Effect of In-Office Samples on Dermatologists' Prescribing Habits: A Retrospective Review

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PRACTICE **POINTS**
- There has been growing concern that pharmaceutical interactions and incentives can influence physicians' prescribing habits.
- Many academic centers have adopted policies that attempt to limit the pharmaceutical industry's influence on faculty and in-training physicians.
- This study aimed to investigate if there was a change in the prescribing habits of academic dermatologists after the medical school implemented new policies that banned in-office samples.

The relationship between physicians and pharmaceutical companies has caused the medical community to question the degree to which pharmaceutical interactions and incentives can influence physicians' prescribing habits. Our study aimed to analyze whether a change in institutional policy that restricted the availability of in-office samples for patients resulted in any measurable change in the prescribing habits of faculty physicians in the Department of Dermatology & Cutaneous Surgery at the University of South Florida (USF)(Tampa, Florida). Medical records were retrospectively reviewed for common dermatology diagnoses—acne vulgaris, atopic dermatitis, onychomycosis, psoriasis, and rosacea—before and after the pharmaceutical policy changes, and the prescribed medications were recorded. These medications were then categorized as brand name, generic, and over-the-counter (OTC). Statistical analysis using a mixed effects ordinal logistic regression model accounting for baseline patient characteristics was conducted to determine if a difference in prescribing habits occurred.

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Over the years, there has been growing concern about the relationship between physicians and pharmaceutical companies. Many studies have demonstrated that pharmaceutical interactions and incentives can influence physicians' prescribing habits.[1-3] As a result, many academic centers have adopted policies that attempt to limit the pharmaceutical industry's influence on faculty and in-training physicians. Although these policies can vary greatly, they generally limit access of pharmaceutical representatives to providers and restrict pharmaceutical samples.[4,5] This policy shift has even been reported in private practice.[6]

At the heart of the matter is the question: What really influences physicians to write a prescription for a particular medication? Is it cost, efficacy, or representatives pushing a product? Prior studies illustrate that generic medications are equivalent to their brand-name counterparts. In fact, current regulations require no more than 5% to 7% difference in bioequivalence.[7-9] Although most generic medications are bioequivalent, it may not be universal.[10]

Garrison and Levin[11] distributed a survey to US-based prescribers in family practice, psychiatry, and internal medicine and found that prescribers deemed patient response and success as the highest priority when determining which drugs to prescribe. In contrast, drug representatives and free samples only slightly contributed.[11] Considering the minimum duration for efficacy of a medication such as an antidepressant vs a topical steroid, this pattern may differ with samples in dermatologic settings. Interestingly, another survey concluded that samples were associated with "sticky" prescribing habits, noting that physicians

would prescribe a brand-name medication after using a sample, despite increased cost to the patient.[12] Further, it has been suggested that recipients of free samples may experience increased costs in the long run, which contrasts a stated goal of affordability to patients.[12,13]

Physician interaction with pharmaceutical companies begins as early as medical school,[14] with physicians reporting interactions as often as 4 times each month.[14-18] Interactions can include meetings with pharmaceutical representatives, sponsored meals, gifts, continuing medical education sponsorship, funding for travel, pharmaceutical representative speakers, research funding, and drug samples.[3]

A 2014 study reported that prescribing habits are influenced by the free drug samples provided by nongeneric pharmaceutical companies.[19] Nationally, the number of brand-name and branded generic medications constitute 79% of prescriptions, yet together they only comprise 17% of medications prescribed at an academic medical clinic that does not provide samples. The number of medications with samples being prescribed by dermatologists increased by 15% over 9 years, which may correlate with the wider availability of medication samples, more specifically an increase in branded generic samples.[19] This potential interaction is the reason why institutions question the current influence of pharmaceutical companies. Samples may appear convenient, allowing a patient to test the medication prior to committing; however, with brand-name samples being provided to the physician, he/she may become more inclined to prescribe the branded medication.[12,15,19-22] Because brand-name medications are more expensive than generic medications, this practice can increase the cost of health care.[13] One study found that over 1 year, the overuse of nongeneric medications led to a loss of potential savings throughout 49 states, equating to $229 million just through Medicaid; interestingly, it was noted that in some states, a maximum reimbursement is set by Medicaid, regardless of whether the generic or branded medication is dispensed. The authors also noted variability in the potential savings by state, which may be a function of the state-by-state maximum reimbursements for certain medications.[23] Another study on oral combination medications estimated Medicare spending on branded drugs relative to the cost if generic combinations had been purchased instead. This study examined branded medications for which the active components were available as over-the-counter (OTC), generic, or same-class generic, and the authors estimated that $925 million could have been saved in 2016 by purchasing a generic substitute.[24] The overuse of nongeneric medications when generic alternatives are available becomes an issue that not only financially impacts patients but all taxpayers. However, this pattern may differ if limited only to dermatologic medications, which was not the focus of the prior studies.

