

## Strategies to Increase Generic Drug Utilization and Associated Savings

Generic drugs, which are typically less expensive than their brand name counterparts, have grown in popularity as health care costs have continued to rise. This paper describes the techniques used to encourage generic drug utilization and briefly reviews the evidence of their effectiveness.

### Introduction

Prescription drugs provide consumers with a myriad of treatments that can increase life expectancy and enhance lives.<sup>1</sup> However, pharmaceutical spending has been rising rapidly in recent years, and prescription medicines have quickly become a target in the struggle to contain health care costs. The increase in spending has been a function of price increases and utilization; more than two-thirds of office visits result in the patient receiving either a prescription or a medication.<sup>2</sup> One increasingly attractive option to reduce costs is to encourage the utilization of generic drugs, which are typically as little as one-third the cost of their brand name counterparts.<sup>3</sup>

A variety of approaches are used to encourage prescribers and patients to choose generic drugs, including health benefit designs that make generic drugs more attractive to consumers, educational efforts, and financial incentives. Several of these approaches are credited with making substantial increases in the generic fill rate; others have tended to be smaller in scope. This paper describes the techniques used to encourage generic drug utilization and briefly reviews the evidence of their effectiveness. A summary of related

state laws and state generic fill rates is also provided.

### Generic Drugs: An Overview

Brand name drugs are sold by pharmaceutical manufacturers under a trademark-protected name. These medications can only be produced and sold by the manufacturer that holds the patent for the drug. In contrast, generic drugs are not patented and can be produced and sold by any manufacturer that has obtained U.S. Food and Drug Administration (FDA) approval. Generic drugs are identical to brand name drugs in dosage, safety, strength, method of administration, quality, performance, and intended use.

Brand name drugs typically come to market after a substantial investment—including research, development, marketing, and promotion—that is protected by patents that give the developer the sole right to sell the drug. While the product is under patent protection, manufacturers can set prices without facing competition, although some brand name products do face competition among similar products. As these patents near expiration, other drug manufacturers can apply to the FDA to sell generic versions. Because generic manufacturers generally do not incur the same development costs, their products

are usually sold at substantial discounts. Six months after the first generic for a brand name drug is approved, additional generic manufacturers can be approved by the FDA to market their products, further lowering the generic (and brand name) drug's price through competition.

Until about twenty-five years ago, the entry of generic pharmaceuticals was slow in the United States. About 150 off-patent brand name drugs had no generic equivalents on the market when Congress enacted the Drug Price Competition and Patent Term Restoration Act in 1984.<sup>4</sup> This legislation, also known as the Hatch-Waxman Act, created a shorter and less costly approval route for generic drugs, and they quickly gained popularity among generic manufacturers and prescribers. Prior to the Hatch-Waxman Act, only 35 percent of brand name drugs had generic competition after their patents expired; today, almost all brand name drugs face such competition.<sup>5</sup>

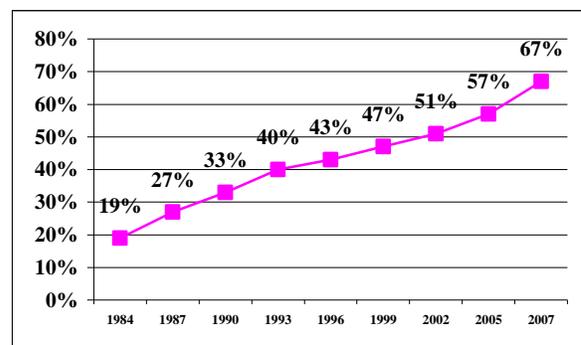
Generic prescription drugs now account for two-thirds of the prescriptions that are dispensed in the United States (figure 1).<sup>6</sup> This percentage varies from state to state (see appendix A), ranging from 44.8 percent (New Jersey) to 60.1 percent (New Mexico) in 2005. Today, the maximum percentage of prescriptions that can be filled using a generic drug is 80 percent.<sup>7</sup> The remaining 20 percent of prescriptions represents brand name drugs that do not have a generic equivalent.

The level of generic drug utilization in the United States, now at 67 percent, is higher than other countries of the world.<sup>8</sup> For example, the generic dispensing rate is 48 percent in Canada,<sup>9</sup> and roughly 30 percent in Australia.<sup>10</sup> Other countries have even lower levels of generic utilization: in Japan, only 17 percent of prescriptions are for generic drugs,<sup>11</sup> and some European countries have generic

market shares of less than 10 percent.<sup>12</sup> This phenomenon is due to a number of factors, including variations in pricing and reimbursement approval that inhibit competition and payment systems that provide a financial disincentive to dispense generic medicines.<sup>13, 14</sup>

The growing popularity of generics in the United States is attributable to a variety of factors. One is that Americans pay more out of pocket for their health care. A survey that included Australia, Canada, Germany, the Netherlands, New Zealand, the United Kingdom, and the United States found that Americans were the most likely to have high out-of-pocket costs. In fact, 30 percent of insured Americans spent more than \$1,000 out of pocket in the past year, significantly more than every other country in the study. In addition, among those with regular medications, U.S. patients were the most exposed to out-of-pocket spending, with more than two-fifths spending \$500 or more a year.<sup>15</sup> This level of cost exposure, as well as consistent increases in drug prices,<sup>16</sup> has helped make lower-cost generics more attractive to consumers.

