



Transcript-Enhanced Guidebook

A continuing education activity for pharmacy technicians



OTC Products in Patient Self-Care And the Role of Pharmacy Technicians

OTC Products in Patient Self-Care And the Role of Pharmacy Technicians

This activity has been developed for pharmacy technicians who encounter patients who have questions or concerns about using over the counter (OTC) medications. This program will assist technicians in determining when to engage the pharmacist with specific patient concerns. The role of generic OTC and store-brand products are reviewed, as well as their economic benefits to the patient and pharmacy. Despite their perceived safety, OTC products can be associated with adverse effects. Important updates on the safe use of OTC products for peptic ulcer disease, allergies, birth control, and pain management are also discussed.

Learning Objectives

The target audience for this activity is pharmacy technicians.

At the completion of this activity, the participant will be able to:

- Describe the evolving patient attitudes toward self-care and wellness, specifically in the context of OTC products
- List important considerations for educating patients who may benefit from pharmacist counseling on the attributes and efficacy of OTC products
- Identify specific situations in which a pharmacy technician should engage the pharmacist with a patient who is asking about OTC drug products
- Summarize the emergence of pharmacist-dispensed OTC products and the technician's role in assisting patients and pharmacists with these products

Faculty

Mary Lynn Moody BSPHarm
Director, Business Development
Drug Information Group
University of Illinois at Chicago
College of Pharmacy
Chicago, Illinois

James H. Wisner, BBA, MBA
President
Wisner Marketing Group, Inc.
Libertyville, Illinois

Accreditation



ProCE, Inc. is accredited by the accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. ACPE Universal Activity Number 0221-9999-14-185-H01-T has been assigned to this knowledge-based, home-study activity (initial release date 08-08-14). This CE activity is approved for 1.0 contact hour (0.10 CEU) in states that recognize ACPE providers. The activity is provided at no cost to participants. Completion of an evaluation and post-test with a score of 70% or higher is required to receive CE credit. CE credit will be uploaded automatically to NABP/CPE Monitor within 3 to 4 weeks after completion of the evaluation. No partial credit will be given.

Release date: August 8, 2014

Expiration date: August 8, 2017



ProCE, Inc.
848 W. Bartlett Road
Suite 3E
Bartlett, IL 60103
www.ProCE.com

Funding

This activity is supported by an educational grant from Perrigo.

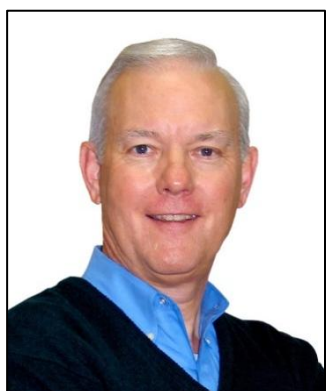
About the Faculty

Mary Lynn Moody, BSP Pharm



Mary Lynn Moody, BSP Pharm, is a Clinical Associate Professor in the Department of Pharmacy Practice at the University of Illinois at Chicago College of Pharmacy. She is also the Director of Business Development for the Drug Information Group. In this role, she is responsible for development and coordination of business relationships with clients of the Drug Information Group. Mary Lynn completed her pharmacy degree at the University of Illinois at Chicago and a PGY1 residency at Northwestern Memorial Hospital in Chicago.

James H. Wisner, BBA, MBA



Jim Wisner is President of the Wisner Marketing Group in Libertyville, IL. He launched his company in 1999 after accruing over 30 years of senior management experience in the food and drug industry at Jewel Food Stores, Shaw's Supermarkets, and Topco Associates, where he was responsible for the OTC product area and launched the Topco Pharmacy Program. He has developed several industry-wide research and education programs in consumer healthcare and other topics. Jim has contributed to many pharmacy education activities, focusing on self-care and patient behavior in the community pharmacy setting. He received his BBA in Marketing from the University of Notre Dame and his MBA from the Kellogg Graduate School of Management at Northwestern University. He previously held a visiting position at the University of Illinois at Chicago College of Pharmacy.

Disclosures

It is the policy of ProCE to require the disclosure of the existence of any significant financial interest or any other relationship a faculty member or a sponsor has with the manufacturer of any commercial product(s) discussed in an educational presentation. **Mary Lynn Moody** has disclosed that she has served as a consultant and/or speaker for the Perrigo Company. **Jim Wisner** has disclosed that he has served as a consultant and/or speaker for the Perrigo Company. A portion of grant funds received by ProCE from Perrigo will be used to compensate the faculty for this activity.

The opinions expressed in this program should not be construed as those of the CE provider or Perrigo. The information and views are those of the faculty through clinical practice and knowledge of the professional literature. Portions of this program may include the use of drugs for unlabeled indications. Use of drugs outside of labeling should be considered experimental and participants are advised to consult prescribing information and professional literature.



**OTC Products
in Patient Self-Care
and the Role of
Pharmacy Technicians**

**This Activity Takes You
in Front of the Counter**

- It is concerned with “front-of-the-counter” issues and patient *self-care* motivations
- We will explore the economic impact of OTC and store brands on both the patient and your pharmacy operation
- We will also focus on your practice environment



Pharmacy Technicians are often the first point of contact for patients who have questions about OTC products

This CE activity is a little different from many others in that it deals with front of the counter issues and patient self-care motivations.

The patient’s perspective on the pharmacy and interaction with the pharmacist will be discussed along with the economic impact of OTC and store brands on both the patient and your pharmacy operation.

This CE focuses as much on the practice environment as it does on the pharmacy itself.

Pharmacy technicians are often the first point of contact for patients with questions about OTC.

