirds of their sample treatments dispensed without any written prescriptions.

Sample Dispensing and Source of Business:

NWRx measures new prescriptions of a drug. When a patient switches pharmacy or changes his family doctor, or visits a specialist for the first time, the prescriptions are generally recorded as NWRx. To avoid such ambiguity, the concept of "source of business" (SOB) is used to further define types of prescription treatments by incorporating patient prescription history information. Starting in the year 2000 as patient longitudinal prescription data became widely available, SOB has been gradually adopted in pharmaceutical market research and promotion analysis practice.

Table 4 Definition of Source of Business

Source of Business	Diagnosis Type	Prescription Type
(1) New diagnosis	Newly diagnosed	NWRx

(2) Switched from non-drug treatment	Previously diagnosed	
(3) Switched to new medication		
(4) Add-on therapy		
(5) Ongoing diagnosis		RWRx
(6) Titration of current medication		

The definition of SOB is described in Table 4. A written prescription script can be classified into one of the six categories of "Source of Business", which are (1) new diagnosis, (2) switched from non-drug treatment, (3) add-on therapy, (4) switched to new medication, (5) ongoing diagnosis, and (6) titration of current medication. Among all these six categories, except for the first one which is used for a newly diagnosed condition, all the others are for a condition that was previously diagnosed. (1)-(4) corresponds to NWRx and (5)-(6) corresponds to RWRx.. Using SOB, different types of NWRx prescriptions can be distinguished by considering patients' treatment histories, which was missing in the NWRx/RWRx categorization. In particular, (1) in SOB refers to a condition that is newly diagnosed. (2) and (3) correspond to a situation in which a patient was previously diagnosed with a particular disease but just switched to the prescription from either non-drug treatment or some other medical/drug treatment. (4) "Add-on Therapy" refers to a situation that a patient is prescribed with additional and different prescription treatment given existing prescription treatment. For example, diabetes patients who have Actos may get Januvia as an "add-on" therapy. Based on the SOB classification, renewal prescription consists of two types of treatments: (5) ongoing diagnosis, which refers to a continued prescription of the same brand for a patient with a previously diagnosed condition; and (6) titration of current medication,

which refers to a continuing prescription of the same brand at a different dosage. For example, a physician may prescribe a 20 mg Lipitor to a patient who is currently getting 10 mg Lipitor because she decides the current dosing is not sufficient. By incorporating the information regarding patients' treatment histories, the SOB concept offers a deeper and more precise understanding of brand usage comparing to the traditional NWRx and RWRx concepts. For example, some brands are considered by doctors as first line therapies so they are better measured by using market share among new patients. Other brands are considered as second line treatments and are used more often as add-on therapy. The SOB concept helps to distinguish these two situations. Since longitudinal patient level data became available in early 2000's, "Source of Business" has become a popular data measure for physician segmentation and targeting, as well as promotion response analysis in the pharmaceutical industry.

Similarly, further breaking down of the sample treatments by source of business can provide more insight into how samples are used by physicians. To demonstrate the SOB patterns for sample and prescription treatments, we conducted an analysis using data from the Antidepressant class. The data records prescriptions and samples dispensed from primary care physicians in a six-month period from January to June of 2008. In this analysis, only three heavily detailed brands are considered (LEXAPRO, EFFEXOR/XR and PRISTIQ). Generic drugs and non-drug treatments are excluded from this analysis. As plotted in Figure 4, the majority of antidepressant prescription treatments (73%) were given without samples at all. "Sample Only" treatments account for 15% of the total prescription treatments, and "prescription treatments with samples" account for the remaining 12%.

