

Review Article

Prescription to over-the-counter switches in the United States

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ABSTRACT

As the role of the pharmacist becomes more patient and counseling-centered, the healthcare market is changing to keep pace with more modern needs, such as self-treatment. Self-treatment provides patients the ability to diagnose their own condition and pick an appropriate medication from the pharmacy to treat their symptoms. This process allows a certain freedom for consumers to actively engage in their own health. In order for patients to self-treat, access to over-the-counter (OTC) medication is of prime importance. Many medications that are available as OTC today were previously labeled as prescription medications. As more safety studies and trials are conducted for different drugs, they can be deemed appropriate for use without a prescription. This review study discusses the process of switching of prescription medications to OTC medications in the United States and the implications of switching on patients, practitioners, drug makers, and insurers.

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INTRODUCTION

Historically, the government of the United States passed the Durham-Humphrey amendments to the Food, Drug, and Cosmetic Act in 1951 which created two classifications of drugs: prescription and nonprescription. The bill mandated that any drugs that can cause a habit or be dangerous to a patient must be dispensed by a healthcare provider through

a prescription and must be labeled appropriately stating that you cannot receive the drug without a prescription.^[1] With time, the government also took a more proactive role in testing the safety and efficacy of dispensed medications. In 1962, the Kefauver-Harris amendment was passed and it required that drug manufacturers prove the safety and efficacy of their medications were not before marketing them to the public. Following this amendment, stricter

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labeling laws for both prescription medication and over-the-counter (OTC) medications were implemented.^[2]

DRUG REQUIREMENTS FOR SWITCH

When drug manufacturers are ready to take their medications from prescription to OTC, there are three big factors they must be taken into consideration: benefit-risk comparison, consumer-friendly labeling, and how to make the drug a good choice as an alternative to prescription medication.^[3]

The benefit-risk comparison focuses primarily on whether patients are capable of reaching the intended medical result in a safe manner. After the Food, Drug, and Cosmetic Act, safety of the medications for consumers had to be proven. Medications always have some risks or possible side effects, but the federal drug administration makes a decision to switch to OTC based on how likely those risks can occur when a patient self medicates. If the drug is highly toxic or addictive, the medication status will remain as “prescription-only.” However, if the drug has labels that consumers can understand and adhere to and if patients are capable of properly diagnosing their condition, then the medication may make the switch to OTC.

Another requirement for switching to an OTC medication is the appropriate verbiage and use of labeling. For a medication to be used for self-treatment by patients, the language must be clear to decrease instances of unsafe dosages and administration. Anticipating and minimizing problems by making the labels consumer-friendly is a responsible action that needs to be taken by a manufacturer before switching to OTC. Labeling must include the active ingredient, uses, warnings, inactive ingredients, indication, directions, and other information (such as how the product should be stored).^[4]

OTC products can legally be marketed differently than prescription products. There are not many legal requirements for OTC products in regards to advertisements through media outlets such as newspapers, TV, or the Internet. For OTC drugs, the information is relayed directly from manufacturers to consumers, for example, in a commercial, whereas with prescription products, there is a requirement that the associated risks be explained by a physician. Once medications are nonprescription they will be monitored by the Federal Trade Commission and will be responsible for representing both benefits and risks of medication.^[5]

Conditions that are commonly treated OTC often include acute diseases such as headaches and common cold that can be easily identified by a patient without medical training. A recent example of such a medication is Flonase that transitioned from prescription only to OTC and is available to consumers without a prescription starting 2015. The availability of Flonase as an OTC product was made after its approval by the US Food and Drug Administration (FDA) as a medication that consumers can use with safety guidelines after self-diagnosing.

If a company plans to switch their medication from prescription to non, they must follow the guidelines set out by the FDA. The drug indications for the new OTC release must be comparable to the indication for the prescription drug while still allowing the patient to accurately and easily self-diagnose. The OTC drug should also be relatively safe in regards to toxicity, drug-drug interactions (DDIs), and side effects as well as a minimized potential for abuse. Many clinical trials are performed to determine whether a drug can meet these criteria. Beyond this, labeling must be a clear indicator for patients in how to properly administer the drug in an appropriate dose [Figure 1].^[6]

IMPACT OF THE SWITCH ON STAKEHOLDERS

Consumers

There are multiple advantages to consumers when products are switched from prescription to OTC. One of the most common advantages is the ease of access to essential medications.