Agenda

- | | |
|---|--|
| <p>I. Self-Care Trends and OTC</p> <ul style="list-style-type: none"> ▪ Self-Care Is Health Care ▪ Rx to OTC <p>II. The Role of OTC in Patient Care</p> <ul style="list-style-type: none"> ▪ Importance in Health Care ▪ Patient Economics ▪ How OTC Gets to Market ▪ Packaging and Labeling <p>III. Store Brand OTC</p> <ul style="list-style-type: none"> ▪ Understanding Store Brands ▪ Patient Economics ▪ Quality and Efficacy | <p>IV. The Pharmacy and OTC</p> <ul style="list-style-type: none"> ▪ Patient Understanding and Behavior ▪ Role of the Pharmacy Staff ▪ The Pharmacy Drives OTC <p>V. Important OTC Topics</p> <ul style="list-style-type: none"> ▪ PPIs ▪ Intranasal Products ▪ Acetaminophen ▪ Emergency Contraception |
|---|--|



This learning activity provides an update on self-care trends and OTC. It is very important to understand these trends in order to have a proper perspective regarding how patient behavior is evolving. The role of OTC will be reviewed – and why the pharmacy will have greater involvement than ever before. Store brand medications will be specifically discussed. Store brands are equivalent to generic pharmaceuticals and you may be surprised to find out just how important a role they play in your patients’ lives. Finally your role – and how you should interact with patients and the pharmacist regarding OTC products and store brands – will be addressed.

INTRODUCTION

What Is This Activity All About?

Why OTC and Store Brands?



So, what is this CE activity really all about? Why do we want to focus on OTC products and store brands?

What About Store Brands?



- Store brand (generic) OTC provides:
 - *The best care for your patients at the least possible cost*
 - *Sufficient revenue to maximize the value of the pharmacy to both the patient and your company*

Store brand (generic) OTC addresses both issues

Why are we discussing store brands? The role of the pharmacy is to offer patients the best care at the least possible cost and to ensure that the entire pharmacy operation – including OTC – provides enough revenue to maximize its value to the patient as well as your employer.

Why Is This Important?

- OTC accounts for 60% of all drugs purchased
- Store brands account for:
 - 46% of all OTC items purchased
 - Over one-third of all OTC and RX drugs purchased
 - 59% of all OTC measured by volume (equivalent doses)



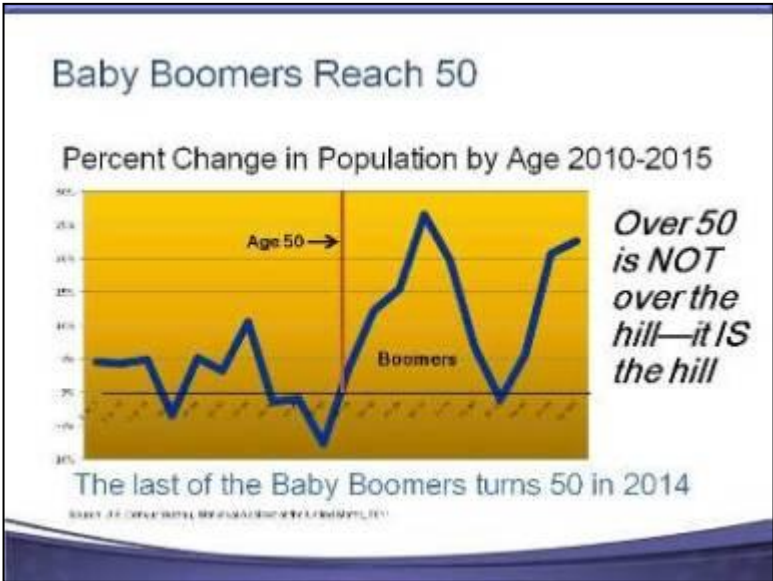
Source: RxPrep, Inc. | www.rxprep.com | This

Just how important are store brands? If we add up all of the doses of pharmaceuticals and OTC products that are taken by patients throughout the United States, what percentage are accounted for by store brand OTC medications?

In unit sales, OTC accounts for over 60% of all drugs purchased, and store brands account for 46% of all of the OTC products. This means that more than 1 in every 4 medications purchased in the United States is a store brand or generic OTC product.



Let's take a look at some store-brand trends, and how they impact individuals.



The last of the baby boomers turn 50 years old in 2014. It is important to understand that “over 50” is really not “over the hill” – *it is the hill* that is driving healthcare today.

Over 50 Drives Healthcare

- They account for 70% of all prescription drugs purchased and more than 50% of OTC purchases
- And 33% of all OTC purchases are made by people over age 65

Average annual personal expenditures for OTC and RX nearly triple between the ages of 45 and 65

Source: U.S. Department of Health and Human Services, Prescription Drug Sales, 2012

Individuals over 50 account for 70% of all prescription drug purchases and more than half of all OTC purchases. One-third of all OTC purchases are made by those over the age of 65. That group will continue to grow in the future as well. Equally important, personal healthcare expenditures begin to increase dramatically at age 45, nearly tripling before most individuals reach retirement age.

Information Access

- Direct-to-Consumer Ads
- Media Coverage
- In-store Kiosks
- Literature
- Newsletters
- The Internet
- New Tools

80% of Internet users look for health or medical information online

Source: "Editorial Board of JAMA: The Journal of the American Medical Association" (2011)



In recent years, direct-to-consumer advertising of prescription drugs has increased. And with the many Rx-to-OTC launches, more healthcare communications and advertising have been targeted to consumers than ever before. Many other channels, such as ongoing media coverage and popular literature, provide even more information. Just take a look at how many magazines – and now even mobile apps – are dedicated to or directed at health and wellness topics.

Over 80% of Internet users today look for health and medical information online. Most everyone looks for that information *before* making a visit to the doctor, and in many cases they feel that they may be as well – or perhaps even better – informed than the doctor when they arrive.

Shoppers Research OTC Online

- **57%** of surveyed users researched OTC medication in the previous 2 months
- It is also significant to note that **73%** of those who research OTC medication online do it at least once a month



Source: "Editorial Board of JAMA: The Journal of the American Medical Association" (2011)

And it is not only information on ailments and prescription drugs; it is also OTC products that consumers are researching. In one survey, 57% of Internet users had researched OTC products sometime within the last 2 months. Significantly, 73% of that group did so at least once a month.