**Figure 1**  
**Generics' Share of the U.S. Prescription Drug Market: 1984–2007**



Sources: Pharmaceutical Research and Manufacturers of America (PhRMA), *2007 Annual Report*, August 2007; and IMS Health, "IMS Health Reports U.S. Prescription Sales Grew 3.8 Percent in 2007, to \$286.5 Billion," Press Release, March 12, 2008.

In addition, several large surveys have shown that older adults, who are disproportionately affected by chronic disease<sup>17</sup> and more likely to need a chronic medication,<sup>18</sup> resort to skipping doses, reducing doses, and letting prescriptions go unfilled when faced with increased medication costs.<sup>19</sup> This, in turn, can lead to expensive hospitalizations and adverse health outcomes.<sup>20</sup> However, researchers have found that patients who initiate therapy with lower-cost generic medications have higher rates of adherence,<sup>21</sup> making them appealing to providers who want to ensure treatment compliance and avoid unnecessary spending.

Another factor driving generic utilization is an unprecedented and prolonged wave of patent expirations: more than three dozen commonly prescribed brand name products are facing generic competition between 2007 and 2012. Combined, these products represent annual U.S. sales totaling \$67 billion.<sup>22</sup> Almost half these sales will be lost by the end of 2008. Brand name drugs representing \$17 billion in U.S. sales lost patent protection in 2007, and another \$13 billion in brand name drugs are expected to lose patent protection this year.<sup>23</sup> These patent expirations can be expected to have an immediate impact, as brand name drugs tend to quickly lose market share once generic versions are on the market.<sup>24</sup> However, it should be noted that generic entry can be delayed for months or even years by litigation and administrative issues such as citizen petitions.<sup>25</sup>

Thus far, there has not been any scientific evidence that the increase in generic drug utilization in the United States has resulted in adverse patient outcomes.

## **The Economics of Increasing Generic Utilization**

Increases in generic utilization can result in substantial cost savings for individuals and payers. According to one study, switching prescriptions from brand name drugs to generic drugs could lead to an 11 percent reduction in annual overall drug costs,<sup>26</sup> a considerable amount given that prescription drug spending is expected to reach \$516 billion in the next ten years.<sup>27</sup> Correspondingly, IMS Health, a company that provides market intelligence to the pharmaceutical and healthcare industries, has estimated that a 1 percent increase in generic utilization would yield almost \$4 billion in savings.<sup>28</sup>

Generics-related cost savings can also be substantial for individual payers. For example, an analysis of six drug therapy classes found an annual savings opportunity of more than \$21.7 billion in 2005 for one pharmacy benefit manager,<sup>29</sup> and generic anticholesterol drugs helped another pharmacy benefit manager's plan sponsors and patients save \$230 million between January 2006 and April 2007.<sup>30</sup> High generic utilization has also had an impact on Medicare Part D; in 2006, costs were \$12 billion lower than anticipated, due in part to greater than anticipated generic drug use.<sup>31</sup> In addition, research has found that a 1 percent increase in generic drug utilization among Medicaid recipients would result in savings of approximately \$201 million per year, and reaching a generic fill rate of 65 percent could save the program more than \$4.5 billion over the next five years.<sup>32</sup>

## **Tools Used to Increase Generic Utilization**

The apparent safety and savings associated with generic drugs have not gone unnoticed; many health insurers, pharmacy benefit managers, and public health programs are adopting policies that encourage generic utilization. A number of these policies, as well as their impact, are discussed below.

### **Generic Substitution**

Generic substitution policies require physicians to take affirmative steps before prescribing brand name drugs. One variation is mandatory generic substitution, under which the generic version of a drug must be dispensed when available. Under these policies, the brand name drug usually remains available to beneficiaries through provisions that allow physicians to specify that only the brand name drug should be dispensed, also known as prior authorization. This can be as simple as writing “dispense as written” on the prescription or as complex as requesting an exception with an indication of why the generic drug is not suitable for the particular patient.

Another form of generic substitution is “step therapy,” when drug therapy is initiated with the most cost-effective and beneficial drug, usually a generic, and progresses to more costly brand name drugs or those with more troublesome side effect profiles only if necessary.

These policies can be highly effective: research has found that mandatory generic substitution lowered drug costs significantly in health plans with two-tiered cost sharing.<sup>33</sup> Similarly, one pharmacy benefit manager found that, among health plan sponsors implementing step therapy for cholesterol-lowering antihyperlipidemics or hypnotics, spending dropped 13 percent and 14 percent in the respective

therapy class, versus 4 percent decreases in each class for those without step therapy.<sup>34</sup>

Many states have enacted policies that encourage generic substitution (see appendix B), usually by regulating pharmacist behavior. Generally, state laws allow pharmacists to fill a prescription with a generic drug even in cases where the doctor has written a prescription for a brand name drug. However, the provisions of the laws can vary. For example, in about 40 states, the pharmacist can substitute the generic drug unless the prescribing physician indicates in writing on the prescription “brand medically necessary” or “dispense as written.” In a subset of these states, the law requires the pharmacist to substitute the generic drug.