Instead of scheduling a physician appointment to obtain a medication prescription to treat symptoms, a patient can self-treat by identifying their symptoms and proceeding to a pharmacy and thereby procuring the proper medication. Most women feel they would benefit if they could receive their birth control pills from a pharmacist instead of requiring a visit to a physician, with 76% of women who took part in a

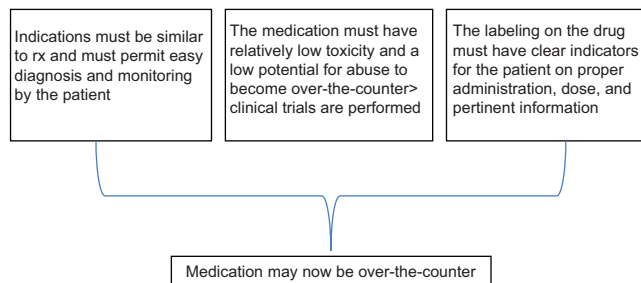


Figure 1: The prescription to over-the-counter switch process

survey said.^[7] By receiving birth control pills from a pharmacy without a prescription at the pharmacy instead of through a clinic, more women continued their medication regimen according to another study.^[8]

Time

Time is also saved when the patient does not have to wait for their prescription to be processed. In totality, OTC medication save the patient time and speed up the process of getting relief compared to patients who have to go through extra two steps of getting the appropriate medication. In addition to saving time, patients can also reduce the cost of their healthcare by avoiding physician fees before coming to the pharmacy.

Cost

The cost of medications can also decrease for patients when medications are switched to nonprescription. While insurance may not cover OTC drugs, the price often has to be competitive to succeed when introduced in the market. This means that the cost of a medication could be cheaper after making the switch from prescription. The pricing will vary for every medication since is dependent upon the medication, though, as some costs from out of pocket could increase for the consumer.

Comfort

An area that health care professionals may not often consider advantageous with OTC medications is the ability to allow the patient their comfort of mind. Pharmacists and physicians maintain a professional air while helping patients seek treatment, yet it is hard to deny that there are patients who would be more comfortable purchasing a medication discreetly. A fairly recent example of this could be the Plan B One-Step medication. When the emergency contraceptive went OTC, it saved women and men the need to discuss their personal lives with more people. One of the top concerns of female college students when purchasing emergency contraception was confidentiality.^[9] While the importance of patient counseling cannot be denied, some decisions and medications do fall subject to scrutiny and having a medication available OTC provides patients the choice to opt out of counseling and handling their treatment at their own discretion.

Healthcare providers

Time is of the essence in health care as professionals must diagnose and treat a multitude of patients. By moving medications from prescription to OTC, the number of patients visiting physicians getting a prescription can reduce. This saves healthcare providers time and allows them to see more patients with disease conditions requiring a more severe treatment.

Beyond physicians, pharmacists can also save time with OTC medications because patients can select medications in aisles in a supermarket instead of bringing in a prescription to fill. With the receipt of less number of prescriptions for conditions that could be self-treated, pharmacists can either get more prescriptions filled in a day or, utilize the additional time to, counsel more patients about the purposes and administration of different medications.

One of the drawbacks of using OTC medications is physician concern for patient well-being. It is hard to monitor and check in on patients who are using OTC medications. Medications can only make the switch from prescription to OTC if they are perceived to be safe for patient use with self-diagnosis. While the step in the process of gaining medication from a physician's prescription is no longer needed for certain medications, there is still a pharmacist available at the retail locations to educate consumers and patients on the advantages and possible side effects of medications.

It is pertinent for pharmacists to maintain a respectable relationship with patients to determine whether or not a patient truly needs a drug. Often advertised benefits may not be as beneficial as education, for example, weight loss effects from different formulations should be replaced or supplemented with exercise and a healthier diet. Pharmacists must be aware of patient lifestyles and whether particular medications will be a value to the consumer.

Drug manufacturers

Drug manufacturers lose their patents on medications after 3 years so often they want to get an OTC approval just as their competitors will when the patent runs out. Currently, there is talk of Cialis making the transition from prescription to OTC with a target date of 2018. If the switch is made, Cialis will become the first nonprescription medication for impotency. 2018 is the targeted period since Eli Lilly, the manufacturing company's patent will expire by the end of that year, thereby allowing cheaper generics to saturate the market and take away much Eli Lilly's profit. If Eli Lilly can get the medication approved for OTC use, Cialis can remain marketable and competitive against the soon to be introduced generics.^[10]

Another advantage of OTC medications, besides staying competitive with their generic counterparts is when their patents run out, a plethora of advertising opportunities open up to them. Companies switching to nonprescription have more leeway in their advertisements and marketing plans. Drug companies can also display more information to guide patients in a more general manner, quite similar to the

information that a physician explains to individual patients about medication intake.

Health insurers

Health insurance companies benefit from OTC switches because their costs are reduced. An example of health insurance is Medicare Part D, which is meant to help cover prescription medications. When medications are switched to OTC, it means a drop in costs for insurance companies because they don't have to cover OTC medications in their plans.

ISSUES OF CONCERN

Some concerns need to be brought to the forefront of the conversation switches to nonprescription. Patients may make an inaccurate self-diagnosis. Certain disease-states are easily recognized with characteristic symptoms, yet there are many that are difficult to identify. There are a variety of medications on the market that are made to treat a variety of symptoms such as headache, stomach pain, and nausea. When a patient experiences only one of the symptoms listed, the best course of treatment is to seek a medication that more directly correlates with the symptom they are experiencing.