To limit conflicts of interest in interactions with the pharmaceutical, medical device, and biotechnology industries, the University of South Florida (USF) Morsani College of Medicine (COM)(Tampa, Florida) implemented its own set of regulations that eliminated in-office pharmaceutical samples, in addition to other restrictions. This study aimed to investigate if there was a change in the prescribing habits of academic dermatologists after their medical school implemented these new policies.

We hypothesized that the number of brand-name drugs prescribed by physicians in the Department of Dermatology & Cutaneous Surgery would change following USF Morsani COM pharmaceutical policy changes. We sought to determine how physician prescribing practices within the Department of Dermatology & Cutaneous Surgery changed following USF Morsani COM pharmaceutical policy changes.

Methods

Data Collection—A retrospective review of medical records was conducted to investigate the effect of the USF Morsani COM pharmaceutical policy changes on physician prescribing practices within the Department of Dermatology & Cutaneous Surgery. Medical records of patients seen for common dermatology diagnoses before (January 1, 2010, to May 30, 2010) and after (August 1, 2011, to December 31, 2011) the pharmaceutical policy changes were reviewed, and all medications prescribed were recorded. Data were collected from medical records within the USF Health electronic medical record system and included visits with each of the department's 3 attending dermatologists. The diagnoses included in the study—acne vulgaris, atopic dermatitis, onychomycosis, psoriasis, and rosacea—were chosen because in-office samples were available. Prescribing data from the first 100 consecutive medical records were collected from each time period, and a medical record was included only if it contained at least 1 of the following diagnoses: acne vulgaris, atopic dermatitis, onychomycosis, psoriasis, or rosacea. The assessment and plan of each progress note were reviewed, and the exact medication name and associated diagnosis were recorded for each prescription. Subsequently, each medication was reviewed and placed in 1 of 3 categories: brand name, generic, and OTC. The total number of prescriptions for each diagnosis (per visit/note); the specific number of brand, generic, and OTC medications prescribed (per visit/note); and the percentage of brand, generic, and OTC medications prescribed (per visit/note and per diagnosis in total) were calculated. To ensure only intended medications were included, each medication recorded in the medical record note was cross-referenced with the prescribed medication in the electronic medical record. The primary objective of this study was to capture the prescribing physician's intent as proxied by the pattern of prescription. Thus, changes made in prescriptions after the initial plan—whether insurance related or otherwise—were not relevant to this investigation.

The data were collected to compare the percentage of brand vs generic or OTC prescriptions per diagnosis

to see if there was a difference in the prescribing habits before and after the pharmaceutical policy changes. Of note, several other pieces of data were collected from each medical record, including age, race, class of insurance (ie, Medicare, Medicaid, private health maintenance organization, private preferred provider organization), subtype diagnoses, and whether the prescription was new or a refill. The information gathered from the written record on the assessment and plan was verified using prescriptions ordered in the Allscripts electronic record, and any difference was noted. No identifying information that could be used to easily identify study participants was recorded.

Differences in prescribing habits across diagnoses before and after the policy changes were ascertained using a Fisher exact test and were further assessed using a mixed effects ordinal logistic regression model that accounted for within-provider clustering and baseline patient characteristics. An ordinal model was chosen to recognize differences in average cost among brand-name, generic, and OTC medications.

Results

In total, 200 medical records were collected. For the period analyzed before the policy change, 252 brand-name medications were prescribed compared to 231 prescribed for the period analyzed after the policy changes. There was insufficient evidence of an overall difference in brand-name medications prescribed before and after the policy changes ($P=.145$; Fisher exact test)(Table 1). There also was insufficient evidence of an overall difference

in generic prescriptions, which totaled 153 before and 134 after the policy changes ($P=.872$; Fisher exact test) (Table 2). Over-the-counter prescriptions totaled 49 before and 69 after the policy changes. There was insufficient evidence of an overall difference before and after the policy changes for OTC medications ($P=.192$; Fisher exact test)(Table 3).