Some states have also developed generic substitution policies that are directed specifically toward their Medicaid programs (see appendix C). These policies, which generally require generic substitution or provide incentives for dispensing generics, have the potential to produce substantial cost savings. For example, Massachusetts’s Medicaid program was found to be paying \$10 million to \$11 million a month for brand name drugs that had generic equivalents. When a generic substitution policy was implemented, spending on brand name drugs with generic equivalents dropped to between \$200,000 and \$300,000 a month.<sup>35</sup> A similar policy was recently implemented in New York’s Elderly Pharmaceutical Insurance Coverage program, and is projected to save the state \$45 million per year between 2009 and 2012.<sup>36</sup>

### **Plan Benefit Design**

Today, virtually all health plans assign higher co-payments to branded drugs to promote the economic benefit of generics. This price differential is created by placing drugs on tiers: One of

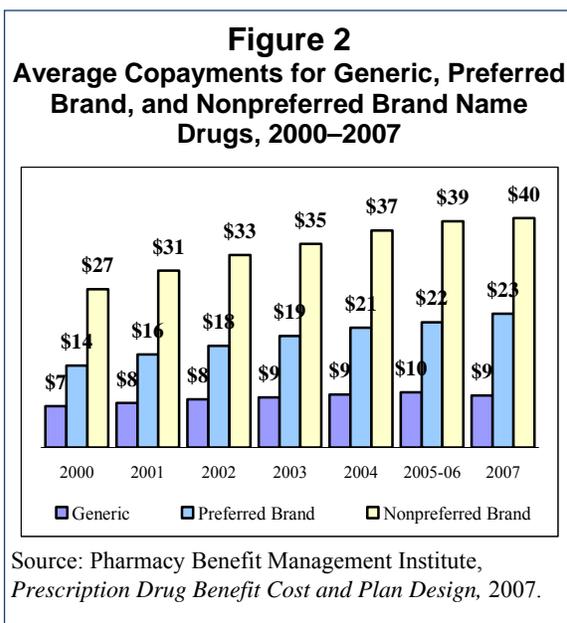
the more common designs splits prescription drugs into three tiers and assigns an escalating co-payment to each tier. Tier 1 drugs have the lowest co-payments and are usually generic drugs. Tier 2 drugs have a higher co-payment and are “preferred” brand name drugs, or drugs that have been determined to have the best value by the health plan. Tier 3 drugs have the highest co-payment and are “nonpreferred” brand name drugs, or drugs that are usually more expensive and no more effective than the drugs on the “preferred” brand name drug list. Some plans have also started using a fourth tier, which is reserved for more expensive specialty and injectable drugs. Plans now have up to six tiers, and some tiers may require coinsurance, or paying a percentage of the prescription cost, instead of a set co-payment. Plans may also allow patients to skip their first few co-payments or eliminate co-payments entirely for drugs on certain tiers to steer utilization.

These plan structures have a strong impact on generic usage. A recent study of one pharmacy benefit manager’s clients found that increasing the co-pay difference between tiers by \$10 to \$15

led to a 17 percent increase in the number of prescriptions filled with a generic, and upping the difference to \$25 or more resulted in a 25 percent increase in generic prescriptions.<sup>37</sup> Consequently, it is hardly surprising that, over the past seven years, average generic copayments have increased by less than \$2, while preferred brand and nonpreferred brand drug co-payments have increased by roughly \$9 and \$12, respectively (figure 2).

Some health plans have also begun to reduce or eliminate co-pays for generic drugs entirely. One large health plan has begun waiving the first co-payment on generics for six therapeutic classes to all commercially insured members on tiered formularies. The company claims to have saved members about \$1 million on co-pays and plans to expand the program to more therapeutic classes.<sup>38</sup> Another large health plan identified therapeutic areas with the lowest generic utilization rates and now offers coupons that allow members to skip a co-payment if they are using a generic drug. The plan has also announced that, in some regions and under some plans, it will waive co-pays entirely if members switch from certain brand name antidepressants to generic counterparts.<sup>39</sup> These co-pay waiver programs have historically been unavailable to Medicare Part D enrollees.

An additional plan design feature that increases generic utilization is allowing patients to obtain their prescription drugs through the mail. Besides the convenience of having medications delivered to patients’ homes, mail-order services also benefit payers by making it easier to implement generic substitution. For example, one pharmacy benefit manager reported a 95 percent generic substitution rate in its mail-order pharmacy within the first week of a brand name drug losing patent protection.<sup>40</sup> This unusually high level of



effectiveness stems from the plan's complete control of dispensing and ability to ensure that generic substitution occurs.

