

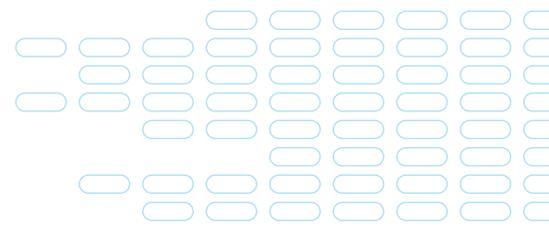
MARCH
2019

VALUE OF OTC MEDICINES

to the U.S. Healthcare System



Executive Summary



Millions of Americans rely on over-the-counter (OTC) medicines as an accessible and effective solution for commonly occurring conditions. This white paper presents the findings and conclusions of an independent study to estimate and document the value created by OTC medicines to the United States.

In the U.S., two categories of pharmaceutical products are available: branded or generic prescription drugs, and nonprescription (OTC) medicines. While the first requires a prescription (Rx) from a physician and is distributed by pharmacies, the second is available without a prescription and is sold in a wide variety of retail outlets, including grocery stores, drug stores, and mass merchandisers. Both categories of pharmaceutical products are regulated by the U.S. Food and Drug Administration (FDA).

On average, U.S. households spend about \$442 annually on OTC products¹. As such, consumers have benefited from self-treating conditions such as the common cold, allergies, body pain, upper and lower gastrointestinal (GI) tract issues, fungal infections, skin inflammation, smoking cessation, and difficulty falling asleep. OTC medicines enable the healthcare system to utilize its limited resources on the diagnosis and treatment of more serious diseases and medical conditions that necessitate the direct involvement of a physician, while at the same time providing safe, effective, and accessible treatment for a range of conditions to consumers and their families.

SUMMARY OF FINDINGS

\$146
billion

The **availability** of OTC medicines provides **\$146 billion** in value to the U.S. healthcare system annually.

\$7
saved

Each dollar spent on OTC medicines **saves more than \$7** for the U.S. healthcare system.

27
million

OTC medicines provide additional value through expanded **access** to over **27 million consumers** (and \$5 billion in potential savings) and productivity savings (\$34 billion).

\$8
billion

OTC medical devices for the purposes of treatment and testing **generate** additional value of **~\$8 billion** to U.S. healthcare system.

Based on 9 categories analyzed.

Previous studies have examined the benefits that a single OTC category² or a limited range of OTC categories³ provide. This study determined the value of OTC medicines across a larger set of categories relative to alternatives, such as prescription drugs and clinical visits.

In order to determine the value of OTC medicines, the study estimated cost savings by payer status (i.e. commercial plans, Medicare, Medicaid, cash) and by OTC category.

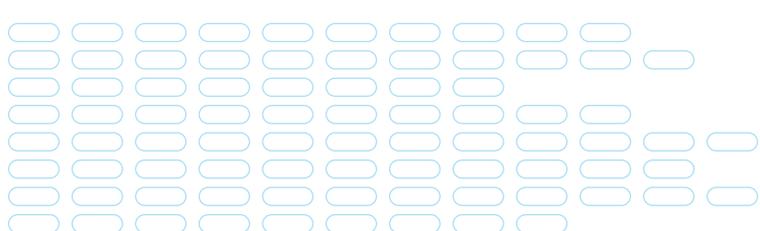
The analysis was performed for the following nine distinct OTC categories that represent the majority of OTC medicine purchased in the U.S.:

1. Allergies
2. Analgesics
3. Antifungal
4. Cough/Cold/Flu
5. Lower Gastrointestinal (GI)
6. Medicated Skin
(including first aid and anti-itch)
7. Sleep Aids
8. Smoking Cessation
9. Upper Gastrointestinal (GI)

Ultimately, the availability of OTC medicine to treat the nine categories evaluated creates substantial value for the U.S. healthcare system, totaling approximately \$146 billion in savings per year from drug cost savings and clinical visit cost savings when compared to alternatives. Most of these savings are generated by OTC medicine value as a less expensive option compared to prescription medicines and an alternative to seeing a physician for mild conditions, creating \$52 billion and \$95 billion in savings respectively. OTC medicine increases treatment access to over 27 million consumers and reduces losses in productivity, creating additional savings of approximately \$5 billion and \$34 billion respectively. On average, each dollar spent on OTC medicines saves the American healthcare system approximately \$7.20.