The mixed effects ordinal logistic regression model for the dependent variable—prescription type (branded,

TABLE 2. Generic Medication Prescriptions Before and After Institutional Policy Changes

Diagnosis	Medications Prescribed, %		P Value
	Before Policy Changes (n=153)	After Policy Changes (n=134)	
Acne vulgaris	25.5	28.4	.584
Atopic dermatitis	33.3	29.9	.527
Onychomycosis	7.2	6.7	.875
Psoriasis	19.6	23.1	.466
Rosacea	14.4	11.9	.543
Overall[a]	100	100	.872

[a]P value for Fisher exact test of the entire table.

TABLE 1. Brand-Name Medication Prescriptions Before and After Institutional Policy Changes

Diagnosis	Medications Prescribed, %		P Value
	Before Policy Changes (n=252)	After Policy Changes (n=231)	
Acne vulgaris	25	22.1	.45
Atopic dermatitis	7.1	8.7	.537
Onychomycosis	13.1	6.9	.025
Psoriasis	25.4	26.8	.718
Rosacea	29.4	35.5	.149
Overall[a]	100	100	.145

[a]P value for Fisher exact test of the entire table.

TABLE 3. Over-the-counter Medication Prescriptions Before and After Institutional Policy Changes

Diagnosis	Medications Prescribed, %		P Value
	Before Policy Changes (n=49)	After Policy Changes (n=69)	
Acne vulgaris	4.1	15.9	.043
Atopic dermatitis	73.5	62.3	.204
Onychomycosis	4.1	8.7	.326
Psoriasis	12.2	10.1	.719
Rosacea	6.1	2.9	.392
Overall[a]	100	100	.192

[a]P value for Fisher exact test of the entire table.

generic, or OTC)—showed an odds ratio (OR) of 1.27 for prescribing habits before and after the policy changes (OR, 1.27; 95% confidence interval, 0.97-1.67; $P=.08$) after accounting for provider and baseline characteristics. Despite the P value exceeding the predefined significance level, the confidence interval suggests anywhere from a 3% decrease, no change, and up to a 67% increase in postpolicy odds relative to the prepolicy odds, with a point estimate of a 27% increase in postpolicy odds over prepolicy odds. As an observational study, this suggests moderate evidence of a change based on the odds after the policy change relative to the odds before implementation (Figure).

Comment

Although some medical institutions are diligently working to limit the potential influence pharmaceutical companies have on physician prescribing habits,[4,5,25] the effect on physician prescribing habits is only now being established.[15] Prior studies[12,19,21] have found evidence that medication samples may lead to overuse of brand-name medications, but these findings do not hold true for the USF dermatologists included in this study, perhaps due to the difference in pharmaceutical company interactions or physicians maintaining prior prescription habits that were unrelated to the policy. Although this study focused on policy changes for in-office samples, prior studies either included other forms of interaction[21] or did not include samples.[22]

Pharmaceutical samples allow patients to try a medication before committing to a long-term course of treatment with a particular medication, which has utility for physicians and patients. Although brand-name prescriptions may cost more, a trial period may assist the patient in deciding whether the medication is worth purchasing. Furthermore, physicians may feel more comfortable prescribing a medication once the individual patient has demonstrated a benefit from the sample, which may be particularly true in a specialty such as dermatology in which many branded topical medications contain a different vehicle than generic formulations, resulting in notable variations in active medication delivery and efficacy. Given the higher cost of branded topical medications, proving efficacy in patients through samples can provide a useful tool to the physician to determine the need for a branded formulation.

The benefits described are subjective but should not be disregarded. Although Hurley et al[19] found that the number of brand-name medications prescribed increases as more samples are given out, our study demonstrated that after eliminating medication samples, there was no significant difference in the percentage of brand-name medications prescribed compared to generic and OTC medications.