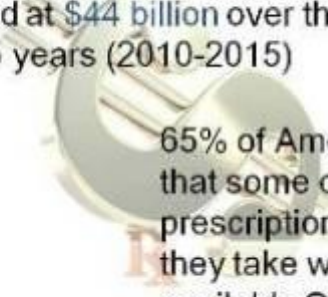
Information Access: New Tools for Self Care



There are many new tools and information available today that weren't available a few years ago. There are mobile apps that a shopper can take to the store and a variety of touchscreen-enabled devices in many stores. There are fitness and diet apps to track every step you take and every bite you eat. The list goes on and will only continue to get bigger.

Growth in Rx-to-OTC

Rx-to-OTC switches are estimated at \$44 billion over the current 5 years (2010-2015)



65% of Americans wish that some of the prescription medicines they take would be made available OTC

Source: The Bureau of Economic Analysis, BEA, 5/12/10

Rx-to-OTC switches are estimated to be \$44 billion during the 5-year period between 2010 and 2015. Nearly two-thirds of all Americans wish that at least some of the prescription medications they currently take would be made available over the counter. OTC is accessible, convenient, and can often preclude the need to see a doctor.

Switch Activity Will Increase

The FDA will again be more active in encouraging new switch activity



Switch activity is likely to increase. The FDA is becoming proactive in moving more drugs to OTC status.

One of the reasons is that many other countries have a much greater focus and reliance on self-care. They also have a longer life expectancy than citizens of the U.S. These countries have historically been more aggressive in moving products to OTC status. The FDA believes that drugs that can be safely taken and managed by patients should be made available as OTC products.

FDA Regulation of OTCs

- FDA revamping its system of OTC regulation
- Overhaul the “Over-the-Counter Monograph”
 - Put into place in 1972
- Steps needed before a revised OTC Monograph can be published
 - Scientific review
 - Public hearings

The FDA is looking to revamp the current system for regulating OTC drugs. The decades-old process that is currently in place is not flexible enough to keep pace with modern medical developments. The plan is to overhaul the Over-the-Counter Drug Monograph, a system that was put into place in 1972. It was designed to set the dosing, labeling, and other standards for nonprescription drug ingredients – everything from aspirin to antibacterial hand scrubs. The regulators at the FDA have acknowledged that the process is extremely time-consuming, requiring multiple rounds of scientific review followed by public hearings and comments, before a final monograph can be published. We will continue to see changes in OTC regulations in the future.

FDA Requirements for Switch

- OTC drugs generally have these characteristics:
 - Benefits outweigh the risks when used as OTC
 - Potential for misuse and abuse is low
 - Consumers can recognize conditions
 - They can be adequately labeled for use
 - Consumers use them correctly
- Actual use and label comprehension studies may be required, costing millions
- Product safety handled on case-by-case basis



FDA Advisory Committee Hearing

The FDA has several very specific requirements to be met before a drug can be switched to OTC status. First, the benefits must outweigh the risks when it is used as an OTC as opposed to a prescription product. Second, there must be little potential for misuse and a low likelihood of abuse. Next, consumers should be able to recognize the medical conditions for which the product is used and should also be capable of self-treating and using the drugs correctly. Finally, the drug must be adequately labeled for use in a way that is clear and understandable. Rx-to-OTC conversions take time – they can be very costly. Generally, both use and label comprehension studies are required before the drugs are approved. Product safety issues are handled on a case-by-case basis.

Future Switch Categories

- Statins
 - Lipitor (atorvastatin calcium)
- Proton pump inhibitors
- Allergy products
- Intranasal steroids
- Others
 - Migraine
 - Prostate
 - Sleep
 - Bladder



\$10 billion expected over next 5 years

This list includes some of the drugs currently being reviewed for future switches. The list is fluid and changes as the FDA assesses new information.

A renewed interest in bringing statins to OTC status will have a major impact. *Mevacor* is already OTC in the United Kingdom.

Patient Risks with OTC

- It is important for Pharmacy Technicians to recognize that if a drug has switched from Rx to OTC, the patient:
 - May need just as much pharmacist counseling as before
 - May wrongly presume that there is less risk of interaction or depletion because it is OTC
- Patients who have questions or appear unsure should be referred to a pharmacist

Pharmacy Technicians are cautioned that patients may need just as much pharmacist counseling regarding usage of a drug that has gone Rx-to-OTC as some may wrongly presume that there is less risk of interaction or depletion because it OTC.

Patients who have questions or appear unsure should be referred to the pharmacist for additional counseling.

How does OTC impact patient care?

The Role of OTC in Patient Care

OTC Is Important

- U.S. consumers make 26 trips per year to purchase OTC products
- They make only 3 trips per year to doctors¹
- 35% use OTC medications on a regular basis²



OTC is important. 35% of all adults in the United States use OTC medications on a regular basis. U.S. consumers make an average of 26 trips per year to purchase OTC products, but only 3 trips per year to the doctor's office.

Consumers Take Charge of Health with OTC Medicines

OTCs make it easy to care for minor medical ailments

96%

Prefer to self-treat with OTCs before seeking professional care

93%

OTCs make Doctor visits unnecessary

86%

Prefer to treat children w/OTC before seeking professional care

85%



Nearly all consumers believe that OTC medicines make it easy to treat minor medical ailments and prefer to treat themselves before seeking professional care. 86% of OTC users believe these products make doctor visits unnecessary. 85% of parents even prefer to treat their children with an OTC product first – before visiting the doctor.