Figure 4 Treatment Volume Distribution: Antidepressant Class

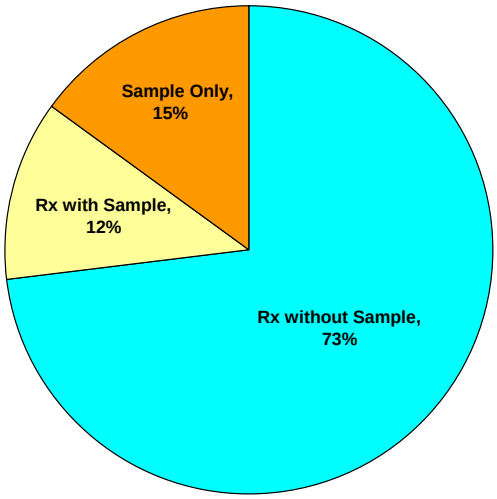
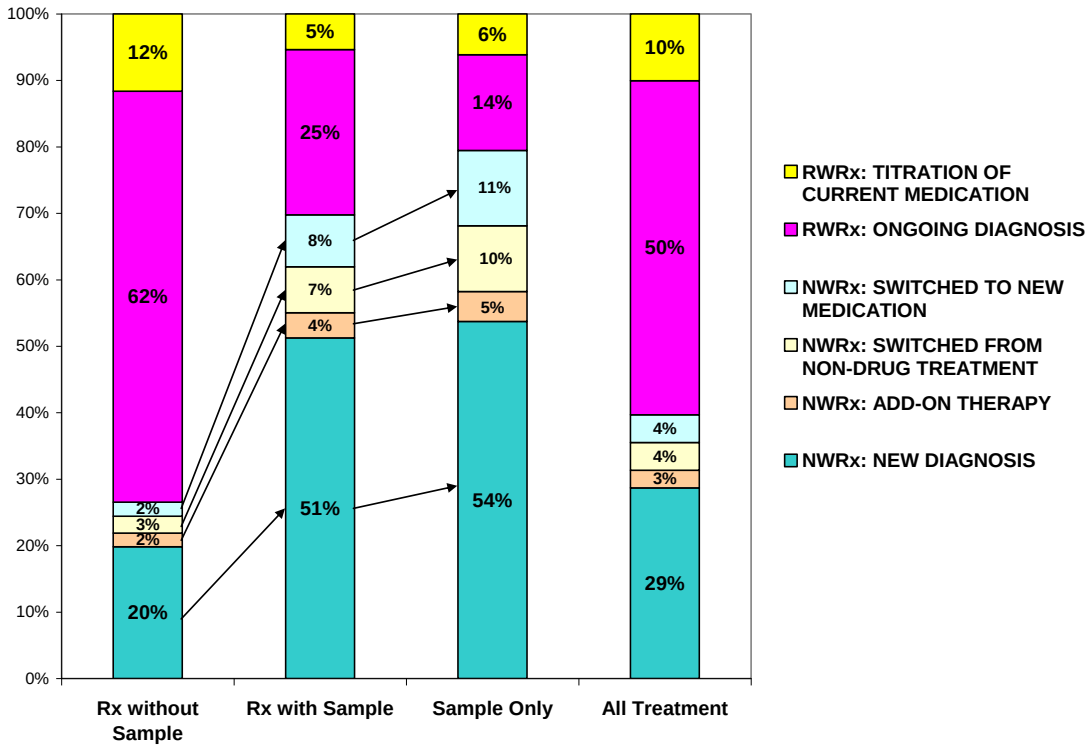


Figure 4 provides a breakdown of source of business distribution by treatment types in the antidepressant class. We notice the following three patterns in sample dispensation from this analysis. First, in the antidepressant class, samples were most frequently used to initiate new patient therapy among all of the SOB measures. Fifty-four percent of "Sample Only" treatments and 51% of "prescription with Sample" prescription treatments were prescribed to patients with a new diagnosis, while only 20% of "prescription without Sample" treatments were prescribed for newly diagnosed patients. In addition, 10% of "Sample Only" prescription treatments and 7% of "prescription with Sample" prescription treatments were prescribed to patients who switched from non-drug therapy, while only 3% of "prescription without Sample" treatments were prescribed to these patients. Second, samples also play an important role in competitive treatment switching; 11% of "Sample Only" treatments and 8% of "prescription with Sample" treatments were prescribed to patients who switched to new drug therapy, whereas only 2% of "prescription without Sample" treatments were prescribed for the same purpose. Third, samples are also used for renewal treatments, including titration and continuing current treatment, but at a relatively lower percentage than prescription treatment without sample category. In summary, samples are