The Medicare Part D prescription drug program provides evidence of the impact of plan benefit design. Despite Medicare's inability to mandate generic utilization, 63 percent of Part D prescriptions are filled using a generic drug,<sup>41</sup> which is 13 percentage points higher than the generic utilization rates found in private third-party plans.<sup>42</sup> This phenomenon is due to a variety of design-related factors. For example, many Part D plans utilize tiered formularies to promote generic utilization, and mail-order services are also commonly offered. Another feature is Part D's coverage gap, also known as the doughnut hole. Because Medicare enrollees can be required to pay more than \$3,000 out of pocket when they are in the coverage gap, less expensive generic drugs have become an increasingly attractive option for enrollees who want to cut costs or avoid the coverage gap entirely.<sup>43</sup> Further, only 6 percent of enrollees return to their brand name medication after leaving the coverage gap,<sup>44</sup> meaning that the program's benefit design is helping generics become part of Medicare Part D enrollees' permanent drug regimens.

### **E-prescribing**

Electronic prescribing (e-prescribing) is a system that allows physicians to generate prescriptions with the use of a personal computer or handheld device. E-prescribing can provide physicians who may not be aware of generic availability with immediate access to formulary information and patients' medication histories, allowing them to discuss generic drug options at the (optimal) time of prescribing, rather than having pharmacists address them. One study found that physicians using e-

prescribing technology increased their generic substitution rates by more than 15 percent and their generic prescribing rates by more than 8 percent.<sup>45</sup>

Nationally, only 2 percent of eligible prescriptions were transmitted electronically in 2007.<sup>46</sup> However, local health organizations in several states, including Massachusetts, Illinois, New Jersey, and Florida, have recently implemented programs designed to increase e-prescribing. One example is a group practice that already had a relatively high generic prescribing rate of 65 percent in early 2003. The group began using e-prescribing and raised its generic rate to 73 percent in less than two years, resulting in \$4.75 million in annual savings.<sup>47</sup> A similar program in another part of the country improved the organization's generic use rate by 7.3 percent, saving \$3.1 million in pharmacy costs over a one-year period.<sup>48</sup>

E-prescribing has also proven popular in public programs. A recent regulation issued by the Centers for Medicare and Medicaid Services (CMS) established four Part D e-prescribing standards. The standards, which will take effect in April 2009, deal with four types of information: formulary and benefits; medication history; fill-status notification; and provider identifiers. The standards will govern how physicians, pharmacies, and drug plans will communicate electronically to handle drug orders. Prescribers, pharmacies, and other providers are not required to implement e-prescribing, but those that do must comply with the new Medicare standards when using e-prescribing to send prescriptions and prescription-related information for covered drugs prescribed for Part D eligible individuals.<sup>49</sup>

In addition, the U.S. Department of Health and Human Services has taken steps to speed the adoption of e-

prescribing by offering incentive payments to physicians and other eligible professionals. Beginning in 2009, Medicare will provide incentive payments to successful electronic prescribers. Eligible professionals will receive a bonus of two percent of all covered professional services in 2009; a bonus of one percent in 2011 and 2012; and a bonus of one half percent in 2013. Beginning in 2012, eligible professionals who are not successful electronic prescribers will receive a reduction in payment. However, eligible professionals may be exempted from the reduction in payment if they can demonstrate that compliance would result in significant hardship.<sup>50</sup>

Further, several states are expanding their e-prescribing initiatives in their Medicaid programs, and nineteen states plan to add e-prescribing initiatives in the near future.<sup>51</sup>

### **Education**

Many health plans or the pharmacy benefit managers with which they contract have developed educational strategies to provide more information on the benefits of prescribing generic drugs. These programs are targeted to prescribers or consumers and may include broad-based media campaigns, signs or other information provided through pharmacies, direct communications with consumers or prescribers, or providing generic drug samples to prescribers.

#### **Consumer Education**

While consumers are increasingly confident about using generic drugs as an alternative to brand name drugs, some knowledge gaps remain: Nearly 40 percent of consumers admit to knowing very little about generic drugs.<sup>52</sup> In addition, some adults still consider brand name drugs to be superior to generic drugs,<sup>53</sup> or believe that switching to a

generic may compromise the quality of their medications.<sup>54</sup>

A variety of communication channels have been used to increase consumer knowledge of generic drugs. Online pricing tools have been shown to be particularly effective. Health plan members who viewed generic and brand name price comparisons were 60 percent more likely to switch to a generic drug than those who did not compare prices. Direct-mail campaigns encouraging use of generic medicines are also highly effective in convincing patients to make the switch. According to one survey, generic education campaigns employing targeted mailings increased generic conversion by 22 percent, at a savings of \$88 per switch per year.<sup>55</sup>

Large-scale education campaigns on the use of generic drugs have also been undertaken. One health plan conducted an extensive campaign to increase awareness of generic drugs. The campaign included mailing coupons to members to cover the co-pay for a generic drug, placing a series of consumer awareness advertisements in newspapers and business journals to dispel myths about generic drugs, and sponsoring a competition among pharmacies to increase the dispensing rate on generics. The plan invested \$1 million in the advertisements but saved an estimated \$13 million in reduced drug costs.<sup>56</sup>

Consumer groups have also initiated educational efforts. For example, in 2002, AARP launched a \$10 million national advertising campaign that promoted the availability and affordability of generic prescription drugs. AARP has also entered a multiyear partnership with Walgreens that provides educational resources about health, wellness, and medications to adults age 50 and over, with a focus on the wise use of prescription drugs.

