
Maximising generic utilisation: The power of pharmacy benefit management

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David B. Snow Jr.

is Chairman and Chief Executive Officer of Medco Health Solutions, Inc. Prior to joining Medco in 2003, he held executive leadership positions at Wellchoice, Oxford Health Plans, American International Healthcare, and US HealthCare. He also co-founded Managed Healthcare Systems (later renamed AmeriChoice). He earned a master's degree in healthcare administration from Duke University and a bachelor's degree in science and economics from Bates College. Medco is the leading pharmacy benefit manager in the United States based on its 2006 net revenues of more than US\$42bn. Medco's prescription drug benefit programmes are designed to moderate the cost and enhance the quality of pharmacy healthcare for private and public employers, health plans, labour unions and government agencies, and for individuals served by the Medicare Part D Prescription Drug Program.

Abstract Over a seven-year period (2006–2012), a US\$77bn market in brand-name drugs will open to generic competition in the United States, dramatically expanding the opportunities to lower the costs of pharmaceutical care. To capitalise on this emerging market, benefit plans will need highly effective strategies for increasing the use of generics in day-to-day clinical practice — including financial incentives for plan members, expanded use of mail-order pharmacy, and vigorous efforts to communicate cost-savings opportunities to members and their physicians. Online cost comparison tools are an especially powerful vehicle for informing members about their options and motivating them to switch to lower-cost alternatives. At an industry level, maximising the generic market opportunity will require a more favourable regulatory framework and a realignment of incentives for new drug development.

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INTRODUCTION

In the US healthcare market, generic medicines are transforming the delivery of pharmaceutical care as generics become more widely available and accepted as first-line therapy for many conditions. This transformation has been accelerated by benefit plan sponsors, who have implemented a wide

range of strategies for capitalising on the market introduction of new generic drugs. For prescription benefit plans, and the patients they serve, generics are one of the best bargains available in today's healthcare market. They offer the therapeutic benefits of their brand-name counterparts for only a fraction of the cost, providing more affordable access to pharmaceutical care.

The market transformation is being driven by a large wave of new generic drugs, beginning over the past few years and continuing well into the next decade. Generics for many 'blockbuster' drugs are becoming available for the first time, as many

David B. Snow Jr.
Medco Health Solutions, Inc.
100 Parsons Pond Drive
Franklin Lakes, NJ 07417, USA
Tel: +1 201 269 5920
Fax: +1 201 269 1222
E-mail: David_Snow@medco.com

high-volume brand-name drugs lose their longstanding patent protection. As therapy has shifted toward the new generic products, generic dispensing rates have climbed rapidly (Figure 1). Generic drugs now account for almost 60 per cent of prescription drugs dispensed under managed benefit plans in the United States. In some therapeutic classes — including some classes of antihypertensives and pain medications — almost all of the therapeutic options are now available in generic form.

The impact of generic dispensing on plan costs has been profound. Spending growth for pharmacy benefits has slowed sharply over the past five years, coincident with the rapid increase in generic drug dispensing (Figure 1). Although other factors have contributed to the slowdown in spending growth, the increased utilisation of generic drugs has been the largest sustained contributor to the decline.

Two key attributes of generic drugs — low unit costs and low price inflation — have helped moderate the growth in plan spending for prescription drugs. Unit costs for generic drugs are generally 30–80 per cent lower than

for their brand-name counterparts.¹ Spending growth has also been moderated by the slow rate of price inflation for generic drugs. In 2006, the average price inflation for generic drugs purchased by Medco plan members was only 0.2 per cent — compared with 6.9 per cent for brand-name drugs.²

THE GROWING MARKET OPPORTUNITY

Over the next few years, the market opportunity for generic drugs will expand dramatically as additional brand-name drugs become available in generic form. For the seven-year period beginning in 2006, the total size of the generic market opportunity is approximately US\$77bn, based on current market volumes for the brands that are expected to go off-patent during this period (Figure 2).