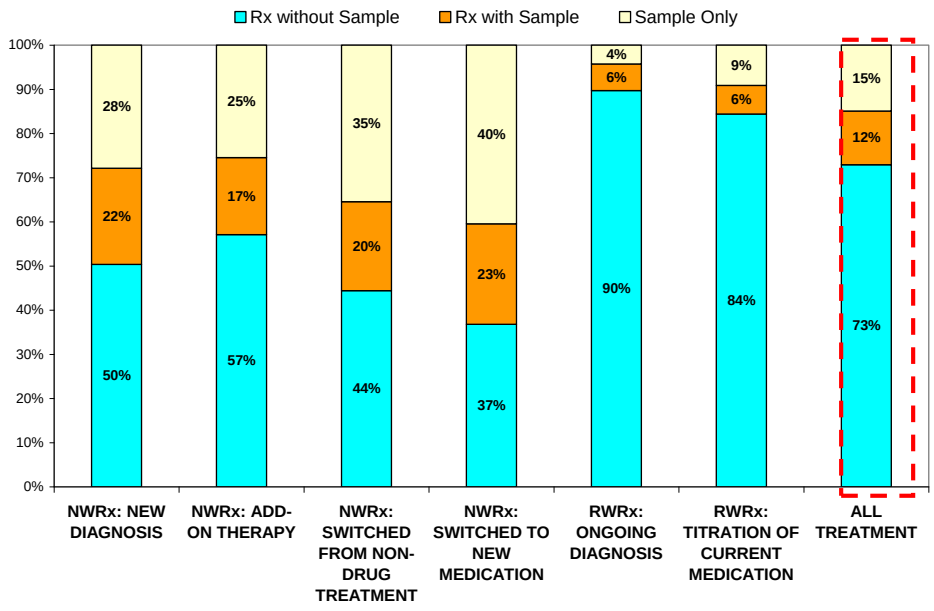
important in getting new patients to start on a particular brand rather than ensuring renewal prescription.

Figure 5 Source of Business Distribution by Treatment Type: Antidepressant Class



Examining the data from a different angle, we plot the treatment type distribution by "Source of Business" in Figure . This plot allows us to examine how different types of sample treatments were used across different types of patients. The graph shows that "Sample Only" treatments had the highest share among patients who "Switched to New Medication", which is also referred to as competitive switches. "Sample Only" treatments account for a higher share in "Switched from Non-drug Treatment" and "New Diagnosis" patients relative to other categories in SOB. Finally, samples are used more often in starting new treatments than in preserving renewal treatments. These results indicate that sampling is important in helping drug manufacturers gain access to patients that are new to the brand.

Figure 6 Treatment Type Distribution by Source of Business: Antidepressant Class



Sample Data Sources for Marketing Research

In this section, we provide an overview of three major data sources that are available for marketing research on pharmaceutical sampling.

IMS Health Data:

In the pharmaceutical industry, the most widely used drug sample data comes from the Integrated Promotional Services™ (IPS) by IMS Health. The database started in 1992, while its predecessor the National Detailing Audit™ collected data from 1958 to 1992. IPS is a physician detailing activity audit that tracks office-based pharmaceutical promotion in the continental United States. Each brand's promotion volume is projected to national level. The IPS physician panel sample consists of 3,800 physicians in 25 specialty groups (100 specialties) from 43 states across the US. Physicians are asked to participate for at least a year. Some physicians may choose to stay on the panel for multiple years.

The IMS sampling data is collected from one third of its members (i.e. 1265 physicians) of the IPS physician panel. The nurses or office administrators from those physician offices report sample drops by sales reps from manufacturers as well as samples mailed to the panel physicians. All sampling measures are projected to the national level for each specialty. The data report three main sample drop measures for each brand:

(1) Number of extended sample units[4] for each product form and strength.

(2) The mode of sample size for each product form and strength.

(3) The average number of tablets, capsules, or grams.

In addition, the data also record three delivery types, including in-person detailing, service visit and mail delivery. Most market research applications using these data are based on projected sample volume and market share for each brand within a market. One major limitation of the IMS sample audit is that the projection error can be significant for some small brands or brands with fewer sample drops. To the best of our knowledge, no physician level modeling analysis has been conducted using IPS sample data.

Scott-Levin/Verispan/SDI Health Data:

As the one of the main competitors to IMS' IPS, Scott-Levin Associates started Personal Selling Audit (PSA) in 1993. Physicians reported similar sales rep activities over time, which normally takes them about 10-15 minutes per month. PSA has a panel of about 4,300 physicians from 32 specialty groups. Scott-Levin was acquired by Quintiles in March 1999 and became a part of Verispan in March 2002. Verispan was bought out by SDI Health, LLC in July 2008.