Another educational effort was developed by Consumers Union, the publisher of *Consumer Reports*, called “Best Buy Drugs.” This public education project is designed to provide condition-specific comparative effectiveness information for consumers making decisions about prescription medicines.

#### Prescriber Education

Like consumers, some prescribers maintain erroneous beliefs about generic prescription drugs. For instance, even though the FDA states that generic drugs must be therapeutically equivalent to brand name drugs, only about four in ten (42 percent) physicians say they strongly or somewhat agree that this is true. In addition, more than one-third (36 percent) of physicians say that they strongly or somewhat agree with the statement that, “therapeutic failures are a serious problem with generic products.”<sup>57</sup>

To correct these misperceptions and encourage generic prescribing, some health organizations have begun implementing prescriber education strategies. Most of these efforts utilize academic detailing.

Academic detailing is an attempt to drive more rational, cost-effective prescribing choices, based on many of the same marketing tactics used by brand name manufacturers. The pharmaceutical industry spends more than \$7 billion a year on direct marketing to doctors.<sup>58</sup> Consultants who work for the state or health plans—not for drug manufacturers—visit prescribers and provide evidence-based information about drug effectiveness to promote the use of lower cost generic medications whenever possible. In some instances, academic detailing includes providing free generic drug samples to prescribers, a countermeasure to the free brand name drug samples that manufacturers’ marketing

representatives regularly provide to prescribers.

Several states have begun to implement academic detailing measures. One is Pennsylvania, whose program was implemented in late 2005 and is considered one of the most extensive. The state spends \$1 million a year on eleven consultants who visit prescribers in the twenty-eight counties with the highest concentrations of seniors enrolled in discount drug programs.<sup>59</sup> Thus far, the program has been moderately successful; for patients of nearly 300 participating doctors, average monthly spending on some pain relievers dropped from \$400 to \$340 per doctor within six months after a state consultant visit. An additional analysis found that the program saved Pennsylvania about \$572,000 a year just on heartburn drugs.<sup>60</sup>

Louisiana is also utilizing academic detailing. The Prescriber Education and Intervention program is targeted at top prescribers, who accounted for approximately \$25 million in annual spending. The program has been a key contributor to the state’s Office of Group Benefits’ generic substitution rate increasing by 5 percent and its generic utilization rate increasing by 7.2 percent.<sup>61</sup>

#### Pharmacist/Prescriber Incentives

A growing number of health plans have begun experimenting with programs that offer providers financial incentives for increased use of generic drugs or for meeting certain target rates for using preferred drugs. For example, one health plan conducted a program that paid participating physicians \$100 for each patient who converted from a brand name cholesterol-lowering statin to a generic statin. The program reportedly spent \$2 million in incentive payments and saved \$5 million in annual drug costs for the health plan and \$1 million

in co-payments for members. Other insurers are encouraging doctors to prescribe more generics by making it a factor in annual “pay-for-performance” bonuses. In these programs, physicians’ practices are typically paid 2 percent to 8 percent more if they meet certain criteria designed to improve care and efficiency, such as issuing more prescriptions electronically and reducing patients’ cholesterol levels.<sup>62</sup>

In addition, some pharmacy benefit managers have begun providing incentive payments to pharmacies that meet set standards for dispensing generic drugs, dispensing preferred brand name drugs, or meeting standards as measured in drug utilization review programs.

#### **Drug Pricing/Reimbursement**

Health plans and pharmacy benefit managers can limit the amount reimbursed to pharmacies for certain drugs in order to promote generic utilization. One technique some health plans use is a maximum allowable cost (MAC) program. These programs establish a ceiling price on the amount reimbursed to pharmacies for specific brand name and generic drug products. Pharmacies retain more of this reimbursement if they dispense a less costly generic product, creating a strong incentive to dispense generic drugs. Currently, 65 percent of employers use MAC pricing for retail generic prescriptions, and 47 percent use it for mail-service generic prescriptions.<sup>63</sup>

#### **Prescription Pads**

The format of a prescription pad can vary from state to state. At least thirty-five states require a prescriber make the extra effort to handwrite “no substitution,” “dispense as written,” or a similar mandate on the pad (see appendix B). Other states allow an easier override such as a check-off box or signing on a different line if brand

dispensing is being mandated. Changing the design of the prescription pad form can lead to savings for public and private health care providers and consumers.