It is difficult to estimate the generic market opportunity with precision, given the uncertainties associated with patent litigation, patent extensions, marketing agreements, and other factors that affect the timing of first-time generics. It is, however, clear that new generic products will continue to open major

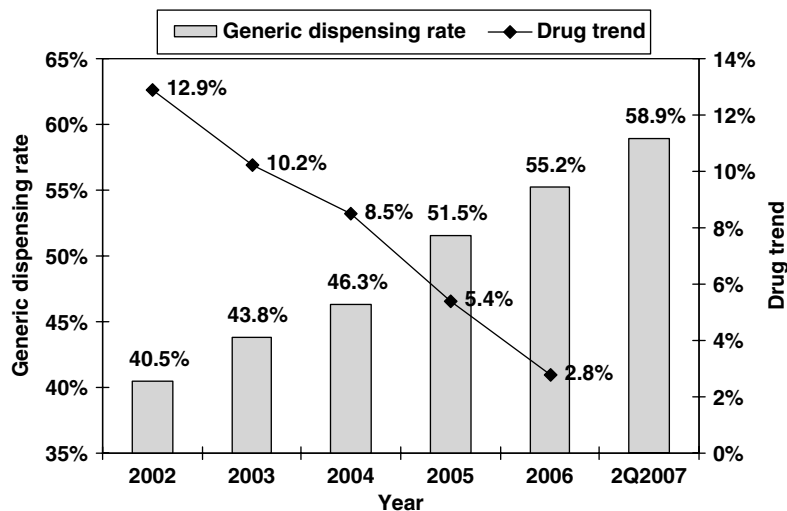


Figure 1: Generic dispensing rates and spending growth

Note: Generic dispensing rate (GDR) is the percentage of days’ supply dispensed as generics. Drug trend is the year-over-year change in plan spending per member. Data are for pharmacy benefit plans managed by Medco.

First-time generics			Market opportunity (US\$bn)						
Year	Brands	Annual spend (US\$bn)	2006	2007	2008	2009	2010	2011	2012
2012	Avandia®, Lexapro®, Plavix®, Seroquel®, Singulair®	13.1							7.9
2011	Actos®, Effexor® XR, Lipitor®, Protonix®, Zyprexa®	18.9						9.6	18.9
2010	Flomax®, Keppra®	4.1					3.2	4.1	4.1
2009	Aciphex®, Imitrex®, Lamictal®, Prevacid®, Topamax®, Valtrex®	13.0				4.8	13.0	13.0	13.0
2008	Depakote®, Fosamax®, Risperdal®	5.1			3.1	5.1	5.1	5.1	5.1
2007	Ambien®, Coreg®, Lotrel®, Norvasc®, Toprol-XL®	9.3		5.6	9.3	9.3	9.3	9.3	9.3
2006	Flonase®, Pravachol®, Zocor®, Zolof®	13.4	6.8	13.4	13.4	13.4	13.4	13.4	13.4
Total opportunity (US\$bn)		76.9	6.8	19.0	25.8	32.6	44.0	54.5	71.7

Figure 2: Generic growth opportunity, US market (2006–2012)

Note: Analysis is based on estimated market availability of first-time generics for off-patent brands; leading brands for each year are listed. Actual generic availability may vary due to litigation, patent challenges, etc. Market estimates are based on US brand sales for 2005 and 2006, unadjusted for inflation in future years.⁵ First-year market estimates are prorated due to partial-year availability of new generics. Plavix® is excluded from 2006 going-forward market volume, since it was available in generic form for only a limited period.

new opportunities for cost savings. On average, for every US\$100m in brand spending that moves off-patent, patients and plan sponsors can save an estimated US\$45m in annual costs.

Until recently, plan sponsors have focused on maximising cost savings through generic substitution — the use of *generic equivalents* for multisource brand-name drugs. Generic equivalents contain the same active ingredients, strength, and dosage form as the original brand-name drug, and they are bioequivalent on key pharmacokinetic measures.³ Most plan designs include financial

incentives for members to use generic equivalents in place of the corresponding brand-name drugs.