[4]Extended sample unit represents basic unit of a sample package such as tablets, capsules, grams, tubes, bottles and etc. Since extended units for any products can represent a variety of forms, these data cannot be logically summed up beyond product/form/strength level.

These data are provided at monthly level and report the following information by product, company and physician specialty:

(1) Number of details

(2) Duration of each detailing call

(3) Detailing sequences

(4) Number of samples dropped

Similar to IPS, only a portion of PSA panel (about 1600 physicians) report sample information.

ImpactRx Panel:

ImpactRx started collecting data from its physician panel in 2002. By 2011, they had a panel of more than 4,100 physicians from 14 specialties. Similar to IMS IPS audits, ImpactRx panel records a complete audit on promotion details; in addition, it also collects information on patient treatment, diagnosis, and demographic data from the same physician panel. ImpactRx data are not projected to national level. This data is ideal for measuring treatment responses to various promotional tools at the individual physician level.

ImpactRx collects sample usage data as a part of physician treatment activities. The data reports the type of sample treatment prescribed by physicians (i.e., whether it is new prescription treatment with samples, renewal prescription treatment with samples, or sample only treatment), as well as the amount of samples dispensed on each prescription occasion measured by sample counts and sample days of therapy. Each sample or prescription treatment has a unique diagnosis code (ICD-9) so that a treatment can be identified for a specific medical condition.

As a measure of sales reps' detailing activities, ImpactRx data recorded sample signature data starting in October of 2010. Physicians reported sample signature signed as well as vouchers and coupons distributed to each doctor during each product detailing.

Literature Review of Academic Research on Pharmaceutical Sampling

In this section we review existing academic studies on prescription sampling from both the marketing and medical literature. We first summarize prior literature on the effects of free drug samples on physicians' prescription choices and prescription drug sales. We then discuss previous studies that examine the drivers of physicians' free drug sample dispensing behavior and explore the roles free samples play in physician's prescription decisions.

The Effects of Free Drug Samples on Prescription Choice

The vast majority of the existing marketing studies on the effects of free drug samples have focused on evaluating the impact of free samples on prescription drug sales or physician's prescription choice.

Gönül et al. (2001) studied the effects of detailing and sampling on an individual physician's prescription decision. They found that sampling had a positive effect on physician's prescription decisions, but this effect had diminishing returns. Using a large pooled time series of cross-sectional data involving three drugs and 74,075 individual physicians, Mizik and Jacobson (2004) also find that detailing and free drug samples have statistically significant positive effects on the number of monthly new prescriptions issued by a physician. However, the magnitudes of these effects are modest compared to the findings in previous studies.

Using individual level panel data, Manchanda, Rossi, and Chintagunta (2004) analyzed physician's prescription decisions with a Hierarchical Bayesian framework. They suggest there is

a significant and positive influence of drug sampling on an individual physician's prescription decisions. The influence affects both the physician's base prescription rate and the physician's responses to detailing. This concept is furthered by Manchanda, Xie and Youn (2007). They found that sampling stock positively affects the probability of a physician's adoption of a new drug. Finally, Montoya, Netzer and Jedidi (2010) use a nonhomogeneous hidden Markov model, and find that while detailing may be more useful as an acquisition tool, sampling is more useful as a retention tool.

The effect of drug samples on prescription decisions is also a topic that is frequently discussed in the medical literature, yet the findings are mixed. Some studies suggest free samples may cannibalize regular prescriptions in the short term. For example, Boltri, Gordon and Vogel (2002) reported that usage of recommended antihypertensive drugs increased when samples were removed from one clinic. In another study, Brewer (1998) found that residents in two programs with restrictions on samples prescribed more recommended nonsteroidal anti-inflammatory drugs (NSAIDS) than residents in a comparable program but without restrictions on samples. However, other studies suggest the opposite effect that free samples help to enhance the sales of the promoted drugs. For example, the findings by Symm et al. (2006) and Adair and Holmgren (2005) suggest that physicians who distribute free samples are more likely to prescribe those medications than their counterparts. One obvious limitation of such studies is that free sample dispensing was the only determinant considered, while a wide range of other factors that would impact a physician's prescription decision, such as other marketing mix and patient characteristics, were left out of the studies.