For example, Texas had a two-line prescription pad on which the physician could sign the “brand only” line and override the substitution of a generic for the brand. The state implemented a new pad that required a physician to handwrite “brand necessary” or “brand medically necessary” in order to prohibit generic substitution. The University of Texas’s Center for Pharmaco-economic Studies estimated that this one policy could save patients and drug benefit programs as much as \$257 million each year.<sup>64</sup>

#### **Federal Legislation**

Federal legislation also has the potential to increase generic utilization. One example is the Fair Medicaid Drug Payment Act of 2007, which would require prior authorization in the Medicaid program for brand name drugs that have generic alternatives.

Additional legislation co-sponsored by several House and Senate Democrats would create a federal academic detailing program that would provide prescribers with unbiased information about prescription drugs. The legislation would also provide grants to produce educational materials for doctors on the safety, efficacy, and cost of prescription drugs, including generic drugs. A second set of grants would be made available in order to dispatch trained medical staff into physicians’ offices to distribute and discuss the independent information.<sup>65</sup>

#### **Challenges for Policies That Encourage Generic Utilization**

The myriad successes of the approaches used to encourage generic utilization do not indicate that such policies have been perfected; in fact, they currently face a

number of challenges. For example, some professional organizations and patient advocates have argued that switching from a brand name drug to a generic drug could be problematic for some patients.<sup>66</sup> However, the American Medical Association recently reviewed all English-language articles on generic drug therapeutic equivalence published between 2002 and February 2007 and concluded that “scientific evidence to support these concerns does not exist or is extremely weak,” and that “a separate and more stringent process for generic substitution... is not necessary.”<sup>67</sup> Nonetheless, efforts to limit generic substitution for certain therapeutic classes have had some success,<sup>68</sup> and it remains to be seen whether this phenomenon will spread to other drug classes.

There is also some concern that generic utilization is reaching a ceiling. Generic efficiency, which measures the number of times a generic is dispensed versus the number of times a generic could possibly be dispensed, is currently at about 89 percent across the chain drug industry. Generic efficiency is also high in state Medicaid programs, with rates that range from the high 80s to the low 90s.<sup>69</sup> It is questionable whether these rates can be raised much higher using traditional generic substitution methods.

Efforts to increase generic utilization may also be stymied by consumers who prefer brand name drugs to generic drugs and are willing to pay for them. This phenomenon may be due to deep-seated tendencies. Researchers have found evidence that price affects expectations about medications,<sup>70</sup> making it unlikely that generic policies will change the utilization patterns of patients who associate a higher price with increased value.

A final, unique challenge is the lack of generics for biologic drugs, one of the

fastest growing segments of the pharmaceutical industry. The FDA currently lacks a statutory pathway that would allow it to approve generic, or bioequivalent, versions of biologic drugs.<sup>71</sup> Therefore, unless new legislation is passed, comparable versions of these drugs will never be sold, making generic utilization policies irrelevant.

## Conclusion

The savings associated with policies that encourage the utilization of low-cost generic prescription drugs make them an obvious choice in the struggle to contain health care costs. However, policymakers and researchers should address the questions surrounding the therapeutic equivalence of generic drugs; develop methods of encouraging generic utilization among all consumers; and create a statutory pathway for the approval of generic biologic drugs. In addition, given the inherent complexity of the health care system, it is likely a number of generic utilization policies will have to be combined in a more comprehensive approach before generic drug utilization can be maximized.

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**Appendix A**  
**Generic Fill Rates by State, 2005**

<b>State</b>	<b>Generic Fill Rate*</b>	<b>State</b>	<b>Generic Fill Rate*</b>
Alabama	54.4%	Montana	55.6%
Alaska	N/A	Nebraska	51.1%
Arizona	56.2%	Nevada	55.3%
Arkansas	53.9%	New Hampshire	56.2%
California	53.8%	New Jersey	44.8%
Colorado	54.1%	New Mexico	60.1%
Connecticut	51.5%	New York	48.8%
Delaware	51.8%	North Carolina	51.8%
District of Columbia	N/A	North Dakota	57.4%
Florida	49.0%	Ohio	52.2%
Georgia	51.0%	Oklahoma	53.3%
Hawaii	N/A	Oregon	59.0%
Idaho	54.0%	Pennsylvania	51.9%
Illinois	50.9%	Rhode Island	57.4%
Indiana	51.1%	South Carolina	51.8%
Iowa	54.9%	South Dakota	53.8%
Kansas	52.8%	Tennessee	53.5%
Kentucky	53.1%	Texas	49.8%
Louisiana	48.7%	Utah	56.3%
Maine	56.7%	Vermont	55.3%
Maryland	49.5%	Virginia	50.5%
Massachusetts	59.3%	Washington	56.1%
Michigan	52.7%	West Virginia	54.7%
Minnesota	54.9%	Wisconsin	57.2%
Mississippi	51.9%	Wyoming	56.0%
Missouri	55.4%		

\* Based on top six therapeutic drug categories (nonsteroidal anti-inflammatory, antihypertensive, antidepressant, gastrointestinal, calcium channel blocker, and lipid-lowering drugs). Rates have been age and gender adjusted.

Source: E. Cox, A. Behm, and D. Mager, "2005 Generic Drug Usage Report," Express Scripts, May 2006.