Plan sponsors have recently begun to focus more attention on a second approach to generic drug management — the use of *generic alternatives* to single-source brand-name drugs. Generic alternatives contain different active ingredients, but they are likely to have comparable efficacy when used in place of a brand-name drug in the same therapeutic class. For example, some plans encourage the use of generic omeprazole as a therapeutic alternative to patent-protected

brands in the proton pump inhibitor (PPI) class.

Generic alternatives expand the market opportunity for generic drugs beyond what can be accomplished by traditional 'like-for-like' generic substitution. The incremental opportunity is illustrated in Figure 3, which shows the components of current brand dispensing that are appropriate for generic conversion over the next three years. In 2006, brand-name drugs accounted for approximately 42 per cent of the total dispensing volume (on a days' supply basis). In principle, over half of this brand volume could be converted to generics over the next three years, if all of the opportunities could be exercised fully.

Approximately 9 per cent of the current dispensing volume could be converted to generic *equivalents* over the next three years, principally as a result of the first-time generics that will be introduced during that time period. An additional 11–16 per cent of current dispensing could be converted to generic *alternatives*, as new generics expand the range of options in many therapeutic classes. Higher-priced brands offer the best opportunities for switching to generic alternatives, because these are cases where the cost differentials between brand and generic options provide the largest incentive for payors and members to initiate a change in therapy.

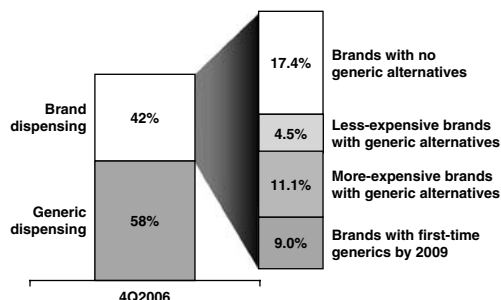


Figure 3: Savings opportunities associated with new generic drugs and generic alternatives
 Note: Dispensing rates are averages for pharmacy benefit plans managed by Medco.

LIMITS ON GROWTH

Although the future market opportunity for generics is large, it is also subject to some practical limits. Many brand-name drugs will remain patent protected, and many will have no viable generic alternatives in the same or related therapeutic classes. These brand-name drugs account for approximately 17 per cent of current dispensing (Figure 3), and they set a practical upper limit on generic dispensing over the next three years.

In some therapeutic classes, patent-protected brands dominate the product mix because they offer the most favourable efficacy and safety profile for the treatment of a given condition. For example, the newer, more targeted cancer drugs are likely to dominate cancer treatment for many years to come, since the new products have extended patent protection and no generic drugs of comparable efficacy are available.

In some cases, the product mix may be dominated by patent-protected drugs that offer superior convenience, even when generic drugs of comparable efficacy are available. For example, brand-name products have displaced generics in the paediatric treatment of attention deficit hyperactivity disorder, because the newer extended-release products offer the convenience of administering the drugs only once a day.⁴

Market share erosion

Maintaining high generic dispensing rates can be a major challenge even when generic products have similar efficacy, safety, and convenience to brand-name products in the same therapeutic class. In advance of a scheduled patent expiration, brand manufacturers often launch new patent-protected products in an effort to retain or grow their market share in the class. Strong brand marketing, including direct-to-consumer advertising, can drive market share toward new brand-name drugs, reducing the share of older brand-name drugs before they go off-patent.

Market share erosion can make it difficult to capitalise on the introduction of new generics for a brand-name drug. Share erosion reduces the base of brand users, limiting the opportunities for generic substitution when the generics become available. Also, as members develop loyalties and preferences for the new brand, plans may encounter considerable resistance to their efforts to transition members to the new generic alternative.

Recent shifts in the sedative-hypnotic market provide an excellent case in point. A leading insomnia treatment, Ambien[®] (zolpidem), lost significant market share before generic equivalents were introduced in April 2007. During the same period, market share grew rapidly for new brand-name products, including Lunesta[®] and Ambien CR[®], which were heavily advertised to American consumers. Ambien accounted for almost 70 per cent of sedative-hypnotic prescriptions in the United States in early 2005, but its market share dropped to only 43 per cent by the end of 2006.⁵ This sharply reduced the potential savings when the new generics for Ambien were introduced in 2007, since the base for generic substitution was significantly lower than it would otherwise have been.