Drivers of Physician's Free Sample Dispensing Decision

Most research that examines the determinants of a physician's drug sample dispensing decision exists in the medical literature. Two main motives suggested by the literature are an *experimentation* role and a *subsidy* role. The experimentation role of free drug samples hinges on the belief that free samples are a cost-effective way for a physician to test for the match between a new drug and a particular patient. The subsidy role relates to the cost saving to indigent patients through supply of free drug samples. For example, Chew et al. (2000) conducted a physician survey to investigate the purpose of dispensing drug samples. They found avoiding cost to the patient is the primary reason for dispensing drug samples and evaluating treatment effectiveness is the secondary reason when the diagnosed condition is complicated. In addition, Backer et al. (2000) conducted a field study that found individual physicians vary in their intent when dispensing samples. In particular, physicians use samples to test for efficacy, as a temporary relief for convenience of their patients, or to save cost for their patients.

If an "experimentation" role of free drug samples exists, we would expect that a patient is more likely to receive free samples (rather than a full prescription) of a drug from her physician if she has not been prescribed the drug before. Furthermore, it usually only takes a few trials to find out whether a drug is working for a patient. Thus, if the physician's main motive is to experiment when she gives free samples to a new patient, we would expect that the sample dosage will be lower in this case. On the other hand, if free drug samples play a "subsidy" role in physician's prescription decision, we would expect that an indigent patient (e.g., one with low income or with inadequate insurance coverage) is more likely to receive free samples from her physician. In fact, a number of studies in the medical literature provide empirical evidence for this view. Taira et al. (2003) showed that among elderly patients, those with financial problems are more likely to receive free drug samples. Through a patient survey, Stevens et al. (2003) found that self-

pay/uninsured patients more frequently report receiving free drug samples than patients with public aid. Morgan et al. (2006) find that giving out free samples to help patients with financial difficulties was a common practice among the 397 obstetricians and gynecologists who participated in the study. However, a more recent study by Cutrona et al. (2008) reported a somewhat unexpected finding that poor and uninsured Americans are less likely than wealthy or insured Americans to receive free drug samples. As the authors speculate, this finding could be partly due to the cofounding facts that the poor and uninsured might be less likely to visit physicians. Thus, their access to free samples is more limited compared to other patients. Nevertheless, the question of whether the indigent patients are more likely to receive free drug samples conditional on their visits to the doctors remains unanswered and warrants further investigation.

As mentioned before, the majority of marketing studies have focused on evaluating the impact of samples dropped by pharmaceutical firms on physician's prescription choice, but have not investigated individual physician's decision on free drug sample dispensing. One noticeable exception is Venkataraman and Stremersch (2007), in which the authors find that both detailing and physician meetings have a positive effect on the number of samples dispensed by physicians. However, the authors do not explore further the underlying drivers of physicians sample dispensing behavior (i.e., whether it is due to the "experimentation" role, the "subsidy" role", or both). Dong and Xie (2011) took one step further to provide deeper insights into physician sample dispensing behavior by incorporating patient characteristics that relate to physicians' two fundamental motives in free sample dispensing in both the sample dispensing model as well as the sample dosage model. Using a physician panel dataset of sample dispensing and prescription choices in both the PPI and ED categories provided by ImpactRx, Dong and Xie (2011) jointly

estimate a multinomial logit model of joint brand and treatment mode (i.e., whether to dispense free samples or to write a prescription) choice and a count model of quantity decision at individual physician level in a hierarchical Bayesian framework. They propose that the long-term effect of free samples on brand choice might depend on the underlying motivation of the dispensing physician. On one hand, if the purpose is to stimulate trials through "experimenting", a physician's free sample dispensing would have a positive effect on her future prescription, as demonstrated in existing studies on the effect of sampling in the pharmaceutical industry. On the other hand, if the main objective is to provide financial assistance or subsidy to an indigent patient, a null effect of free sample dispensing on a physician's future prescription of the same brand is observed. This is similar to the cannibalization effect as shown in Bawa and Shoemaker (2004). They find that in general physicians are more likely to dispense free samples to patients who (1) are newly diagnosed; (2) have an ongoing diagnosis but were prescribed a different drug on the previous visit; and (3) do not have any insurance coverage. However, the tendency to dispense free samples to each of the above mentioned types of patients differ considerably across physicians. As for the long run effects, the result shows that free sample dispensing will induce future prescriptions if the samples are dispensed to new patients. In addition, they do not find a significant effect of free samples on future prescription decisions if dispensed to patients without any insurance coverage.