<b>Appendix B</b>					
<b>State Laws Governing Generic Substitution by Pharmacists</b>					
<b>State</b>	<b>Allows for Generic Substitution by Pharmacists if “Brand Only” Not Indicated by Physician</b>	<b>Mandates Generic Substitution by Pharmacists if “Brand Only” Not Indicated by Physician</b>	<b>Allows for Brand if Requested by Patient</b>	<b>Mandates Brand Only if Indicated by Physician</b>	<b>To Ensure Brand Name Only, Physician Must Indicate the Following on the Written Prescription OR Communicate Orally</b>
Alabama	√		√	√	The physician must sign the prescription signature line labeled Dispense As Written.
Alaska	√		√	√	The physician must handwrite the words Dispense As Written or similar phrase.
Arizona	√		√	√	The physician must handwrite the words Dispense As Written or similar phrase.
Arkansas	√		√	√	The physician must handwrite the words No Substitution or similar phrase.
California	√		√	√	The physician must handwrite the words Do Not Substitute or similar phrase.
Colorado	√		√	√	The physician must handwrite the words Dispense As Written or initial the Dispense As Written box.
Connecticut	√		√	√	The physician must handwrite the words No Substitution.
Delaware	√		√	√	The physician must handwrite the words Brand Necessary or Brand Medically Necessary and sign the prescription signature line labeled May Not Substitute or Dispense As Written.
District of Columbia	√		√	√	The physician must handwrite the words Dispense As Written, DAW, or similar phrase.
Florida		√	√	√	The physician must handwrite the words Medically Necessary.
Georgia	√		√	√	The physician must handwrite the words Brand Necessary or similar phrase.
Hawaii		√	√	√	The physician must handwrite the words Brand Medically Necessary or similar phrase.
Idaho	√		√	√	The physician must check the Brand Only or DAW box.

<b>Appendix B continued</b>					
<b>State Laws Governing Generic Substitution by Pharmacists</b>					
<b>State</b>	<b>Allows for Generic Substitution by Pharmacists if “Brand Only” Not Indicated by Physician</b>	<b>Mandates Generic Substitution by Pharmacists if “Brand Only” Not Indicated by Physician</b>	<b>Allows for Brand if Requested by Patient</b>	<b>Mandates Brand Only if Indicated by Physician</b>	<b>To Ensure Brand Name Only, Physician Must Indicate the Following on the Written Prescription OR Communicate Orally</b>
Illinois	√		√	√	The physician must sign the prescription signature line and check the May Not Substitute box.
Indiana		√	√	√	The physician must sign the prescription signature line labeled Dispense As Written.
Iowa		√	√	√	The physician must handwrite the words Dispense As Written or similar phrase.
Kansas	√		√	√	The physician must handwrite the words Dispense As Written or sign the Dispense As Written signature line if using the two-line prescription form.
Kentucky		√	√	√	The physician must handwrite the words Do Not Substitute.
Louisiana	√		√	√	The physician must check the Dispense As Written or DAW box and handwrite his or her signature on the signature line.
Maine		√		√	The physician must check the Dispense As Written or DAW box (if available) or handwrite the words Dispense As Written, DAW, Brand Necessary, or Brand Medically Necessary.
Maryland	√		√	√	The physician must clearly communicate to the pharmacist that the prescription should be filled only as directed.
Massachusetts		√		√	The physician must handwrite the words No Substitution.
Michigan	√		√	√	The physician must handwrite the words Dispense As Written or DAW.
Minnesota		√	√	√	The physician must handwrite the words Dispense As Written or DAW.
Mississippi		√	√	√	The physician must sign the Dispense As Written signature line.
Missouri	√		√	√	The physician must sign the Dispense As Written signature line.

<b>Appendix B continued</b>					
<b>State Laws Governing Generic Substitution by Pharmacists</b>					
<b>State</b>	<b>Allows for Generic Substitution by Pharmacists if “Brand Only” Not Indicated by Physician</b>	<b>Mandates Generic Substitution by Pharmacists if “Brand Only” Not Indicated by Physician</b>	<b>Allows for Brand if Requested by Patient</b>	<b>Mandates Brand Only if Indicated by Physician</b>	<b>To Ensure Brand Name Only, Physician Must Indicate the Following on the Written Prescription OR Communicate Orally</b>
Montana	√		√	√	The physician must handwrite the words Medically Necessary.
Nebraska	√		√	√	The physician must handwrite the words Dispense As Written, DAW, Brand Medically Necessary, BMN, or similar phrase.
Nevada		√	√	√	The physician must handwrite the words Dispense As Written.
New Hampshire	√		√	√	The physician must handwrite the words Medically Necessary.
New Jersey		√	√	√	The physician must initial the Do Not Substitute option.
New Mexico	√		√	√	The physician must handwrite the words No Substitution or No Sub.
New York		√		√	The physician must handwrite the initials DAW in the appropriate box.
North Carolina	√		√	√	The physician must sign the Dispense As Written signature line.
North Dakota	√		√	√	The physician must handwrite the words Brand Necessary.
Ohio	√		√	√	The physician must handwrite the words Dispense As Written or DAW.
Oklahoma			√	√	Pharmacists are actively barred from generic substitution without the authority of the physician.
Oregon	√		√	√	The physician must handwrite the words No Substitution or NS.
Pennsylvania		√	√	√	The physician must handwrite the words Brand Necessary or Brand Medically Necessary.

