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# The Value of OTC Medicine to the United States

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# Executive Summary

For millions of Americans, over-the-counter (OTC) medicines are accessible, relied upon, and effective. This white paper presents the findings and conclusions of an independent study to estimate the Value of OTC Medicine to the United States.

There are two classes of pharmaceutical products available in the United States: branded and generic prescription drugs and nonprescription (or over-the-counter) medicines. The former requires a prescription (Rx) from a physician and is dispensed by retail or mail order pharmacies. The latter, OTC medicines, are available without a prescription in many retail outlets such as grocery stores, drugstores, mass merchandisers (e.g., Wal-Mart or Target), and convenience stores. The U.S. Food and Drug Administration regulates the manufacture of all pharmaceutical products, both prescription and OTC.

According to Euromonitor International, U.S. consumers spent \$23 billion on OTC medicines in 2010<sup>i</sup>. In doing so, consumers benefitted from the ability to self-treat many commonly occurring conditions including the common cold, headaches, body pain, allergies, heartburn, lower gastrointestinal (GI) tract issues, dermatitis, and fungal infections. OTC medicines allow the healthcare system to focus its limited resources on the diagnosis and treatment of more serious diseases that require physician involvement, while providing consumers the opportunity to care for themselves and their loved ones with safe, effective, and readily accessible treatment options for mild-to-moderate conditions.

Previous studies have focused on the broad benefits that OTC medicines provide to society<sup>ii</sup> or only on selected categories or ingredients, such as heartburn medications or nicotine replacement therapy<sup>iii</sup>. This study sought to examine the value of OTC medicines relative to potential alternatives, e.g., consultations with healthcare professionals for self-recognizable symptoms and/or prescription drugs.

## Summary of Findings

- The availability of OTC medicines provides \$102 billion in value to the U.S. healthcare system annually.
- ~50% (\$52.7 billion) of total OTC value is captured by employer-based insurance, ~25% (\$27.5 billion) by government programs (Medicare and Medicaid), and the remaining ~25% (\$21.7 billion) by the self-insured and uninsured populations.
- Each dollar spent on OTC medicines saves \$6-7 for the U.S. healthcare system.
- 240 million people in the U.S. currently use OTC medicines—60 million of them would not seek alternative (e.g., Rx) treatment if OTC medicines were not available.
- If OTC medicines did not exist, an additional 56,000 medical practitioners would need to work full-time to accommodate the increase in office visits by consumers seeking prescriptions for self-treatable conditions.
- If OTC medicines were not available, additional Emergency Department visits, primarily by patients on Medicaid and uninsured individuals, will drive up nearly \$4 billion in healthcare system costs each year.

*\* Based on 7 categories under consideration*

## Executive Summary continued

To estimate the value of OTC medicine, the study assumed a hypothetical world in which it did not exist and all consumers have to either use alternatives or leave the conditions untreated. This analysis was performed for seven categories of the most common acute and chronic, self-treatable conditions representing the majority of OTC medicine purchases: Allergy, Analgesics, Anti-fungals (both foot and vaginal), Cough/Cold/Flu, Lower and Upper Gastrointestinal (GI), and Medicated Skin (first aid and anti-itch). We selected these seven categories because they all provide symptomatic treatment and comprise the largest OTC categories, other than oral care. Likely consumer behavior in this hypothetical world was estimated through a 3,200+ person consumer survey. In addition, we analyzed five Rx-to-OTC switches, which represent real-world examples of making prescription-only medicines available directly to consumers and thus significantly expanding their use.

Overall, the availability of OTC medicine in the seven categories analyzed creates significant value for the U.S. healthcare system—\$102 billion in annual savings relative to alternatives and an important increase in access to medicine. On average every dollar spent by consumers on OTC medicines saves \$6-7 for the U.S. healthcare system as a whole.

On average **every dollar spent** by consumers on OTC medicines **saves \$6-7** for the U.S. healthcare system as a whole.