Many of the new brands that compete with generics are follow-on versions of the original brands. Some follow-on products, like Ambien CR[®], are new formulations of the original brand, and some are chemical modifications of the original compound. Follow-on products are one of the 'evergreening' strategies used by brand manufacturers to protect their market and extend their patent franchise. These products may offer little or no incremental clinical benefit, but they can be very effective at building and extending brand loyalties, and they complicate the efforts of plan sponsors to shift utilisation to lower-cost generics.

Biogenics

Biologic drugs also set a practical limit on the market opportunity for generics, since many

biologics are unlikely to face significant generic competition for several years. The availability of biogeneric (biosimilar) drugs has been slowed by the lack of a broad regulatory pathway for approving these drugs in the United States, and approval standards for more complex biologics may not be developed for several years.⁶ When approval pathways become available, the market impact of biogenics will be significantly reduced in areas where new, patent-protected products have replaced older, off-patent products as the standard of care. New formulations of traditional biologics have already become the dominant therapies for several conditions (eg, pegylated interferon for hepatitis C and modified human insulin for diabetes), and new formulations are rapidly increasing their share in other therapeutic areas (eg, pegylated filgrastim for neutropenia). The extended patent life of these new formulations will limit the competitive options for biogeneric products.

PLAN MANAGEMENT STRATEGIES

Benefit plans have capitalised on generic savings opportunities by developing strong plan management strategies, working in partnership with pharmacy benefit managers (PBMs). In the US healthcare market, PBMs play a central role in the dispensing and use of medications by members of many commercial and public benefit plans — including employers, health insurers, labour organisations, and public programmes for the elderly and disabled (such as Medicare). PBMs offer a wide variety of management services, including claims processing at the point of sale, and they help ensure that members have cost-effective access to medications covered by the plan.

Because of their central role in prescription processing, PBMs are uniquely positioned to help plan sponsors maximise the use of generic medications by their members. They do this through the use of financial incentives,

mail-order services, step therapy programmes, and communications with members and their physicians. Effective communication is crucial, since maximum savings can only be achieved if plan members and their physicians understand the savings opportunities and coverage options available to them.

MEMBER INCENTIVES

Maximising generic use begins with the design of a plan's *formulary*, which identifies the preferred medications in each therapeutic category covered by the plan. The selection of preferred medications is largely based on considerations of clinical benefit and safety, but relative cost may also play a role in cases where multiple options are available and clinical profiles are similar. Inclusion of generic drugs as plan-preferred options, where clinically appropriate, is a crucial starting point for stimulating the more widespread use of generics.

Once the formulary is defined, benefit plans often use financial incentives to encourage the selection of therapies that result in lower net costs to the plan sponsor. A common strategy is to assign covered drugs to different 'tiers' and to assign different levels of cost sharing to each tier. Members generally pay either a fixed-dollar *co-payment* or a percentage-based *coinsurance* amount for the drugs in each tier.

In a typical three-tier plan design, the lowest co-payment is assigned to generic drugs (in the first tier), an intermediate co-payment is assigned to plan-preferred brand-name drugs (in the second tier), and the highest co-payment is required for non-preferred brands (in the third tier). Plans vary widely in the number of tiers and the types of cost-sharing arrangements they use, but the common denominator is to create incentives for members to pursue the lowest-cost option that meets the clinical need.

The art of plan design is to create member incentives that are aligned with the financial interests of the plan. Generic drugs are a good

case in point, because these medications are generally associated with the lowest out-of-pocket costs for members and the lowest net costs for plan sponsors — hence incentives to use generics are favourable for both parties. The incentives, however, need to be strong enough to motivate members to seek out and accept generics. Some plans find that a difference of at least US\$20 between co-payment levels is required to create a large enough incentive to affect members' actions. Even stronger incentives can be created using add-on strategies like generic co-payment waivers and member-pays-the-difference programmes.