Physician education concerning the price of each brand-name medication prescribed in office may be one method of reducing the amount of such prescriptions. Physicians generally are uninformed of the cost of the medications being prescribed[26] and may not recognize the financial burden one medication may have compared to its alternative. However, educating physicians
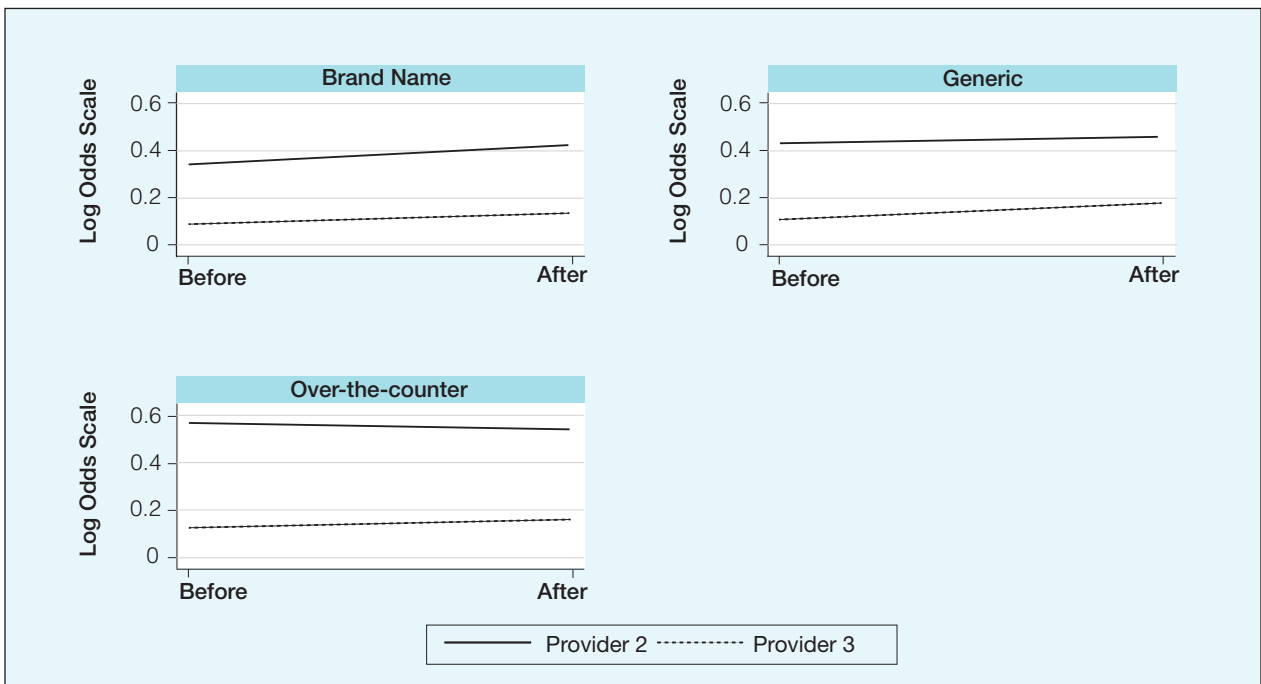
Log odds of prescribing medication—brand name, generic, or over-the-counter—of providers (provider 1 is the reference) before and after policy changes eliminating in-office product samples.

will empower them to make the conscious decision to prefer or not prefer a brand-name medication. With some generic medications shown to have a difference in bioequivalence compared to their brand-name counterparts, a physician may find more success prescribing the brand-name medications, regardless of pharmaceutical company influence, which is an alternative solution to policy changes that eliminate samples entirely. Although this study found insufficient evidence that removing samples decreases brand-name medication prescriptions, it is imperative that solutions are established to reduce the country's increasing burden of medical costs.

Possible shortfalls of this study include the short period of time between which prepolicy data and postpolicy data were collected. It is possible that providers did not have enough time to adjust their prescribing habits or that providers would not have changed a prescribing pattern or preference simply because of a policy change. Future studies could allow a time period greater than 2 years to compare prepolicy and postpolicy prescribing habits, or a future study might make comparisons of prescriber patterns at different institutions that have different policies. Another possible shortfall is that providers and patients were limited to those at the Department of Dermatology & Cutaneous Surgery at the USF Morsani COM. Although this study has found insufficient evidence of a difference in prescribing habits, it may be beneficial to conduct a larger study that encompasses multiple academic institutions with similar policy changes. Most importantly, this study only investigated the influence of in-office pharmaceutical samples on prescribing patterns. This study did not look at the many other ways in which providers may be influenced by pharmaceutical companies, which likely is a significant confounding variable in this study. Continued additional studies that specifically examine other methods through which providers may be influenced would be helpful in further examining the many ways in which physician prescription habits are influenced.

Conclusion
Changes in pharmaceutical policy in 2011 at USF Morsani COM specifically banned in-office samples. The totality of evidence in this study shows modest observational evidence of a change in the postpolicy odds relative to prepolicy odds, but the data also are compatible with no change between prescribing habits before and after the policy changes. Further study is needed to fully understand this relationship.

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