In addition to cost savings relative to alternatives, OTC medicines provide value through significantly expanded access to treatment for the most frequent and common illnesses. The availability of OTC medicines, off-the-shelf, without a prescription, provides symptomatic relief for an estimated 240 million people, 60 million of whom would not seek treatment if OTC medicines were not available. The annual retail sales of OTC medicines currently consumed by those 60 million people are approximately equal to \$4 billion in our target therapeutic categories.

OTC medicines provide value through **significantly expanded access to treatment** for the most frequent and common illnesses.

OTC medicines also contribute to increased economic productivity due to less time out of work for physician visits or to care for a sick child due to the symptoms studied.

# Study Methodology

## Methodology Overview

We assumed that the value of OTC medicine is equal to the cost difference between the current situation (when OTC medicines are readily available) and the next best alternative if OTC medicines were no longer available. To determine this value, our study assumed a hypothetical world in which OTC medicines no longer exist for seven of the most common categories of acute and chronic, self-treatable conditions. We selected these seven categories because they all provide symptomatic treatment and comprise the largest OTC categories, other than oral care. This allowed us to use the same methodology across all seven categories.

In a non-OTC world, consumers suffering from conditions they had previously self-treated with OTCs would have the option to seek an Rx treatment, seek an alternative treatment (such as acupuncture, home remedies, or environmental modification), or leave their conditions untreated. Consumers seeking treatment would have multiple options for engaging with the medical system, options ranging from making an appointment with a primary care physician (PCP) or specialist, visiting a walk-in clinic (e.g., urgent care or retail clinic), or visiting an Emergency Department (ED). These options would trigger significant costs throughout the formal U.S. healthcare system.

For those patients visiting or speaking with a medical professional, the healthcare provider could prescribe an Rx medication or diagnostic test to the patient, refer the patient to a specialist, or recommend behavior or environmental changes (e.g., diet and exercise changes).

A robust model was built based on these options. The total value of OTC medicine today was assumed to include the total direct savings from avoided clinical visits and Rx medication costs. These savings are based on the total costs incurred by the payor under each scenario, regardless of what share of the costs are ultimately borne by the employer/insurer or the patient.

The model also quantified additional value from OTC medicine due to the increased access to treatment it provides and due to the increased productivity it allows (e.g., reducing the number of sick days and time out of work to see a physician). This additional value is incremental to the \$102 billion in annual savings described in this paper.

A key component of our study was a survey of 3,200+ consumers. The survey was conducted to estimate the total number of OTC users and to understand their likely behavior in the situation when OTC medicines are not available. The survey was conducted through an independent research firm maintaining an online panel built on a representative, random sample of U.S. households (including households who do not have home Internet access).

According to the survey results, 79% of consumers had taken an OTC medicine in the last 12 months in one or more of the seven categories studied. Taking 79% of the U.S. population (~308 million in 2010<sup>iv</sup>), we estimated that 240 million people use OTC medicines in the seven categories, categories that represent the significant majority of OTC medicines purchased in the U.S. annually.

The survey results suggested that approximately 92% of today's OTC consumers would seek treatment if OTCs were not available in the seven categories studied. However, consumers are typically overly optimistic in surveys about their future behavior. In this case, we would expect survey responses to overestimate the extent to which consumers would choose to visit healthcare providers to seek an Rx treatment. Therefore we adjusted the consumer survey responses with historical data on consumer behavior during previous Rx-to-OTC switches, the reverse process of the model where an RX medication becomes available over-the-counter. Based on these two sources we estimated that approximately 75% of OTC users (or 180 million) would seek treatment if OTC medicine were not available.

**180 million people** would seek treatment if OTCs were not available, triggering significant price increases for the U.S. healthcare system.

This analysis also implies that more than 60 million people (240 million OTC users less 180 million seeking treatment) would be left without treatment if OTCs did not exist. The retail sales of OTC medicines to these 60 million people are equal to \$4 billion. This revenue represents a direct value of increased access provided by OTC medicines.