© 2010 The National Patient Partnership. OTCs: Consumer's Choice. A.P. Consumer's Choice Products, Inc. Rev. 04, 2010

OTC Is Cost Effective

- The availability of OTC medicines saves \$102 billion annually, relative to alternatives such as doctor visits (\$77 billion saved) and drug cost savings (\$25 billion saved)
- On average, every dollar spent by consumers on OTC medicines saves the U.S. healthcare system \$6 to \$7



OTC products are cost-effective. They save \$102 billion annually relative to alternatives such as doctor visits and prescription drugs. On average, every dollar spent by consumers on OTC medications saves the U.S. healthcare system \$6 to \$7. In an age where the cost of health care is constantly under discussion, OTC medications are probably one of the most immediate and effective ways to rein in healthcare costs.

Patient Savings Are Substantial

Prescription Drugs Switched to Over-the-Counter
 (Omeprazole cost per year)



This is an example of what happens when a drug is switched from prescription status to OTC, and then eventually makes its way to store brand or generic alternative. When *Prilosec* was originally a prescription drug, it cost patients nearly \$1,500 per year to maintain their regimen. When the generic prescription form was introduced, the cost was cut by more than half. Moving to OTC, the branded product again cut the price in half. And, since it could be purchased on sale or at a discounted price, most individuals were able to buy it at about one-third the cost of the generic prescription drug. When Omeprazole became a store brand, the cost again was nearly halved. Ultimately, the patient moved from a medication regimen that cost nearly \$1,500 per year to maintaining the same drug regimen for a little over \$100 a year.

Flexible Spending Accounts



The federal government’s multiple changes in flexible spending accounts have been very confusing for many people. Until 2002, patients paid the full cost of OTC products. In 2003, these products were made reimbursable through flexible health spending accounts. These accounts enable patients to pay for some of their healthcare expenses with pre-tax dollars. In 2011, as part of the Patient Protection and Affordable Care Act, OTC products were not reimbursable without a written prescription. This change has had far-reaching repercussions for patients and the healthcare system.

Flexible Spending Accounts

- Under the Patient Protection and Affordable Care Act, OTCs will now require a prescription to be reimbursed under an FSA
- The economic impact of this decision will add \$4.5 billion to healthcare costs if only 10% seek an OTC prescription



- 51.6% use accounts to purchase OTCs
- 46% indicate they will seek a prescription
- 76% of physicians are somewhat or very likely to write an OTC prescription for patients seeking to be reimbursed

Source: The Institute for Healthcare Consumers, Editorial, December 2010, Copyright Health Care Progress, Inc. All rights reserved. www.ihc.org, 10/13/10, www.ihc.org, 10/13/10

Under the ACA, requiring a prescription will add about \$4.5 billion to healthcare costs if only 10% of patients seek a prescription for an OTC product which they could otherwise purchase off the shelf. In one study, more than half the people were using flexible spending accounts to purchase OTC products, and 46% indicated that with the change in the law, *they would now seek a prescription*. Additionally, 76% of physicians said they were somewhat or very likely to write an OTC prescription for patients seeking reimbursement. There is some discussion about reverting to the previous flexible-spending law, but it has not yet been changed. Meantime, technicians may see many patients bringing prescriptions for OTC products because *for them* it may be less costly than purchasing off the shelf.

BTC and ORx



- Some children's medications, pseudoephedrine products, and emergency contraception items are OTC already, available only from the pharmacist
- Prescription OTC (ORx) items are similar

The pharmacist wouldn't think of not offering your patient a generic Rx alternative. . .

Many more products today are available without a prescription, but must be dispensed by a pharmacist. Examples include children's medications, pseudoephedrine products, and until recently, emergency contraceptives. Drugs that are often dispensed *with* a prescription – even though available on the shelf – include omeprazole and similar drugs. When a patient approaches with a prescription for an OTC product, consider suggesting the patient talk with the pharmacist to see if there is a cost-effective store brand equivalent available – the same as you would do for generic prescription drugs.

STORE BRAND OTC

- What Are Store Brands?
- Store Brand Quality
- Store Brand Economics
- How Consumers View Store Brands



What exactly is store brand OTC? Is the quality the same as national brand drugs? What are the economics of these products, and how do consumers feel about them?

Definition: Store Brands

- The OTC equivalent to generic Rx drugs
- Compare with top-selling national brands
 - Ingredients
 - Possibly packaging
- Sold under a particular store's name or label
- Sometimes referred to by pharmacists as "generic OTC"



Store brands are the OTC equivalent to generic Rx drugs. Their ingredients compare with those of the top-selling national brands, and the packaging often helps patients identify the national brand equivalent. Store brands are most often sold under a particular store's name or label (or a name or label that they control) and sometimes are referred to by pharmacists as generic OTC.



“generic”

The use of the term “generic” makes sense when talking about prescription pharmaceuticals. Most people understand that generic pharmaceuticals have the same efficacy, mechanism of action, and other characteristics as their branded counterparts. They simply cost less. However, for products other than prescription drugs, the term “generic” often has a different connotation.

Store Brand or Generic?

“Generic” has a different connotation based on where it is used



Say “Generic” Here



Say “Our Brand” Here

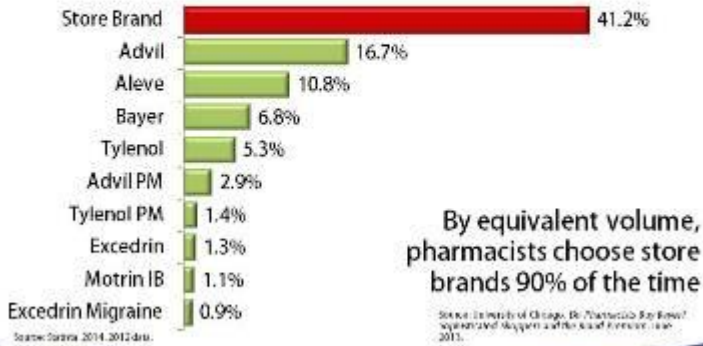


NOT the image you want

Patients understand that when being offered a “generic” prescription they are receiving an equivalent product at a lower price. But all pharmacy personnel are cautioned that referring to an OTC product as a “generic” may suggest to the customer that it is an inferior product. The word “generic” takes on a different context in store aisles where prior consumer experience with generic products is typically with lower-quality, inexpensive items. Therefore, when speaking of store brand OTC products, it is important that pharmacists and other staff use a term such as “our brand” or reference the specific brand name used by the store or chain.

