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The pharmacy channel has been an under-studied area by drug companies relative to for example greater focus on physicians, managed care, and patients/consumers. However, an academic paper recently published provides a very different look at the pharmacy channel through the effects of state pharmacy drug product selection (DPS) laws on generic-to-branded drug switch-back patterns.[1] Switch-backs patterns represent a potential indication of clinical issues involving the original brand-to-generic drug substitution since the movement back to a brand is not because it is less expensive than a generic drug. This paper sheds empirical light on the effects of potential *pharmacist* involvement and motivations in brand-to-generic drug substitutions through DPS laws that have to be later reversed in generic-to-branded drug switch-backs for some patients. Also, this paper demonstrates another application of longitudinal prescription patient-level (LRx) data to show how brand-to-generic substitution (especially therapeutic substitution) may produce unintended effects that are in not in the best interest for some patients as measured by the rate of generic-to-branded drug switch-backs.

For some background, long before the advent of physician-level prescription (Rx) data (the first such database was IMS Health Xponent™ launched in October 1993), pharma sales reps would engage pharmacists to understand local physician prescribing patterns. Pharmacists used to be the focal point for pharma company attention up until the passage of the 1951 Durham-Humphrey Amendment that defined certain kinds of drugs that could be safely used with rules requiring medical supervision and sales restricted by prescription by a licensed practitioner.[2] Beyond this date, pharma companies increasingly focused their commercial efforts on detailing physicians as the channel to disseminate new medical information since they held the power on whether someone received a prescription drug.[3] Lately however, the pharmacy channel has risen even more in importance. For example, drug companies are increasingly trying to hold onto market share against generic competition through the use of coupons that are administered at the pharmacy channel.[4] Academic research shows the use of coupons can improve medical adherence, but with total drug expenditures rising, this approach raises questions whether any potential increase in clinical outcomes is enough to justify the higher cost.[5] Pharma critics echo the costs of coupons are not worth the benefits, while pharma industry advocates note they help with patient access, affordability, and adherence.[4] Further, the push toward and reimbursement mechanisms placed on producing better health outcomes at lower costs, make the combination of patient data contained at large pharmacies and touch points with patients regarding drug adherence, coupled with data from providers of healthcare and their interactions with patients, make for a powerful combination to produce intended policy results.[6]

But what about analyses on the effects of *pharmacist* decisions on prescription drug utilization patterns, especially on the relationship between brand-to-generic drug substitution and subsequent switch-back patterns? All states and D.C. have pharmacy DPS laws that provide pharmacists with the legal means to more easily make brand-to-generic substitutions. The public policy motivation of DPS laws is to drive drug expenditures downward while not sacrificing therapeutic outcomes through encouraging greater generic drug utilization.[7] There are numerous mechanisms DPS laws give to pharmacists have to make brand-to-generic

substitutions (what is allowed varies by state): patient consent, permissive, state drug formulary, two-line Rx format, and no cost saving pass on provisions.[1] The research paper highlighted here conducted a logistic regression on a sample of 397,111 statin patients from 2006-2008 taken on a much larger patient sample from a previous study[8] and estimated the effects of DPS and non-DPS variables on brand-to-generic drug switch-backs versus brand-to-generic substitution.[1] Unique to this paper was analysis of DPS law effects at the *patient level*. The empirical findings showed that all DPS variables were statistically significant in affecting generic-to-branded drug switch-backs in a manner consistent with principal-agent theory.[9] The application of principal-agent theory suggests pharmacists may be making decisions to encourage brand-to-generic substitution that favor their own financial interests, since profit margins to pharmacies are greater by dispensing generics,[10] at the expense of what is good for patients as desired by physicians. Particularly interesting was the finding that the existence of patient consent DPS laws (patient consent is required before a pharmacist can make generic substitution) reduced the likelihood of switch-backs. Prior research suggested relaxing DPS patient consent laws in order to lower drug expenditures by encouraging generic substitution while not forsaking therapeutic benefits.[7] What previous researchers may have ignored is that DPS patient consent laws allow information from physician-patient interactions to inform the generic substitution decision that would be otherwise unknown to the pharmacist. Also and potentially at issue, is the degree to which pharmacists encourage patients to seek approval for generic therapeutic substitution in order to pursue greater profits. Generic therapeutic substitution involves a switch to a different drug (as opposed to generic bioequivalent substitution), and thus not protected under DPS laws, thereby requiring patients and their attending physician to approve the substitution. Previous physician society policy recommendation statements have questioned whether DPS work in practice as intended and thus should be reviewed.[11] Today the honesty/ethics of pharmacists as a profession rated as %Very high/High is second only to nurses 85% vs. 68% and just above medical doctors at 67%, and has been consistently so rated in a regularly-conducted survey by Gallup over many years.[12] However, this study provides empirical evidence potentially suggesting pharmacist motivations placing personal financial interests ahead of patient and physician interests. More research is certainly needed here.