Absent OTC options, the 180 million people who do choose to seek treatment will trigger significant cost increases for the U.S. healthcare system, in particular, additional medical practitioner visits. Many of these visits would result in a prescription for a branded or generic Rx medication. To estimate the added medication costs to the U.S. healthcare system, we took the price differential between Rx medications and comparable OTC products available today for each of the seven categories. Rx pricing was determined based on a weighted average of generic and branded Rx sales; OTC pricing was also calculated as a weighted price per category based on point-of-sales data. Both Rx and OTC pricing were made comparable by equating prices for standard daily dosages, after which the price differential between Rx and OTC price per category was calculated.

The incremental cost of Rx medications to treat these 180 million consumers would be \$25 billion. In addition, consumers, private payors, and the government will spend \$77 billion to cover medical visit and diagnostic costs.

## Data Sources

Likely consumer choices and behavior were estimated through both a 3,200+ consumer survey conducted by Knowledge Networks and actual consumer behavior during Rx-to-OTC switches in five of the seven categories. Overall industry sales and volume data as well as frequency of purchase data for OTC medicines were sourced from SymphonyIRI, a leading aggregator of consumer health products industry sales data. List prices for Rx products were obtained from the 2010 version of the Red Book: Pharmacy's Fundamental Reference<sup>vi</sup>. Ratios of generic-to-branded Rx sales were estimated based on the 2011-2012 Healthcare Distribution Management Association *Factbook* and Booz & Company analysis. Broader literature searches contributed the remaining information.

# Study Findings

## Overall Value

The availability of OTC medicine provides significant value to the U.S. healthcare system—\$102 billion in annual savings relative to alternatives and an important increase in access to medicine. This means that, on average, every dollar spent on OTC medicines results in \$6-7 in value for the U.S. healthcare system.

## Cost Savings

Avoided cost attributed to the availability of OTC medicine falls into two primary categories:

1. Drug Cost Savings
2. Clinical Visit Cost Savings as healthcare provider visits would be required to secure prescriptions for Rx treatments

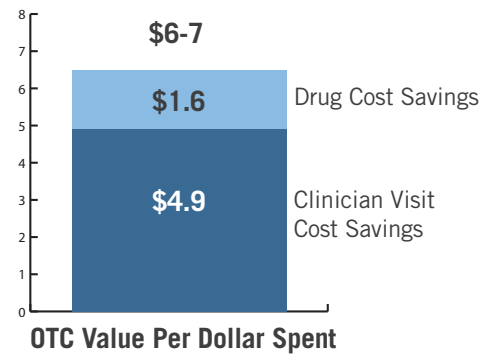
Drug cost savings amount to \$25 billion, which represents 25% of the total \$102 billion in annual savings to the U.S. healthcare system. These savings are the result of utilizing lower-priced OTC medicines, rather than higher-priced branded or generic Rx medicines to treat these currently self-managed conditions.

The majority of clinical cost savings result from avoided clinical visits<sup>vii</sup> which are estimated at \$66 billion or 65% of total savings. These savings are driven by the fact that consumers can obtain OTC medicines off the shelf from their local retailers. In contrast, Rx medicines require consumers to visit a healthcare provider to obtain a prescription before they can go to the pharmacy to purchase the product.