Generic co-payment waivers promote the use of generics by eliminating the co-payment that normally applies to these drugs. While the incentive programme is in effect, members incur no out-of-pocket cost for their generic drug prescriptions. For plan sponsors, this provides a relatively low-cost way of introducing generics to members who may have been reluctant to switch from a brand-name medication. Although plans may incur some additional expense in the short term, they benefit by shifting usage to drugs that lower their net costs when the waiver programme ends. The break-even point occurs fairly quickly, and the savings continue for as long as the patient is on the medication.

Member-pays-the-difference programmes require a member to pay the entire difference in cost between a brand and its generic equivalent — if the member chooses to purchase the brand-name drug instead of the generic. The member pays the difference in addition to the co-payment or coinsurance that normally applies, providing a strong financial incentive for members to become proactive and ask their physicians to prescribe the generic. In 2006, plans with strong member-pays-the-difference incentives achieved an average generic dispensing rate of 61.2 per cent — significantly higher than the 52.8 per cent average rate for plans with no member-pays-the-difference programme.

MAIL-ORDER PHARMACY

Mail-order fulfilment of prescriptions is a rapidly growing area of pharmacy practice in the United States. In pharmacy plans managed by Medco, approximately 16.1 per cent of prescriptions were filled through mail order in 2006, and the remainder were filled through retail channels (such as community pharmacies). On a days' supply basis, mail-order prescriptions represented approximately 36.4 per cent of the total volume of dispensed medications, since mail-order prescriptions generally contain a larger days' supply than prescriptions filled at retail pharmacies. Mail-order fulfilment is frequently used for long-term prescriptions, such as 90-day supplies of maintenance medications for chronic conditions. For benefit plan sponsors, mail order reduces net costs through lower dispensing fees and volume purchasing power, and it can offer improved dispensing accuracy and clinical oversight.⁷⁻⁹

Advanced pharmacy practice

On behalf of its clients, Medco operates an advanced mail-order pharmacy network that dispensed more than 89 million prescriptions for plan members in 2006; most of these orders were 90-day prescriptions for maintenance medications. The pharmacy network is designed to optimise the two primary functions of prescription fulfilment — prescription processing and medication dispensing. These functions are performed in specialised facilities that are closely coordinated through networked databases and electronic communications.

The 'front-end' *prescription processing centres* review incoming prescriptions and prepare the final specifications for dispensing. Pharmacists in these centres communicate with physicians and members, as needed, to discuss any issues of prescription content, medication safety, formulary compliance, benefit coverage, or clinical management. These pharmacists have specialised training and expertise in specific treatment areas (such as oncology or diabetes management), so they can provide in-depth

clinical support and consultation for members and physicians. The 'back-end' *dispensing centres* are highly automated facilities where medications are dispensed and packaged for shipment. These high-tech facilities are designed to achieve high levels of dispensing accuracy and medication safety.⁹

The mail-order pharmacy network provides a powerful platform for accelerating the adoption and use of generic options where clinically appropriate. As part of standard practice, pharmacists in the front-end centres will seek authorisation from physicians to substitute the generic equivalent for a prescribed multisource brand-name drug (in cases where the physician's permission is required under applicable law). The pharmacists may also explore with a physician whether conversion from a single-source brand-name drug to a generic alternative is therapeutically appropriate for a given patient.

To accelerate the use of a new generic product, the mail-order pharmacy will stock the new generic in advance of its market introduction, notify appropriate members and physicians of the new opportunity, and convert prescriptions to the new generic on an expedited basis when it becomes available.

The result of these proactive pharmacy practices is a high overall rate of generic dispensing and a rapid rate of conversion when new generics are first introduced for a brand-name product. For first-time generic drugs introduced in 2006, Medco's mail-order pharmacy achieved a 92.4 per cent generic substitution rate during the first seven days following market introduction — significantly higher than the 54.1 per cent rate achieved by retail pharmacies during the same time period (Figure 4). Although the difference narrowed over time, generic substitution rates at mail continued to exceed those at retail for many months after the new generics were introduced.