Further, regarding non-DPS variables in the model, this empirical study found the strongest log odds estimates ranked in absolute value of factors that were positively associated with switch-backs were switch to a lower dose, switch to a different molecule, physician specialists such as cardiologists/nephrologists and endocrinologists/diabetologists (relative to PCPs), and where patients had added financial support (as in Medicaid support relative to cash). Other positive though weaker influences on switch-backs were Other and IM physician specialties relative to PCPs, higher patient cardiovascular co-morbidity count, greater physician statin Rx volume, and the patient being male.[1] The strongest factors with a negative log odds estimates were the intercept and managed care plan control respectively, followed by a far weaker effect from higher patient age.[1] The strong negative effect on the intercept suggests that when all DPS and non-DPS variables are zero, there are significant environmental effects not specifically modeled that work to reduce the likelihood of switch-backs. The strong negative effect on increases in managed care plan control is consistent with the rise of generic-forcing drug plans and the erection of mechanisms to make it difficult for patients and physicians to engage in switch-backs as a way to reduce drug expenditures (e.g., step therapy conditions, prior authorization, quantity limits).

Below are key points of learning from this research to pharmaceutical practitioners in commercial analytics and public policy:

1. Pharmacists acting through DPS laws have both an impact on brand-to-generic substitution and switch-back drug utilization patterns. More research at the *patient level* is needed to understand more fully how financial incentives affecting pharmacist behavior encourages generic substitution which in turn results in switch-backs for some higher at-risk groups of patients. This research was conducted on the statin drug class. Research on other drug therapy classes would be desired to see if effects are robust.

2. Analyzing LRx data to study patient switch-back patterns can reveal how initial brand-to-generic drug substitution may not be appropriate for certain groups of patients. Patient switch-backs represent a potential indication of clinical failure of the previous brand-to-generic substitution decision. There is a growing importance of pharma companies to show how patterns of patient drug utilization affect health outcomes. Analyzing LRx data in this fashion can be an easy way to elicit early insights into potential issues arising from managed care plan-driven brand-to-generic drug substitution.

3. The use of statistical modeling and logistic regression estimation can identify the characteristics associated with the likelihood of generic-to-branded drug switch-backs. Since the log odds estimates in a logistic regression are scaled, one can rank-order by absolute value to assess the strongest to weakest factors associated with generic-to-brand switch-backs and brand-to-generic substitution.

4. As a public policy implication from (1) – (3), rather than mandated rules forcing brand-to-generic substitution for *all* patients, a more nuanced approach may be to identify first those patients where generic drug utilization has a much lower probability of success, as predicted by generic-to-branded drug switch-backs. The result would be to bypass a period of forced generic drug utilization for certain patients who qualify.

5. This study offers a different conclusion on the intention and effect of DPS patient consent laws than stated from previous research. DPS patient consent laws allow information from physician-patient interactions to enter into the decision whether to permit brand-to-generic substitution by pharmacists. An instructive review of the literature on the therapeutic equivalency of brand-to-generic substitution across different therapy classes can be found here.[8]

6. At least for the statin therapy drug class, differences in drug dosing and molecule technology across various statins, physician specialty vs. PCPs, and managed care plan control were the strongest factors affecting drug switch-backs and generic substitution. Replication of this study design for other therapy classes to determine robustness of effects would be desirable to determine a broader policy perspective on this issue.

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