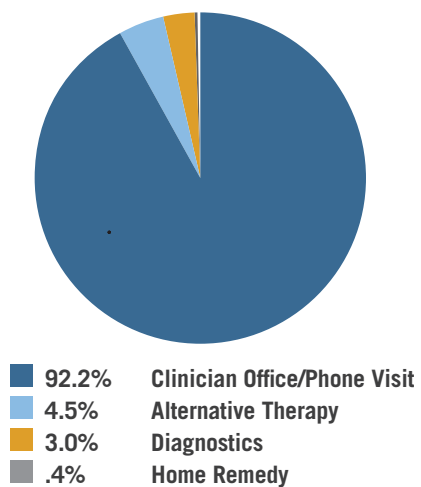
## Expanded Access

When products switch from Rx to OTC status, a much larger number of users typically purchase the product than when it was available by Rx only. This expanded access to medicine, because it is available off-the-shelf, without a prescription, is a material benefit of OTC medicines. In a reverse process if OTC medicines for the target categories were no longer available, there would be a segment of the population that would no longer be able to treat their illnesses. Based on the survey results and Rx-to-OTC switch data, that segment of the population is estimated at ~60 million individuals. The annual retail sales of OTC medicine to that population are \$4 billion.

**Exhibit 1:  
Value Attributed to OTCs**



**Exhibit 2:  
Clinical Savings: Breakdown of  
Alternative Treatment Avoided**



## Productivity

In addition to the \$102 billion in savings and incremental access to treatment described above, OTC medicines provide the U.S. healthcare system several additional sources of value.

Over-the-counter medicines keep America's workforce healthy, offering **\$23 billion** in potential productivity benefits.

Physicians typically see patients during normal working hours and many individuals must miss work for physician visits. We assumed that each visit to a doctor to obtain a prescription results in, on average, two hours of lost work, which includes wait time, clinician interaction time in the physician's office, and travel time to and from the appointment. Based on conservative estimates, the total lost productivity from these incremental physician visits in the hypothetical, non-OTC world could be as high as \$23 billion each year.

## Contribution by Category

Three categories, Cough/Cold/Flu, Upper GI and Allergy, are responsible for 59% of the total OTC savings.

**Exhibit 3:**  
**OTC Savings by Product Category**

Category	% of OTC Savings
Allergy	14%
Analgesics	13%
Anti-fungals	12%
Cough/Cold/Flu	28%
Lower Gastrointestinal	9%
Medicated Skin	6%
Upper Gastrointestinal	16%
<b>Total (All OTC Savings)</b>	<b>100%</b>

The magnitude of savings in the Cough/Cold/Flu category is driven by the large number of individuals with these conditions and by the fact that people tend to have multiple colds per year. The frequency of these conditions would drive a significant number of incremental doctor visits.

Upper GI is the category with the second largest amount of savings. While this category also drives incremental physician visits, a significant source of savings in this case is the price difference between Rx and OTC medicines, driven primarily by more expensive calcium carbonate-based products.

*Note: Sums to 100% before rounding*

The allergy category is the third largest source of savings. There is a large number of individuals with chronic allergies who would visit a physician to obtain an Rx if OTC medicines were not available. In addition, the Rx alternatives in this category are relatively more expensive than OTCs.

With the exception of the anti-fungal category, the savings in other OTC categories are driven primarily by the incremental healthcare professional visits. In the case of anti-fungal, the major driver of savings is the relative price difference between Rx and OTC medicines.



## Impact on Population Sub-Segments

When the value of OTC medicine is broken down by consumer segments with different insurance coverage, approximately 50% of savings accrue through those with employer-based insurance, ~25% through government program enrollees (Medicare and Medicaid), and the remaining ~25% through the self-insured and uninsured. The proportion of OTC savings generated by different consumer segments is mostly proportional to their size. However, the uninsured *population* generates a higher amount of savings than other insurance sub-segments, due to the higher dependence of the uninsured on OTCs as a primary treatment option.

Over-the-counter medicines save the healthcare system **\$28 million** in unnecessary Medicaid and uninsured patient costs.

## Constrained Medical Delivery System

Our study estimated that an additional ~450 million incremental visits in both ambulatory and emergency care facilities would be required annually if OTCs did not exist for the seven categories of symptoms under consideration. This represents a significant incremental increase to the more than 1.2 billion ambulatory care visits currently occurring annually<sup>viii</sup> in the U.S. If we make a conservative assumption that each medical visit is 15 minutes in duration and that there are 2,000 working hours for a healthcare provider in a calendar year, these ~450 million incremental visits are the equivalent of over 56,000 medical practitioners working full-time on clinical care per year. Given the current physician shortages in the U.S., shortages that are especially pronounced for primary care physicians, this benefit only reinforces the value that the availability of OTC medicines provides to an already constrained healthcare delivery system.