Store Brand Analgesics Are Used by More Patients

Total U.S. Analgesic Internal Tablet Dollar Sales: 2012

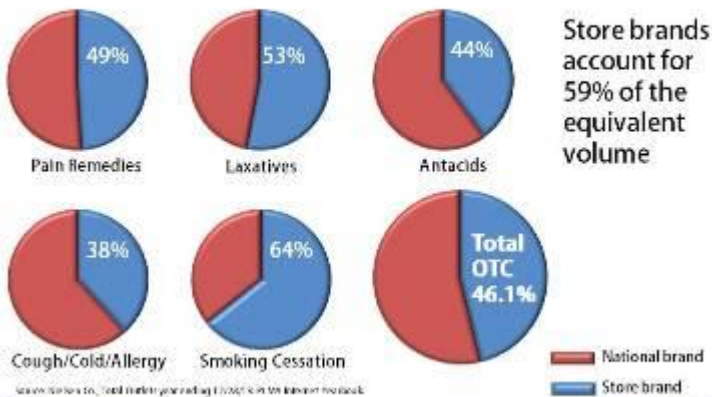


By equivalent volume, pharmacists choose store brands 90% of the time

Source: University of Chicago, Dr. Pharmacia, Dr. Retailer, and Dr. Hospital. University of Chicago, Dr. Pharmacia, Dr. Retailer, and Dr. Hospital. 2013.

Store brands, also referred to as “private label” – dominate most OTC categories in which they are sold. Store brand analgesics far outsell the leading brands, and collectively outsell the next 9 brands combined. A recent University of Chicago study also found that pharmacists choose store brands for themselves 90% of the time.

OTC Store Brand Share of Unit Sales



Store brands account for 59% of the equivalent volume

In unit sales, the store brand share is even higher. Across the board, these products have become the leading choice for most consumers, and they now collectively represent over 46% of total unit sales across all channels. When reassessed on a volume basis (the same as equivalent doses), store brands represent 59% of all OTCs taken.

STORE BRAND ECONOMICS



Let's move on to store brand economics.

Everyone Benefits: SB Economics



Example



\$5.59	Cost	\$1.65
6.99	Retail Price	4.99
1.40	\$ Margin	3.34
20%	% Margin	65%
Consumer savings: 29%		
Retail Margin Increase: 131%		

Everyone benefits with store brands. This comparison (costs are representative) indicates that the store brand product is significantly less expensive when compared with the national brand. The retail price to the consumer is also far lower, but the gross margin dollar return to your store's operation is significantly higher.

It is important to note that everyone comes out ahead. The consumer typically saves around 30% or more, and the increase in the retail margin is dramatically higher.

This helps the pharmacy maintain staffing levels to provide better care.

Changing Minds: Example

Change 10 OTC Recommendations
(per week in 100 stores)

	NB	SB	Difference
Price	\$6.99	\$4.99	\$2.00
Margin %	20%	65%	3.0x
Margin \$	\$1.39	\$3.24	\$1.85

Assume 100 stores: 10x100x52= 52,000 recommendations

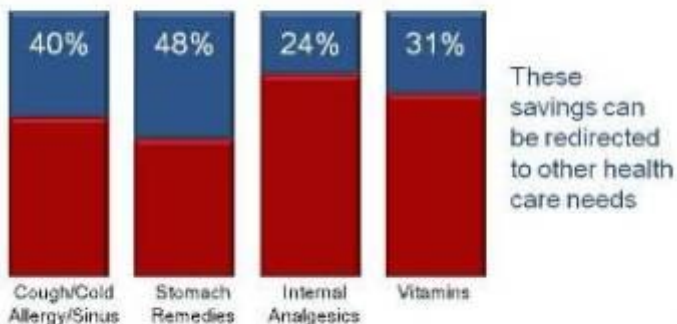
- Benefit to Patient \$104,000/year
- Benefit to Pharmacy \$96,200/year

The cumulative impact from customers switching to less costly but equally effective alternatives is substantial.

For example, if just 10 patients per week switched to a store brand alternative in a pharmacy operation that has 100 stores, the savings to patients totals more than \$100,000 per year. At the same time, additional return to the store is almost as much.

Savings for Patients Are Substantial

Percentage Difference Average Price Per Volume Paid



The savings across all OTC categories are significant. The patient can redirect these savings to other healthcare needs and greatly extend their healthcare budget. For less affluent patients, this is especially important.

Why Do Advertised Brands Cost More?

Over \$2.5 Billion in Advertising!
Just the Top 20 Brands without Internet!

Media Spending Over
22% of Product Cost



Product Cost



Why do advertised brands cost more? For the top 20 brands alone, conventional media spending accounts for more than 22% of the product cost. Add to this other marketing expenses, and it becomes clear why these brands cost so much more.

The net result is a significant difference in cost of product that is unrelated to the product itself.



Store Brand Quality

In terms of quality, are store brands different from their advertised brand counterparts? Let's take a look at store brand quality.

Store Brand Quality

Store brands
must adhere to
the exact same
standards as
advertised
brands



The most important thing to understand about store brands is that they must adhere to the exact same standards as advertised brands.

Both store brand and advertised brand manufacturers are held to the same FDA standards and requirements for safety and common good manufacturing practices (cGMPs). Pharmacists and technicians can be confident that their store brand products meet all of the strict compliance requirements that are defined by the FDA.