<b>Appendix B continued</b>					
<b>State Laws Governing Generic Substitution by Pharmacists</b>					
<b>State</b>	<b>Allows for Generic Substitution by Pharmacists if "Brand Only" Not Indicated by Physician</b>	<b>Mandates Generic Substitution by Pharmacists if "Brand Only" Not Indicated by Physician</b>	<b>Allows for Brand if Requested by Patient</b>	<b>Mandates Brand Only if Indicated by Physician</b>	<b>To Ensure Brand Name Only, Physician Must Indicate the Following on the Written Prescription OR Communicate Orally</b>
Rhode Island		√	√	√	The physician must handwrite the words Brand Name Necessary.
South Carolina	√		√	√	The physician must sign the Dispense As Written signature line.
South Dakota	√		√	√	The physician must handwrite the words Brand Necessary or similar phrase.
Tennessee		√	√	√	The physician must handwrite the words Dispense As Written, DAW, Medically Necessary, No Generic, or similar phrase.
Texas	√		√	√	The physician must handwrite the words Brand Necessary or Brand Medically Necessary.
Utah	√		√	√	The physician must sign the Dispense As Written signature line or handwrite the words Dispense As Written.
Vermont		√	√	√	The physician must clearly communicate to the pharmacist that the prescription should not be substituted.
Virginia	√		√	√	The physician must handwrite the words Brand Medically Necessary.
Washington	√		√	√	The physician must sign the Dispense As Written signature line.
West Virginia		√	√	√	The physician must handwrite the words Brand Medically Necessary.
Wisconsin	√		√	√	The physician must handwrite the words No Substitutions, NS, or similar phrase.
Wyoming	√		√	√	The physician must handwrite the words Brand Medically Necessary.

Source: Astellas Pharma US, Inc, State Laws or Statutes Governing Generic Substitution by Pharmacists, December 2007. Available on the Web at: [http://www.prograf.com/pdf/daw\\_flashcard.pdf](http://www.prograf.com/pdf/daw_flashcard.pdf)

<b>Appendix C</b>			
<b>Mandatory Substitution in State Medicaid Programs</b>			
<b>State</b>	<b>Incentive Fee for Generic Substitution</b>	<b>Dispensing of Generic Multiple Source Drug Required</b>	<b>Dispensing of Lowest-Cost Multiple Source Drug Required</b>
Alabama	No	Yes	No
Alaska	No	Yes	No
Arizona*	-	-	-
Arkansas	\$2.00	Yes	Yes
California	No	No	Yes
Colorado	No	Yes	No
Connecticut	No	Yes	No
Delaware	No	Yes	No
District of Columbia	No	Yes	No
Florida	No	Yes	No
Georgia	No	Yes	No
Hawaii	No	Yes	No
Idaho	No	Yes	No
Illinois	No	No	No
Indiana	No	Yes	Yes
Iowa	No	No	Yes
Kansas	No	Yes	No
Kentucky	No	Yes	Yes
Louisiana	No	No	No
Maine	No	Yes (preferred generics)	Yes
Maryland	No	Yes	No
Massachusetts	No	Yes	No
Michigan	No	No	No
Minnesota	No	Yes	Yes
Mississippi	No	Yes (if less costly)	No
Missouri	No	Yes	Yes
Montana	No	Yes	No
Nebraska	No	No	No
Nevada	No	Yes	Yes
New Hampshire	No	Yes	No
New Jersey	No	Yes	Yes
New Mexico	No	No	Yes
New York	\$1.00	Yes	No
North Carolina	\$1.60	Yes	Yes
North Dakota	No	Yes	No
Ohio	No	No	No
Oklahoma	No	Yes	No
Oregon	No	Yes	No
Pennsylvania	No	Yes	No
Rhode Island	No	Yes	No

<b>Appendix C continued</b>			
<b>Mandatory Substitution in State Medicaid Programs</b>			
<b>State</b>	<b>Incentive Fee for Generic Substitution</b>	<b>Dispensing of Generic Multiple Source Drug Required</b>	<b>Dispensing of Lowest-Cost Multiple Source Drug Required</b>
South Carolina	No	Yes	Yes
South Dakota	No	Yes	No
Tennessee	No	Yes	Yes
Texas	\$0.50	Yes	No
Utah	No	Yes	No
Vermont	No	Yes	Yes
Virginia	No	Yes	No
Washington	No	No	Yes
West Virginia	No	Yes	No
Wisconsin	No	Yes	No
Wyoming	No	Yes	No

\* Within federal and state guidelines, individual managed care and pharmacy benefit organizations make formulary/drug decisions.  
Source: National Pharmaceutical Council, *Pharmaceutical Benefits under State Medical Assistance Programs*, 2007.