The difference in substitution rates at mail and retail translates into a major opportunity cost for plan sponsors. During the first 12 months of generic availability, the channel

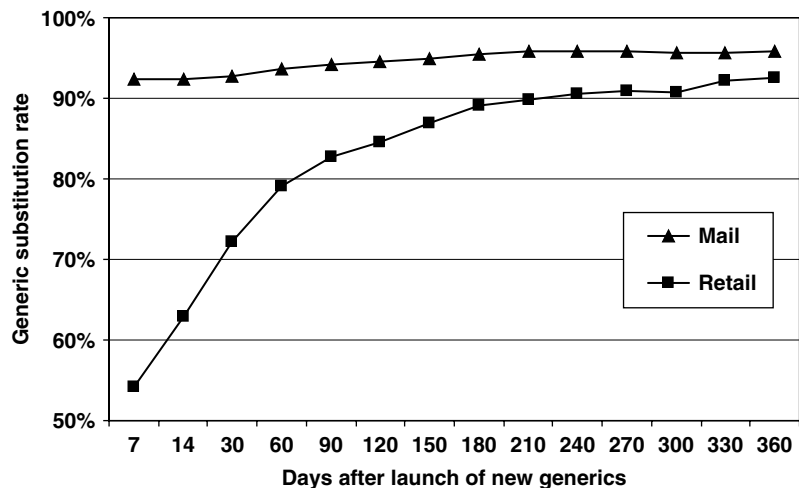


Figure 4: Generic substitution rates following market introduction of new generics
 Note: Rates are volume-weighted averages for all drugs that became available in generic form during 2006. Averages are cumulative through May 2007. Data for Plavix (clopidogrel) are not included.

difference represented approximately US\$430m in brand market volume that could have been addressed through generic substitution if the prescriptions had been processed at mail rather than at retail.

Mail-order incentives

Plan sponsors use several strategies for encouraging members to make greater use of mail-order services. The most common technique is to set lower levels of cost sharing for mail-order fulfilment. For example, if the retail co-payment for a 30-day supply of a generic maintenance medication is US\$10, the co-payment for a 90-day supply of the same drug at mail could be set at US\$25 — a 17 per cent lower cost for the member on a days’ supply basis. These cost-sharing incentives help to align the financial interests of members and plan sponsors. Members benefit from lower out-of-pocket costs, and plan sponsors benefit from the lower dispensing fees and improved discounting available through the mail-order channel.

In addition to the basic channel incentives, many plans use co-payment waivers and retail refill allowances to encourage members to move their prescriptions from retail to mail. *Co-payment waivers* are short-term reductions

of the co-payments that normally apply at mail. *Retail refill allowances* promote mail-order use by increasing the member cost for medications purchased at a retail pharmacy after a predetermined number of fills. The number of retail fills allowed, as well as the increase in cost after that limit is reached, can vary depending on how strongly the use of mail order is encouraged.

COVERAGE DESIGN

In several treatment areas, step therapy programmes offer another effective tool for increasing the use of generics. These programmes require a course of therapy with a generic drug before coverage is provided for a brand-name drug in the same therapeutic class. For example, plans may require a trial with a generic intranasal steroid (fluticasone or flunisolide) before providing coverage for a brand-name medication for allergic rhinitis.

Step therapy programmes are most appropriate for therapeutic classes where one or more generic options are available, and where the generic options are similar in efficacy and safety to commonly used brand-name drugs in the class. These programmes can reduce plan costs by encouraging the

use of generic options that are likely to be effective for the majority of plan members.

Step therapy rules can also be used to increase the utilisation of brand-name drugs that are expected to go off-patent in the near future. For example, some plans have implemented osteoporosis step therapy rules to increase the utilisation of Fosamax[®] (alendronate) in advance of the market introduction of generics in 2008. By anticipating these market events, plans are able to reduce share erosion to other brands and convert more of their member base to the new generics when they become available.