Patients could also treat a symptom with OTC medication under the assumption that it is a momentary, minor pain. However, caution must be advised, as these symptoms can be a warning of a more severe condition that needs to be examined by a medical professional. For example, patients may treat a cough OTC, but when a cough has been present for a prolonged length of time, it would be prudent to seek advice from a physician.

Efficacy of medications could be diminished when patients do not adhere to the directions that are explicitly on the product packaging, for example, the early discontinuation of antibiotics. The importance of continuing antibiotic treatment until the entirety of the medication is gone can be explained and brought to the attention of the patient. However, if an antibiotic goes OTC, a patient might realize that his or her symptoms are better and discontinue the antibiotic before he/she has taken the entire dispensed medication, which has consequences for the population as a whole.

Safety in general must be considered in regards to patient welfare. Patients should read labels, follow dosage directions, check for tampering, and keep vials and bottles in a safe location.^[11] While utilizing OTC medications patients must also be aware of active ingredients. It is plausible a patient may take two separate medications under the assumption

that two pills could make them feel better twice as quickly as one. For example, a study showed that patients feel that can choose their own doses for OTC acetaminophen regardless of the recommended doses on the labels and were more likely to take higher doses than recommended.^[12] To keep patients safe in this scenario it is important that packaging is explicit and that education on these matters is readily available to the public. These labels should also emphasize concerns such as pregnancy or DDIs. Many DDIs occur because patients consider OTC medications to be somewhat risk-free and hence drink alcohol in combination with medications such as NSAIDs, which increases health risks.^[13]

There is potential for advertisements to sway patients, as consumers, in regards to what medication will be chosen to treat symptoms. Yet, Kalyanara and Phelan found that advertising directly to the consumer can cause a significant impact, they are not as great as the power price has nor the advertisements directed at physicians.^[14] The results of direct-to-consumer advertising should be evaluated as time goes on to further interpret the impact of the advertisements on patients' choices.

Patient costs could rise for certain medications if insurance will not cover the drug without a prescription. When medications are dispensed by prescription, a physician will identify the needs of the patient and recommend a drug and insurance companies will cover some of the costs to the patient. When drugs become nonprescription, insurance companies don't cover the medication as they do not have the professional opinion given by a physician. For some drugs, this can increase the price for patients because the insurer will not cover the cost any longer.

Talks of Cialis switching from prescription to OTC have opened some discussions on contraindications or drug interactions. Since Cialis is a vasodilator, it is important to consult with a physician in regards to what medications would cause drug interactions. Drug interactions may not be readily apparent by reading the labels on the drug packaging [Table 1].

OUR RECOMMENDATIONS

Based on the research of medications that have switched from prescription only to OTC it seems a logical step to help patients manage their own treatment. Of course, the guidance of a physician and a pharmacist is ideal when it comes to administration of medications, there is no reason patients couldn't utilize their knowledge to self-treat for certain medical conditions. There are proper processes in

Table 1: Examples of drugs previously available in the United States only by prescription and now are available over-the-counter

Histamine H1-receptor antagonists
Diphenhydramine
Histamine H2-receptor antagonists
Cimetidine
Ranitidine
Famotidine
Nonsteroidal anti-inflammatory drugs
Ibuprofen
Naproxen
Ketoprofen
Smoking-cessating aids
Nicotine (gum and patches)
Hair growth stimulants
Minoxidil (2% and 5%)
Anti-fungal drugs
Clotrimazole
Ketoconazole
Anti-diarrheal drugs
Loperamide
Miralax (polyethylene glycol 3350)
Decongestants
Pseudoephedrine
Antihistamines
Allegra (fexofenadine)
Zyrtec D (cetirizine)
Allergy medications
Fluticasone propionate
Nasacort allergy 24 h (triamcinolone)
Contraceptives
Plan B (levonorgestrel)

place to test whether medications should be switched from prescription to OTC.

There are many advantages that encourage the growth of the OTC market such as increased time for the patient, convenience, peace of mind, a competitive market, and more time for physicians and pharmacists. While there are risks associated with medications becoming nonprescription, the benefit-to-risk ratio seems to lean in favor of following the guidelines set by the FDA.

Allowing patients to have access to more information on the medications is also vital to the success of OTC drugs. Making sure that there is proper labeling (with appropriate font size) that is clear and straightforward is important for proper medication adherence. Patients still need to have pharmacists available to consult if they need guidance on the proper way to use a medication and for what conditions. Keeping the standards high is the best way to ensure that OTC medications will be safe and effective for patients.

AUTHORS' CONTRIBUTION

JC: Design and concept of the manuscript. AL: Writing of the manuscript. IP: Design, and concept and revising the manuscript. DB: Revising and reviewing the manuscript. XT: Revising and reviewing the manuscript. RB: Revising and reviewing the manuscript.

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Conflicts of interest

There are no conflicts of interest.

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