Manufacturing Best Practices

- FDA cGMPs
- In-bound material audits
- Outside plant audits
- Store-shopped samples
- Product testing
- Validation testing
- Response procedures
- USP standards
- History of responsiveness



All generic and store brand manufacturers must commit to the same manufacturing best practices, or cGMPs. They are reviewed, audited, and controlled by the FDA to the same extent as all other manufacturers. These manufacturing best practices extend all the way from in-bound raw materials to the shelf.

What Does National Brand Equivalent (NBE) Mean?

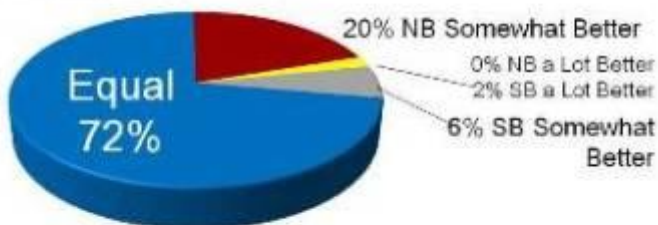
- Same active ingredients
- Comparable product attributes
- Packaging that invites comparison



The phrase “national brand equivalent” means that the active ingredients in the store brand product are the same as those of the advertised national brand. There may be differences in excipient ingredients, colors, flavors, or other ingredients that have nothing to do with how the drug acts. Often, the packaging invites some comparison. This is not meant to confuse the customer but to help in selecting the appropriate alternative product. Most customers don’t have an understanding of the chemical names that describe the active ingredients. Technicians should be aware of some potential issues. Even though active ingredients are the same, some patients may have allergies or other issues related to the other ingredients. Also, the store brand may not be right next to its branded counterpart on the shelf, potentially creating some confusion. Be sure to involve the pharmacist if there are any questions from the patient about either of these issues.

Consumers Believe Store Brand Quality Is Equal

“Which best fits your perception of the difference in QUALITY between store brand and advertised brand OTC medications?”



80% believe store brands are equal or better!

Source: PwC, ©2013 Kaiser Family Foundation, November 20, 2013

The majority of customers believe in store brand quality. In fact, 80% of all consumers believe that store brand OTC products are of equal or better quality than their nationally advertised counterparts.

Bioequivalence Studies

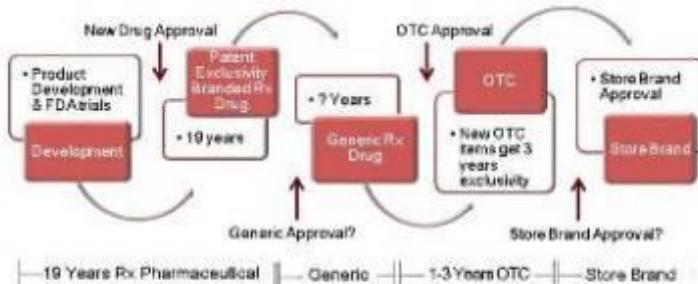
- Brands must prove safety and effectiveness
- Generics need only show bioequivalence to branded drug
 - Exception is topicals and other dosage forms that are not systemically available in the bloodstream



To be approved by the FDA, generic or store brands must first conduct bioequivalence studies. They must demonstrate both safety and effectiveness in a very controlled fashion.

How Long Does It Take a Store Brand to Get to Market?

It Takes a Generation



All OTC products, national brand, and store brands go through the same approval process

It often takes a generation for a store brand item to reach the shelves, especially if it began as an Rx-only item. Manufacturers are given patent exclusivity for 19 years when the newly developed drug is released as an Rx pharmaceutical. When the patent expires, other manufacturers may then make that drug in a generic form, subject to FDA approval. If it later converts from Rx-to-OTC, the original drug maker is generally granted exclusivity for the OTC item for 3 years. Only after that may a store brand be released, again subject to FDA approval.

Understanding Store Brand Users



Who uses store brands? Many people have predictable top-of-mind reactions to the difference between store brands and nationally advertised brands. In the case of store brands, shoppers will generally say they “cost less” and have the “same ingredients.” Advertised brands generally will draw comments about being “effective,” but also that they are “expensive” and have “good packaging and advertising.”

Are Store Brand Users Different?



About 1 in 4 shoppers today are loyal to advertised brands, and a nearly equal number of shoppers prefer to buy a store brand when one is available. But most individuals are undecided about store brand OTC, and switch from store brands to advertised brands based on their knowledge and perception of individual brands, prices, and a wide variety of other factors. These “switchers” are those who are more likely to be influenced by information they receive in the store and at the pharmacy.

Children Change the Game

- Parents are more likely to purchase national brands and be more cautious for their kids
- They purchase store brands for themselves to save money and because it is “good enough” for them



Studies have indicated that parents want to err on the side of caution when purchasing OTC medications for their children, and are more likely to select national brands. This may explain why there is a somewhat lower store brand penetration in cough and cold medications (often purchased for children) than in other OTC categories.

OTC dosing for children can be complicated and can be based on age, weight, or other factors. Appropriate measurement of doses, such as liquids, can be a common source of error. This is a **KEY** area for engaging the pharmacist. However, keep yourself aware of various delivery devices and how to use them so that you can be prepared to assist the pharmacist when needed – such as marking or bringing an oral syringe to the pharmacist.

THE PHARMACY & OTC



Making the connection between the patient and the store

Pharmacists continue to play an increasingly larger role in counseling patients regarding OTC medications. In a retail community pharmacy setting, the pharmacist truly is viewed as the center of the in-store patient-care universe, bringing together not only prescription medications, but also an understanding of OTC medications, healthy foods, and nutrition and lifestyle factors that impact patient self-care.

The path to the pharmacist, though, often comes through a first contact with the pharmacy technician.

Where do patients go after visiting the doctor?

They go shopping!



Where do patients go after seeing the doctor? They go shopping!