EDUCATING MEMBERS

Plan sponsors are becoming increasingly aware that well-informed members are essential allies in their efforts to manage the rising costs of prescription healthcare. If members are aware of their options and the relative value of the options, they are more likely to become active participants in the process of making their healthcare more cost effective. For this reason, plan sponsors are focusing more attention on communicating cost-savings opportunities to members — including the opportunities offered by generic drugs.

Many plans use mailings, telephone calls, or e-mail messages to alert members to opportunities for lowering their out-of-pocket costs for maintenance prescriptions. For example, users of non-preferred brand-name statins may be encouraged to talk with their doctors about the possibility of switching to a preferred brand or to an available generic (such as simvastatin, pravastatin, or lovastatin). Communications of this type have been effective at increasing generic use in several therapeutic categories, including statins, PPIs, and selective serotonin reuptake inhibitors (SSRIs).

Plans also use mailings and online messages to accelerate conversions to new generics. When generics become available for a blockbuster drug, many plans notify current users that generic equivalents are now

available and alert them to the opportunities for converting their prescriptions.

USING ONLINE TECHNOLOGY

Effective use of information technology can magnify the power of a plan's contacts with its members. Medco recently began deploying a web-based cost comparison tool, called My Rx Choices[®], that provides members with detailed information about their prescription drug choices. Using the tool, members can easily compare the cost of their current maintenance medications against the costs of other generic and brand-name options, both at retail and by mail. The potential cost savings are clearly displayed for each option. Information about the potential therapeutic benefits and side effects of the medication options is also accessible through the same portal.

The online tool helps members communicate with their physicians about the possibility of shifting from their current medication to a lower-cost alternative, or shifting prescription fulfilment from retail to mail when that would reduce their costs. For example, members can print out a summary of the options to review with their physician, and in some cases they can ask that a Medco pharmacist contact their physician to review the therapeutic alternatives.

In 2006, Medco evaluated a prototype of the My Rx Choices programme to determine whether it increased the likelihood that members would change to a lower-cost drug or distribution channel. The study focused on members who had current prescriptions for maintenance medications and who used Medco's online system (medco.com[®]) to manage their prescriptions. Members in the intervention group used the online tool to evaluate potential savings opportunities. Members in the control group were carefully matched on demographics and medication use, but they did not use the online cost-savings tool at any time during the study.

The study found that members who used the online tool were 58 per cent more likely

to convert at least one prescription to a lower-cost option, compared with members in the control group ($p < 0.001$). Members who used the tool often converted their prescriptions to generic drugs (51.1 per cent of all conversions) or to mail-order dispensing (30.3 per cent of all conversions). Each prescription conversion produced an average annual savings of US\$171 for the member.²

Conversions from single-source brands to generic *alternatives* accounted for 41.9 per cent of all conversions in the study (Figure 5). This is a striking demonstration that members and their physicians are willing to consider generic alternatives to single-source brands when the change is clinically appropriate and financially favourable. Conversions from multisource brands to generic *equivalents* accounted for only 9.2 per cent of all conversions in the study, because other programmes already ensure high levels of generic substitution.

These results demonstrate the remarkable power of online technology to educate plan

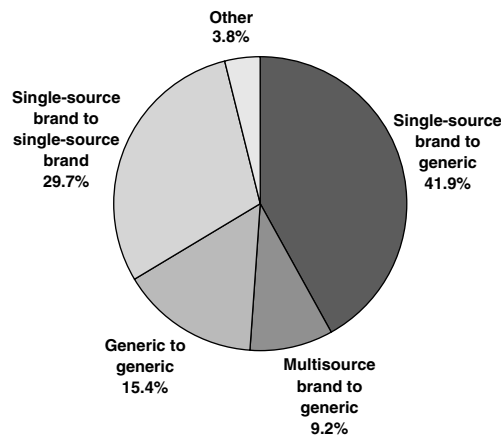


Figure 5: Prescription conversions following use of an online cost-comparison tool

Note: Data are percentages of conversions for plan members who used an online tool to review cost-savings opportunities. Each sector indicates the drug type (brand or generic) before and after the conversion. Where the drug type is the same (eg, generic to generic), the conversion was often a change in distribution channel, not a change in drug.

members about their options and motivate them to make changes that reduce their healthcare costs. Members are more likely to select cost-effective treatments when their choices are presented in a clear, personalised, and actionable format. Consumers of pharmaceutical care can be motivated to shop for the best value — just as they commonly do for other products and services — when they are given convenient access to information on features and pricing.

