$4 generics: How low, how broad, and why patient engagement is priceless

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The year 2011 marks the 5-year anniversary of two landmark developments in the pharmacy marketplace: the implementation of Medicare Part D and inauguration of Walmart's $4 generic prescription drug program. Both are generally perceived as enhancing access to medications for millions of Americans; Walmart claims that its program has saved patients more than $3 billion.[1] Also, both developments may be intertwined, as some Part D enrollees who experience the coverage gap may seek self-pay refuge with $4 generics.

In addition, it is likely that the economic recession is leading an increasing number of patients to search out deeply discounted drugs, further entrenching these programs[2] in the U.S. pharmacy arena. In 2007, more than one-third of uninsured, working-age Americans reported unmet prescription drug needs, up from 26% in 2003.[3] Walmart estimated that 30% of its $4 generic patients in 2007 were uninsured.[4] By 2009, the ranks of the uninsured grew to more than 50 million patients.[5] Indeed, abandonment of prescriptions (ordered but unclaimed at pharmacies) in 2009 rose dramatically and stood at 8.6% for brand-name prescriptions—an increase of 68% since 2006.[6]

How low? Shaking up the pharmacy landscape in 2011

Walmart, whose stores serve more than 100 million shoppers (although not necessarily pharmacy patients) each week,[7] is poised to shake up the pharmacy landscape again with its 2011 entry into the Part D drug plan market. Launched in partnership with veteran Part D sponsor Humana, this plan features a nationwide monthly premium of less than one-half the national average and $2 copays for "preferred" generics obtained only at network (defined as Walmart, Sam's Club, and Neighborhood Market) pharmacies.[8] Generic drugs purchased at nonnetwork pharmacies will have $10 copays, while zero copays will be available for mail service generics. However, the Humana–Walmart plan requires a $310 annual deductible and steep coinsurance (20–50%) on all brand-name drugs, which varies based on pharmacy provider.[9] It would be premature to predict whether this plan will be a long-term player or a temporary blip in a Part D market where 10 national prescription drug plans have traditionally captured 70% of standalone drug plan enrollees.[10,11]

True value of deep discount

A closer examination of $4 generic programs is warranted to better distinguish perceived or real value, including the breadth of drug offerings (Table 1) compared with overall and Part D generic drug use in the United States. This low-cost option has positive attributes and points of caution for patients, caregivers, and health care professionals.

Known versus rogue pharmacies

Filling a valid prescription, whether for $4 or $400, at a legitimate community pharmacy (bricks and mortar, as well as online pharmacies that meet the National Association of Boards of Pharmacy Verified Internet Pharmacy Practice Sites standard) remains a safer strategy than surfing the Internet. Patients may be tempted by a rogue pharmacy's e-mail offers for deeply discounted branded prescription medications that (1) may represent a counterfeit product and (2) can too often be secured by completing an online questionnaire with no licensed prescriber or pharmacist involved. Perhaps in recognition of medical conditions that are frequently targeted by such solicitations, Walmart's discounted drug list includes the erectile dysfunction drug vardenafil, sold at $9 per tablet (with a limit of 10 per patient per month).[1]

How broad? Program offerings may fit (clinical) bill

Although new generics for off-patent blockbuster drugs are usually excluded from $4 generic programs, older generics to treat common conditions are fairly well represented. The author's comparison of the *Drug Topics* 2009 top 200 generic drugs by total prescriptions[12] with the Walmart $4 generics list[1] found the following:

- About one-third (35) of the top 100 generics (from the top 200 list) are included in Walmart's program. Drugs with the same active ingredients on both lists, but with different formulations (e.g., extended release, slow release), did not count toward this proportion. Walmart's own list features multiple dosages or formulations of the same generic medication, such as 14 listings for amoxicillin and 11 for levothyroxine.
- Drug categories for these 35 drugs included cardiovascular, analgesic, antidepressant, antibiotic, antiarthritic, antidiabetes, respiratory tract, and oral contraceptive medications.
- Only about a dozen of these 35 fall into the top 100 generics by retail dollars,[13] implying that Walmart $4 generics tend to represent multisource generics with a lower per-unit cost and/or lower prescription volume.
- Walmart also offers a few $9 generics for categories such as smoking cessation, osteoporosis, asthma, and benign prostatic hypertrophy.

Through the doughnut hole

Some Medicare Part D enrollees who suddenly find themselves responsible for 100% of their prescription drug costs in the coverage gap may turn to $4 generic programs to maintain their regimens, if clinically possible. The Centers for Medicare & Medicaid Services (CMS) found that in each year since Part D began, about one-quarter of enrollees who do not qualify for "extra help" via the low-

Table 1. Sample of Walmart $4 generics among top 200 generic drugs by total fills (2009) and among Medicare Part D top 100 drugs by total fills for non-LIS enrollees (2008)

Walmart $4 prescription program generic drug	Ranking, top 200 generics by total fills	Ranking, top 100 Medicare Part D non-LIS by fills
Lisinopril	2	1
Furosemide	13	3
Levothyroxine	4	5
Amoxicillin	5	48
HCTZ	7	8
Metformin	10	11
Atenolol	12	6
Metoprolol	14	10
Ibuprofen	21	Not in top 100
Fluoxetine	22	57
Warfarin	24	14
Cephalexin	29	67
Cyclobenzaprine	30	90
Triamterene-HCTZ	35	Not in top 100
Pravastatin	36	31