Medical devices (i.e. muscle simulators, pregnancy tests, etc.) were also evaluated as part of the scope of the analysis. Medical devices (both for treatment and testing purposes) available over the counter create an additional \$8 billion in potential savings by reducing the need to see a physician. Research estimated that 46 million consumers would seek clinical office visits if OTC medical devices for treatment of mild conditions were not available. An additional 28 million consumers would seek clinical office visits if OTC medical devices for testing were not available.

In addition to the cost savings as compared to alternatives, OTC medicines provide value to the American healthcare system through expanded access to treatment. Approximately 90 percent of consumers who treat a condition with OTC medicine would seek professional medical treatment if OTC medicines were not available in the marketplace, thereby creating a tremendous burden on the U.S. healthcare system.



Study Methodology



METHODOLOGY OVERVIEW

For this study, we utilized the “Theoretical OTC-to-Rx Switch” methodology utilized by the 2011 Booz study³, which assumed that the value of OTC medicine is equivalent to the difference in cost between a scenario in which OTC medicines are readily available and one in which they are not, prompting consumers to seek Rx treatment or alternative treatments, or not seek treatment at all. Consumers seeking treatment would have a range of alternatives for treating conditions, including visiting a primary care physician (PCP) or a specialist, or visiting a walk-in clinic or Emergency Department. Each of these alternatives would incur substantial costs throughout the U.S. healthcare system.

This methodology was applied across nine distinct categories of OTC medicines. The total value of OTC medicines was assumed to comprise the total direct savings generated from fewer clinical visits and reduced prices of OTC medicines relative to Rx medications. These savings are determined by total costs incurred by the payer, irrespective of what proportion of the costs are shared by the employer/insurer or the patient in the end.

The increased access to treatment and increased productivity (in, for example, the reduced number of sick days and time away from work for clinical visits) was also included in the model.

One crucial aspect of our study was a survey of 5,000+ consumers to ensure it was sufficiently powered to be representative in each of the nine categories. The survey was conducted to estimate the total number of OTC medicine consumers and to simulate their behavior in the event that OTC medicines are not readily available. The survey was conducted through an independent research firm that maintains a longitudinal household panel comprised of purchases from all outlets and retailers that are balanced to represent the demographics of the most recent United States Census.

DATA SOURCES

The survey was conducted by Information Resources, Inc. (IRI) which utilized National Consumer Panel to survey 5,000+ consumers. Prescription drug costs were sourced from Symphony Health. IRI was also commissioned to lead the overall study and develop savings estimates.

Study Findings

OVERALL VALUE

The availability of OTC medicine creates substantial value for the U.S. healthcare system, totaling approximately \$146 billion in savings per year when compared to alternatives. OTC medicines also significantly increase access to treatment. On average, each dollar spent on OTC medicines saves the U.S. healthcare system approximately \$7.20.

COST SAVINGS TO THE U.S. HEALTHCARE SYSTEM

Cost savings due to the availability of OTC medicine comprised two major categories:

1. Drug Cost Savings (price differential between OTC medicines versus Rx alternatives)
2. Cost Savings due to avoidance of clinical visits (since Rx treatments require prescriptions that must be obtained through clinical visits)

Drug cost savings total \$52 billion, representing 35 percent of the total \$146 billion in savings for the U.S. healthcare system annually. These savings are generated by the lower prices of OTC medicines as compared to more expensive branded or generic Rx medicine alternatives to treat self-managed conditions.

The majority of cost savings are produced by avoided clinical visits, which represent approximately \$95 billion, or 65 percent of total annual savings. These savings are the result of the fact that OTC medicines are readily available off the shelf at local retailers, enabling consumers to purchase them easily. On the other hand, Rx medicines require visits to healthcare providers to secure a prescription, which can then be used to obtain the medicine at a pharmacy.

In addition to providing value through cost savings outlined above, OTC medications also help reduce the overall burden on the U.S. healthcare system. This study estimates that nearly 90 percent of consumers who treat a condition with an OTC medicine would seek professional medical treatment if OTC medicines were not available in the marketplace. It is inconceivable that the U.S. healthcare system would be able to absorb additional office visits from hundreds of millions of consumers to get treatment or obtain prescriptions for mild conditions that they can self-treat.