PARTNERING WITH PHYSICIANS

Educating patients about their treatment options is clearly important, but prescription drug choices are ultimately made by the physicians who write the orders on their behalf. For this reason, it is also important that physicians be well informed about generic drug choices — and motivated to prescribe them. Plan sponsors and pharmacists work with physicians in many different ways to inform them about patients' coverage options and encourage generic prescribing where clinically appropriate.

Many of the contacts initiated by pharmacists are focused on opportunities for generic interchange. For example, when processing 'dispense as written' prescriptions for a multisource brand, pharmacists will frequently contact the prescribing physician to determine whether it would be appropriate to substitute the generic equivalent. For selected therapeutic categories, pharmacists may also contact physicians to determine whether a generic drug might be an appropriate alternative to a single-source brand that a member is currently taking. These physician contacts accelerate the market conversion to generic products, both at retail and at mail.

As an added incentive, some plans provide periodic 'report cards' to physicians to help them track their generic prescribing rates. These programmes can be very effective at motivating changes in prescribing patterns. A large US-based employer recently increased generic dispensing from 41.2 to 53.2 per cent

during the course of a communications programme that included quarterly progress reports for top-prescribing physicians.² These reports used Six Sigma[®] charts to track each physician's generic substitution rate, generic dispensing rate, and dispense-as-written rate. The employer estimated that it saved about 1.5 per cent in total plan costs for every 1 per cent increase in the generic dispensing rate, and its employees saved money through lower out-of-pocket costs.

CHALLENGES FOR THE FUTURE

Using cost-sharing incentives, mail-order dispensing, member communications, and physician engagement, plan sponsors have been very successful at increasing generic utilisation and throttling back on the overall rise in healthcare costs. Their efforts, however, continue to be hampered by market forces and regulatory constraints that limit the availability of generic products. Two key challenges must be addressed if generics are to achieve their maximum potential in the delivery of prescription healthcare.

Modify the regulatory framework to accelerate the availability of new generics

There are several regulatory obstacles that impede the full potential of generics to moderate healthcare costs. Reaching that potential will require an effective approval process for biogeneric drugs, limits on evergreening strategies that enable originators to prolong patent life, limits on marketing agreements that may disrupt or delay generic availability, and regulation of authorised generics to reduce their impact on market incentives for new generics. Many brand manufacturers market 'authorised generics' in competition with first-time generics, reducing the value of the initial period of exclusivity that is granted to first-to-file generic manufacturers.

There is a high opportunity cost associated with the failure to address these issues. When

generic availability is delayed, healthcare costs increase for payors and patients alike, and opportunities to invest in additional care, or to fund new research, are lost. On the other hand, earlier generic availability helps lower the current costs of care and permits greater investment in opportunities to expand or advance care in new areas.

Reshape market incentives to encourage innovation in drug development

The current market environment encourages originator companies to invest in prolonging the patent life of older compounds — through reformulations, extensions to new patient populations, and other strategies. This reduces the investment that goes into the development of new therapeutic compounds, and it delays the availability of generics for older therapeutic compounds.

In the long run, our healthcare system will benefit from the availability of newer, more targeted, more effective, and more personalised medications. Market incentives need to be designed to maximise investment in these new medical technologies, while permitting older therapies to become more widely available in generic form. Some of the newer therapies will carry higher price tags, but the upward pressures on cost can be offset by the more widespread use of generics and the more cost-effective care that many of the newer medications will make available.

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