More than three-fourths of all patients visit a store within 4 hours of seeing the doctor. While 52% of patients purchase prescription medications, another 52% also buy food, 25% purchase OTC medications, and 17% shop for other health- and beauty-related products.

Particularly when these patients are dealing with a health condition, they may have many questions for their pharmacist.



Patients will often ask the pharmacist or technician about drug interactions, or wish to receive personal counseling on a specific health condition. In one study, 73% wanted information about traditional OTC products and 51% wished to learn more about vitamins and supplements. These interactions with the patient present opportunities to educate consumers on the reliability and cost savings offered by OTC products in general and store brands in particular.

While these questions must be referred to the pharmacist, the technician can also play an important role in being alert for drug interactions and assist patients in locating OTC items. If a store brand alternative is available, the pharmacist can advise if it is appropriate for use.

Consumers Want Help



"...shopping for OTC medications is confusing."	23%
"I ask the pharmacist for help in choosing the right product."	43%
"I expect to find store brands next to the advertised brands."	85%

Many people find shopping for OTC medications confusing and want help from the pharmacist to choose the right product. This is not surprising. But 85% of consumers also expect to see store brand products displayed prominently – right next to the advertised national brands.

Helping the customer locate products is an important role that technicians can perform. Technicians cannot make recommendations though. Only the pharmacist may do so.

Package Attributes



Communicating product benefits is more important to patients than the product description

Store brand package labeling is important – beyond what appears on the drug facts panel. Package attributes also let the consumer know what to expect from a product without the need to read the fine print. For store brands, it is most important to communicate product benefits and comparisons to the national brand. The other items identified here are important for all products.

The “compare to” statements on many products help with identification of the appropriate product.

Gluten-Free Labeling

- Some manufacturers and retailers are beginning to provide gluten-free labeling for foods and medications
- This makes it easier for a person with celiac disease to make appropriate selections



Examples of gluten-free symbols

Many patients with a gluten intolerance or celiac disease want to know if the OTC products they purchase are gluten-free. Although very few medications contain gluten, many manufacturers have begun labeling their products as gluten-free when they follow a set of defined processes to validate them as such.

Technicians can help the patient determine if there is a gluten-free label on the package. If a label is not present, seek assistance from the pharmacist.

Pharmacists Will Play a Bigger Role



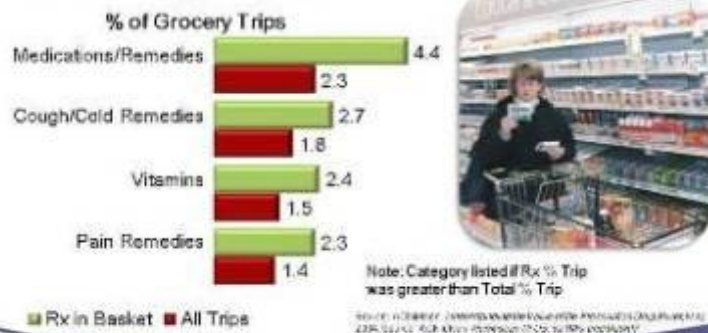
- New Rx-to-OTC items
- PSE Products
- Children's Medications
- Emergency Contraception
- Clinics
- Cost-Effective Access
- Pharmacist Prescribing?

Who can patients turn to?

Many OTC medications require increased pharmacist-patient interaction. These include OTC products that must be obtained from a pharmacist (including pseudoephedrine items, children's medications) and OTC items for which the patient has received a doctor's prescription. These products are referred to as "ORx." The advent of in-store clinics, changes in the availability of emergency contraception, and now Rx-to-OTC items collectively bring even more patients to the store looking for both answers and product solutions.

The Pharmacy Drives OTC

Rx grocery trips are more likely to contain HBC purchases than traditional grocery trips



Pharmacists and pharmacies have a big impact on the purchase of OTC medications. Patients who fill prescriptions are far more likely to purchase OTC products or personal care items than are other shoppers in the same store. In particular, shoppers who purchase a prescription on a *grocery* shopping trip are more likely to purchase OTC items as well.

Again, be aware of potential interactions between prescription and OTC products. Many patients may overestimate the safety of OTC products.

IMPORTANT OTC TOPICS

- Proton Pump Inhibitors
- Intranasal Products
- Acetaminophen
- Emergency Contraception



It is important for the pharmacist and technician to be aware not only of new OTC products, but also new warnings that have been issued on established OTC products.

Let's look at a few of them.

Proton Pump Inhibitors

- 3rd highest-selling class of drugs in the U.S.
- >100 million prescriptions and \$13.9 billion in prescription drug sales in 2010
- With widespread and frequent long-term use of PPIs, some serious adverse effects have been identified that indicate a need for more selective use
- Older adults may be more vulnerable to these adverse effects
- Increasing evidence that PPI therapy may be associated with development of *Clostridium difficile* infections and hip fractures

Pharmacist Combining and Refilling may bring foot of #1. View Full Terms: <http://www.heart.org/healthcare/medication/2010/02/01/20100201a.html> and other may bring foot of #1. Accessed May 9, 2014.

Proton pump inhibitors (PPIs) are the 3rd highest-selling class of drugs in the United States, with more than 100 million prescriptions and \$13.9 billion in prescription drug sales in 2010. With long-term use of PPIs, serious adverse effects have been identified, suggesting a need for more selective prescribing practices. This is particularly important for older adults who may be more vulnerable to adverse effects. There is increasing evidence that PPI therapy may be associated with *Clostridium difficile* infections and hip fractures.

When patients try to purchase an OTC PPI product with a prescription drug, pay particular attention since the combination of these medications may not be appropriate for individuals with these conditions. Check with your pharmacist to be sure.