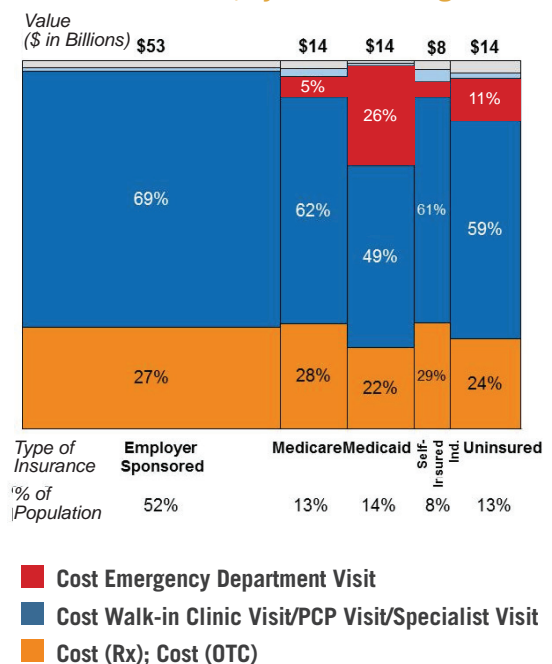
In addition, 26% of Medicaid and 11% of uninsured individuals surveyed in this study were likely to seek treatment at Emergency Departments (ED) as a first recourse for the seven categories studied versus 0-5% for the commercially insured, self-insured, and Medicare populations. Given constraints facing EDs, including long wait times and limited capacity, and the high cost of care for treatment delivered in an ED (to both the consumer and healthcare system), any reasonable measures taken to provide treatment for non-urgent conditions outside of the ED will benefit both the consumer and society overall.

## Study Limitations

As noted earlier, the analysis described in this study is based on seven specific categories of symptoms and OTC medicines: Allergy, Analgesics, Anti-fungals (both foot and vaginal), Cough/Cold/Flu, Lower and Upper GI, and Medicated Skin (first aid and anti-itch). Due to important differences in consumer behavior, medication costs, and other costs across categories of symptoms, it cannot and should not be assumed that a similar proportion of value can be attributed to other categories which can currently be treated or prevented with OTC medicine.

**Exhibit 4:**

### Value Attribution, by Insurance Segment



## Sources

- i “Consumer Health – US,” Euromonitor International: country Market Insight, February 2011.
- ii White paper on the benefits of OTC medicines in the United States: Report of the Consumer Healthcare Products Association’s Clinical/Medical Committee, *Pharmacy Today*, October 2010, pp. 68-79.
- iii See Mansfield and Callahan, “Benefits of over-the-counter heartburn medication to consumers and the healthcare system,” Nielsen Company research paper sponsored by CHPA, December 2008; Gurwitz, et al., “The Effect of an Rx-to-OTC Switch on Medication Prescribing Patterns and Utilization of Physician Services: The Case of Vaginal Antifungal Products,” 30 *Health Services Research* 672 (December 1995); or Keeler, et al., “The Benefits of Switching Smoking Cessation Drugs to Over-the-Counter Status,” 11 *Health Economics* 389 (2002).
- iv U.S. Census Bureau, 2010.
- v Rx prices were estimated based on average discounts off average wholesale price (AWP), as reported in Red Book: Pharmacy’s Fundamental Reference, for typical commercial insurance plans.
- vi Red Book: Pharmacy’s Fundamental Reference, 2010 Edition.
- vii Clinical Visits include in-person and phone-based PCP and specialist consultations, walk-in and ED visits.
- viii U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; National Health Statistics (2007).

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