Industry Research in Practice

The above section reviewed academic research on pharmaceutical sampling. In practice, to gain competitive advantages, pharmaceutical companies also conduct extensive studies on sampling. In general, these studies can be grouped into three categories: (1) sample modeling at aggregate level; (2) sampling modeling at disaggregate level; and (3) sample allocation models. In this section, we provide an overview of these three types of studies.

Sample Modeling at Aggregate Level;

Aggregate modeling using brand level data is one common way of conducting sample analysis in industry practices. The objective is to understand and assess adequacy and effectiveness of sample resource allocation at brand level from a strategic perspective. One approach is to evaluate how a brand's TWRx/NWRx volume or market share is influenced by sample volume in addition to detailing volume. Normally a multivariate time series model approach is employed for such analysis using a brand's own promotion and sales data. This type of analysis is usually constrained by the length of the time series. Another aggregate model approach utilizes competitor promotion and sales data to build a representative brand model by pooling brand level data from all competitors. This approach requires a cross-sectional time-series model by using detailing and sample audit data such as IMS Health IPS data. Since the mid-1970s, some practitioners started using the seeming unrelated regressions (SUR) approach to build a brand level promotion response model, which allows analysis across multiple therapeutic classes. A similar approach is also used in the ROI Analysis of Pharmaceutical Promotion (RAPP) by Neslin (2001) and Wittink (2002). Pooling multi-brand data increases sample size and expands the range of hypotheses to be tested. This type of analysis can provide directional views to a particular company, because it is based on cross brand experience.

From the practice perspective, the advantages of aggregate sample modeling include:

- Sample effectiveness can be compared with both personal promotion such as detailing and non-personal promotion as well as other marketing instruments such as journal spending, direct to consumer spending (DTC).
- Easier to evaluate competitive sample drop effects;
- Can provide life cycle perspective because of historical and cross brand perspective;
- Dynamic effect and seasonality can be easily specified and estimated;
- ROI assessment at brand level can be easily conducted.

Limitations of aggregate sample modeling are:

- Longer historical data is needed for modeling so the result can be useful for long term strategic planning but may not be accurate for short term implementation;
- May be subjected to aggregation errors;
- Limited by sample size or data period;
- Multi-collinearity between detailing and sample drop;
- Not tactical for field implementation and action, for example, at segment level

Physician Level Modeling;

Test-control study is a commonly used approach in the industry to evaluate impacts of promotion such as detailing, new messaging, DTC, direct mail, and sampling at individual physician level. Typically, the response measure is prescription shares by a physician. The test and control groups are selected in such a way that across groups the physicians are similar in prescribing patterns (in terms of volume) and external factors. ANOVA or ANCOVA model is applied to test prescribing share or volume difference between test (sample exposed) and control (no sample exposure) groups while other factors are controlled through either covariates or data selection. The same approach is also used for pre and post analysis, which requires longer duration of the data. The ROI can be easily calculated based on test and control analysis.

Normally, this type of approach is used on secondary data, such as physician prescription data or longitudinal patient data. A large sample size can ensure that a sufficient sample can be obtained with more factors controlled. Different companies used different matching methods to form test and control groups that are comparable. One of the main limitations of the test and control analysis is that it is difficult to eliminate all confounding factors so that physicians in test and control groups are exactly comparable except for differences in sample or other promotion stimuli.

Recently, panel model at the physician level has become a standard analytical practice for most pharmaceutical brands where physician level sales data are available. Pharmaceutical companies started to adopt this approach in late 90s, just a few years after physician level data (such as IMS Xponent) became available. Every large pharmaceutical company by now has

developed an enterprise level modeling system that can produce promotion response analysis at brand and segment level on a regular basis to support call planning, physician targeting and resource allocation. Typically, physicians' NWRx, TWRx or share measures from IMS or NDC are used as a dependent or response variable, and independent variables include number of calls, samples left to physicians, meetings and events, and other promotion and marketing variables such as DTC. The modeling methods are drawn from econometrics and marketing science literature, including dynamic panel models, generalized linear models, mixed models (random effect models), count models (Poisson and NBD), and hierarchic Bayesian models.