Intranasal Triamcinolone Acetonide

- Nasacort Allergy 24 HR
- Allergic rhinitis
- Characterized by 2 or more of the following symptoms:
 - Nasal congestion
 - Rhinorrhea
 - Sneezing
 - Itching of the nose, eyes, and throat
- Not for treatment of colds or flu

Nasacort 24HR is the first OTC intranasal corticosteroid available in the U.S. It is approved for treatment of allergic rhinitis. Allergic rhinitis occurs when patients present with 2 or more symptoms, such as nasal congestion, rhinorrhea, sneezing, or itchy nose, eyes, and throat.

It is not for the treatment of colds or flu and should not be used for an extended period of time. If a patient appears to be purchasing the product to treat cold or flu symptoms, involve the pharmacist to counsel the patient.

Acetaminophen: Facts

- Overdoses account for 55,000 to 80,000 emergency room visits each year
- At least 500 people die from overdose each year
- Used by nearly 1 in 4 American adults every week
- Found in more than 600 common OTC and prescription products

http://www.nabpharmacists.com/files/health/healthcare/overdoses_of_bupropion_article_11140915/keaz51290.pdf. Accessed May 9, 2014.

Although acetaminophen has been on the market for decades, overdoses with acetaminophen still account for 55,000 to 80,000 emergency room visits each year. At least 500 patients die each year from acetaminophen overdose. Nearly 1 out of every 4 adults in the U.S. uses acetaminophen weekly, and it is found in more than 600 prescription and OTC products. In some cases it can cause skin reactions or liver damage.

Here is an example of how a technician can intervene: A patient picks up Rx of product with APAP and now is also purchasing OTC APAP (or just has it in his/her cart). An alert tech could say, "This Rx has a lot of acetaminophen in it, and I see you are buying the OTC. We should check with the pharmacist to see if there may be an issue."

Summary

- Self-care is an increasingly important component of overall healthcare for your patients
- OTC products are a vital part of a patient's self-care regimen
- Store brands are a cost-effective choice for many patients
- Pharmacists and pharmacy technicians play a key role in an ever-changing and complex OTC environment
- Just because a product is OTC does not mean it is safe; the pharmacist must be involved to address any potential issues or patient concerns

Let's review what we've discussed today.

Now, the rest is up to you!



Continuing Education for this activity is processed through the ProCE online CE Center. To receive CE credit:

- Go to www.ProCE.com/OTC-technician
- Click on "Post-Test/Evaluation" to enroll and complete the Post-Test and Evaluation

Post-Test

- When patients have a minor injury or ailment, what percentage will first choose an OTC drug or product before going to the doctor?**
 - 50%
 - 40%
 - 81%
 - 75%
- OTC drugs account for _____% of all drugs purchased.**
 - 10
 - 40
 - 55
 - 60
- Individuals over the age of 50 account for what percentage of OTC purchases?**
 - 40%
 - 50%
 - 60%
 - 70%
- Nearly two-thirds of Americans would like at least some of their prescription medications to be available over-the-counter.**
 - True
 - False
- For every dollar spent on OTC medicines, how much is saved by the U.S. healthcare system?**
 - \$2 to \$3
 - \$4 to \$5
 - \$6 to \$7
 - \$8 to \$10
- According to one study, what percentage of consumers believes that store brand quality is equal to or better than the quality of national brands?**
 - 80%
 - 70%
 - 50%
 - 40%
- Plan B One Step emergency contraception can be purchased by a customer of any age.**
 - True
 - False
- Valerie comes to the counter with an allergy-relief product she would like to purchase. She asks the pharmacy technician if the product is gluten-free. What should the pharmacy technician do?**
 - If the label does not say "gluten-free," assume the product contains gluten and advise Valerie not to purchase it.
 - Immediately consult with the pharmacist.
 - Since few medications contain gluten, it is probably gluten-free. Tell Valerie not to be concerned.
 - Check the product label to determine if it is gluten-free. If so, show Valerie the label.
- Todd is a 23-year-old customer, who comes in each month to pick up his inhaler prescriptions for asthma. When he comes into the store today to pick up his inhalers, he is also purchasing OTC Nasacort Allergy 24HR. What do you do?**
 - Explain that Nasacort is not for asthma, and he should not buy it.
 - Alert the pharmacist about the OTC purchase so that the pharmacist can appropriately counsel the patient.
 - Simply ring up the prescription and OTC purchase.
 - None of the above

10. **Mrs. Duran comes to the pharmacy to pick up her prescription for Ambien. She is also purchasing an OTC sleep aid, Tylenol PM, as well as store brand acetaminophen. What are your concerns?**
- A. Since the customer is purchasing both a prescription and OTC sleep aid, you are concerned about a potential drug interaction. You ask the pharmacist to discuss this with the patient.
 - B. Since Mrs. Duran is purchasing Tylenol PM along with another acetaminophen product, there may be a risk for acetaminophen overdose. You ask the pharmacist to discuss this issue with the customer.
 - C. You are concerned about the potential for acetaminophen overdose, and tell Mrs. Duran that she should buy aspirin instead of acetaminophen.
 - D. A and B
11. **A customer asks if it is safe to take her prescription antibiotic with an OTC proton pump inhibitor (PPI). What do you tell her?**
- A. Explain that there is no interaction between the antibiotic and the PPI.
 - B. Tell her you will check with the pharmacist, and have them discuss her concerns.
 - C. Encourage her to take the antibiotic and the PPI 2 hours apart.
 - D. A and C
12. **Mr. Jackson is on a fixed income and wants to purchase a product that is less expensive than Prevacid, but he is concerned about generic product quality. What information can you provide him?**
- A. The FDA holds store brand manufacturers to a higher level of compliance than national brands.
 - B. The FDA holds store brand manufacturers to the same level of compliance as national brands.
 - C. The FDA holds store brand manufacturers to a lower level of compliance than national brands.
 - D. The FDA does not regulate store brand manufacturers.

Complete Post-Test and Evaluation online at
www.ProCE.com/OTC-technician



ProCE, Inc.
848 W. Bartlett Road
Suite 3E
Bartlett, IL 60103
www.ProCE.com