Abbreviation used: LIS, low-income subsidy.
Source: References 1, 12, and 15.

income subsidy (LIS) entered the so-called "doughnut hole."[14] (LIS enrollees receive covered brand and generic medications at copays ranging from $1.10 to $6.30, including during the gap.) The author's examination of the most commonly prescribed Medicare Part D generic drugs in 2008 and Walmart's $4 generic list revealed the following:

- About one-half (36) of the 70 generics on the Medicare Part D top 100 drug list, by fills, are represented on Walmart's $4 generic list.
- The drug categories represented by the Walmart list in this Part D review included cardiovascular, thyroid, antidiabetes, anti-infective, antidepressant, and gastrointestinal agents.
- Of the 36 Walmart-listed generics, 30 represented cost rankings at least 100th or greater for non-LIS Part D enrollees. A total of 15 Walmart drugs were ranked by CMS as being 100th to 199th in cost, and 15 were ranked as being 200th or greater. A higher CMS cost ranking is associated with a lower per-unit cost and/or lower overall use and is indicative of multisource generics.
- Some of the most commonly prescribed generics for the non-LIS Part D enrollees excluded from the Walmart list were simvastatin, amlodipine, and lovastatin, all of which rank in the top 40 by total Part D cost.

This analysis was based on two of a dozen different Part D top 100 drug lists for 2008 (CMS data released in 2010)—rankings by total fills and rankings by total costs—for enrollees who did not qualify for LIS.[15] This particular population represents about two-thirds of Part D enrollees[14] and is the subgroup most likely to be fully exposed to drug costs in the coverage gap. Thus, non-LIS enrollees would be the most likely candidates for $4 generics programs. (A Walmart list from 2008 was not publicly available for a same-year comparison; therefore, the comparison was made with the October 2010 list.)

Starting in 2011, the Affordable Care Act gradually reduces cost sharing for non-LIS Part D enrollees in the coverage gap, with brand-name medications discounted by 50% and generics discounted as well. However, the gap will not be fully closed until 2020, so affected enrollees might continue to seek relief through discounted generics programs.

Preference for paying cash

Patients with chronic conditions associated with stigma may prefer to pay cash. Where clinically justified, $4 generics may be a valuable option. As psychiatry resident Vidhya Selvaraj, MD, observed, "The medications we prescribe are often quite expensive and frequently indicated for long-term use. In addition, many health plans have limited coverage for mental health and substance use disorders, which increases out-of-pocket costs for our patients." She noted that Walmart's $4 generic list has 15 psychotropic medications, including antidepressants, antipsychotics, mood stabilizers, and anxiolytics. "Although some drugs on the list belong to an older generation of psychotropic drugs, their efficacy and safety data are frequently comparable with those for newer [higher-priced] drugs. In addition to gaining experience with medication cost containment, I was able to gain more knowledge and experience with the older generation of psychiatric drugs," Selvaraj added.[16]

Patient engagement: Priceless

Regardless of benefits to $4 generic programs, neither patients nor health care professionals can afford to discount precautions to optimize safe medication use.

- Recognize that filling prescriptions at multiple pharmacies, combined with a regimen of multiple prescription drugs, greatly increases patients' chances of experiencing preventable drug–drug interactions. The more pharmacies used by patients, the greater the importance of maintaining up-to-date personal medication lists (with all prescription and nonprescription medications, as well as dietary supplements and herbal remedies). Further, such a shop-around practice demands patient responsibility for sharing drug lists with all prescribers and every pharmacist; a patient's principal pharmacy may hold an electronic medication record that may be inaccessible to other pharmacies. Also, clinicians should query patients about the use of multiple pharma-

cies. This could be a good ice breaker for an adherence discussion, given the high rate of cost-related nonadherence.

- Do not short change a counseling opportunity with patients enrolled in $4 generic programs, even if it represents their umpteenth refill. The generic manufacturer of a particular medication may change or vary between pharmacies; therefore, what used to be a familiar green pill may now be yellow. Patients and caregivers should resolve concerns such as these before leaving the pharmacy to avoid potential confusion at home.
- Remind patients to read and keep for future reference all written patient medication information. Regardless of a drug's price, everyone is entitled to a full complement of its benefits and risks.
- Inform patients about common and rare adverse effects, and urge them to follow through on all required monitoring tests. Patients should be encouraged to promptly report any potential drug-related problems to prescribers and pharmacists. Although a $4 generic medication that a patient has been taking for years may not be the culprit, its interaction with a new prescription could be harmful.

Conclusion

For many medication users, both young and old, $4 generic prescription programs have become a staple of their shop-around pharmacy experience. Better information (such as through electronic medical record decision support) at the point of prescribing about patient cost sharing could lead to more affordable alternatives[17]—with fewer pharmacy counter "surprises" and abandoned prescriptions. Until then, however, conserving dollars while bypassing the full complement of professional and educational resources to promote safe medication use could unwittingly reduce a medication's full value many times over or even result in preventable patient harm.

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