Most of the panel models as described above utilize internal promotion data and prescription records from data vendor such as IMS. There are some well-known limitations of using this internal promotion data. First, the promotion information is subject to self-reporting errors (which may be caused by the company's incentive structure). Second, no competitive promotion measures exist at the physician level. Thus, the estimated promotion effectiveness can be significantly biased especially in a competitive market. Third, sample drop measure to any doctor may not be an accurate measure of sample promotion due to sample sharing within a group practice, sample signature practice and the existence of other sample distribution channels.

In the past five years, panel modeling approach using patient transactional level data, instead of monthly physician level data, has become a popular way to evaluate the effectiveness of detailing, message and promotion tactics. There are several advantages of such an approach. First, it models stimuli and response relationship at a more granular level; second, it considers timing between promotion and response explicitly; third, it reduces multicolinearity and data aggregation; and lastly, more transactional level factors can be considered in the model. As non-personal or alternative channel promotion targeting of patients has gained a more important status

in recent years, many pharmaceutical companies also used this platform to evaluate the effectiveness of non-personal promotion such as direct mail, voucher, and co-pay card, etc.

Sample Allocation Model:

The ultimate question for every sales team is how many samples should be distributed to a targeted physician so that paid prescriptions can be maximized in the long run. One approach adopted in the industry is the method of "one-period inventory problem", also called the "newsvendor problem". The objective of this approach is to find the optimal number of samples to distribute that will maximize the expected profit. The expected profit is the sum of expected profit under the uncertainty of demand. Under certain distribution assumptions, such as Normal or Poisson distribution, optimal sample decisions can be obtained with a closed form solution. The implementation of this approach requires some observational measures on physician sample usage. This inventory approach of optimal sample allocation has the following shortcomings. First, it treats sample use the same way as merchandise inventory decision, while ignoring the possible impact from promotional efforts. Second, the implementation of this approach requires the information on physician sample usage rate and sample closet stock level, which may not be observable. Third, the calculation of opportunity cost and revenue potential can be tricky due to the short term and long term trade-off. Lastly, competitive sample drops and stock levels are not considered in this model, which can present significant influences in physician sample usage and prescription behavior.

Future Research

In the above, we summarized the current research in both academia and industry regarding pharmaceutical sampling. Comparing to other promotional tools (such as detailing and direct to

consumer advertising), pharmaceutical sampling is still an under-studied topic. Next, we provide a non-exhaustive list of topics for future research.

First, how to determine the right sample quantity for different physician segments and how to target specific physicians remains to be important questions and calls for more future research. The inventory approach of optimal sample allocation is a passive service model based on several assumptions related to unobserved conditions. Designing a better sampling decision model for group practice physicians that models physician prescribing with unobserved variables such as physician sample usage rate and sample closet stock level continues to be a challenge in the pharmaceutical industry practice.

Second, the dynamic effects of sampling on prescription writing are not well understood. Most business practices focus on the short term effect. However, sampling can have negative short term and positive long term effects on prescriptions. Understanding the dynamics of sampling on future prescriptions, and the effects of detailing on sample usage can be valuable to guide marketers in planning sample strategies.

Third, it is important for marketers to have a better understanding regarding how patient level information influences a doctor's decision on sample usage. In such research, how to address unobserved behavior such as sample closet sharing is a challenging question to researchers.

Fourth, it is important for marketers to understand how sampling strategy should be adjusted based on the drug's product life cycle stage. Historical analogue approach is currently used in new product launch planning practices. In this approach, researchers should evaluate all aspects of historical launches, including both successful and unsuccessful launches, to understand what strategies worked and what did not. This market research intelligence can provide guidance on all major new product launch planning. In addition, more rigorous statistical empirical research

on launch strategies as well as on other stages in the life cycle (growth, mature and decline) will be valuable.

Finally, as the role of physical sample drop declines and alternative sample distribution channels expand, pharmaceutical companies need to understand the relative effectiveness of different sample delivery channels such as sample signature, vouchers, e-sampling, and patient assistance program. This new sampling mix optimization is an important issue in the new era of multiple-channel sample distribution.

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