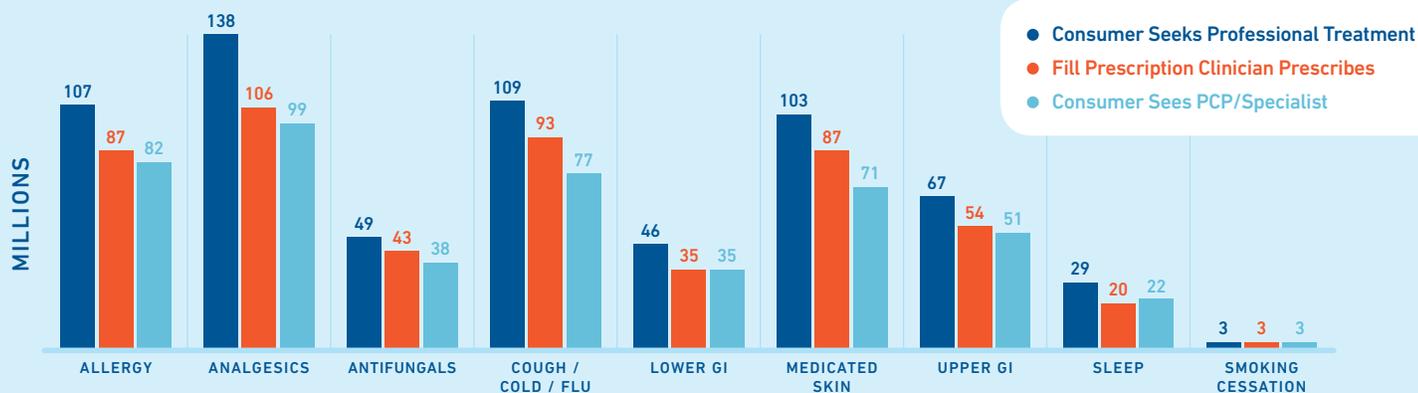
EXHIBIT 1

TOTAL SAVINGS OF OTC TO U.S. HEALTH SYSTEM⁴



EXHIBIT 2

SIZE OF POPULATION SEEKING MEDICAL TREATMENT IF OTC IS NOT AVAILABLE IN THE MARKETPLACE



INCREASED ACCESS TO MEDICINE

When formerly prescription-only medicines are made available as OTC products, a substantially higher number of consumers typically purchase the product compared to when it was only available through prescription. OTC medicines greatly expand access to medicine because they are readily available without a prescription at local outlets and retailers.

OTC products are now many consumers' first line of defense in treating everyday conditions, such as allergies and heartburn. Rx-to-OTC products (commonly referred to as "Rx-to-OTC switches") are an important growth driver for the OTC category. Since 2001, there have been more than 25 different products switched over from Rx to OTC in categories ranging from chronic conditions, such as allergy and heartburn, to contraceptive and weight loss. Consumers trust these products, and in certain conditions, such as allergy and heartburn, more than 50 percent of U.S. households treat their conditions using OTC products only⁵.

If medicines currently offered OTC were only available as prescription, a significant portion of consumers would no longer seek those products.

Based on the survey results, this particular portion of the population is approximately 27 million consumers. The sales annually of OTC medicine to this segment of the population total approximately \$4.8 billion.

EXHIBIT 3

% OF SUFFERERS WHO USED "OTC PRODUCTS ONLY" TO TREAT THEIR CONDITION⁴

OTC Category	% Sufferers
Allergy	62%
Analgesics	58%
Antifungals	55%
Cough/Cold/Flu	68%
Lower Gastrointestinal	36%
Medicated Skin	61%
Upper Gastrointestinal	55%

EXHIBIT 4**NUMBER OF CONSUMERS ACROSS CATEGORIES THAT WOULD NOT SEEK TREATMENT⁴**

OTC Category	# of Consumers	\$ Spend/Person/Year	Total Value (In Billion)
Allergy	13,327,398	\$72.7	\$1.0
Analgesics	17,415,849	\$38.0	\$0.7
Antifungals	4,550,132	\$245.6	\$1.1
Cough/Cold/Flu	9,602,730	\$50.9	\$0.5
Lower Gastrointestinal	9,730,052	\$56.1	\$0.5
Medicated Skin	12,265,966	\$18.8	\$0.2
Sleep	6,000,929	\$49.5	\$0.3
Smoking Cessation	1,837,056	\$55.3	\$0.1
Upper Gastrointestinal	7,536,364	\$55.5	\$0.4
Total			\$4.8

PRODUCTIVITY

In addition to the \$146 billion in savings and the increased access to medicine, OTC medicines also provide value in the form of greater productivity.

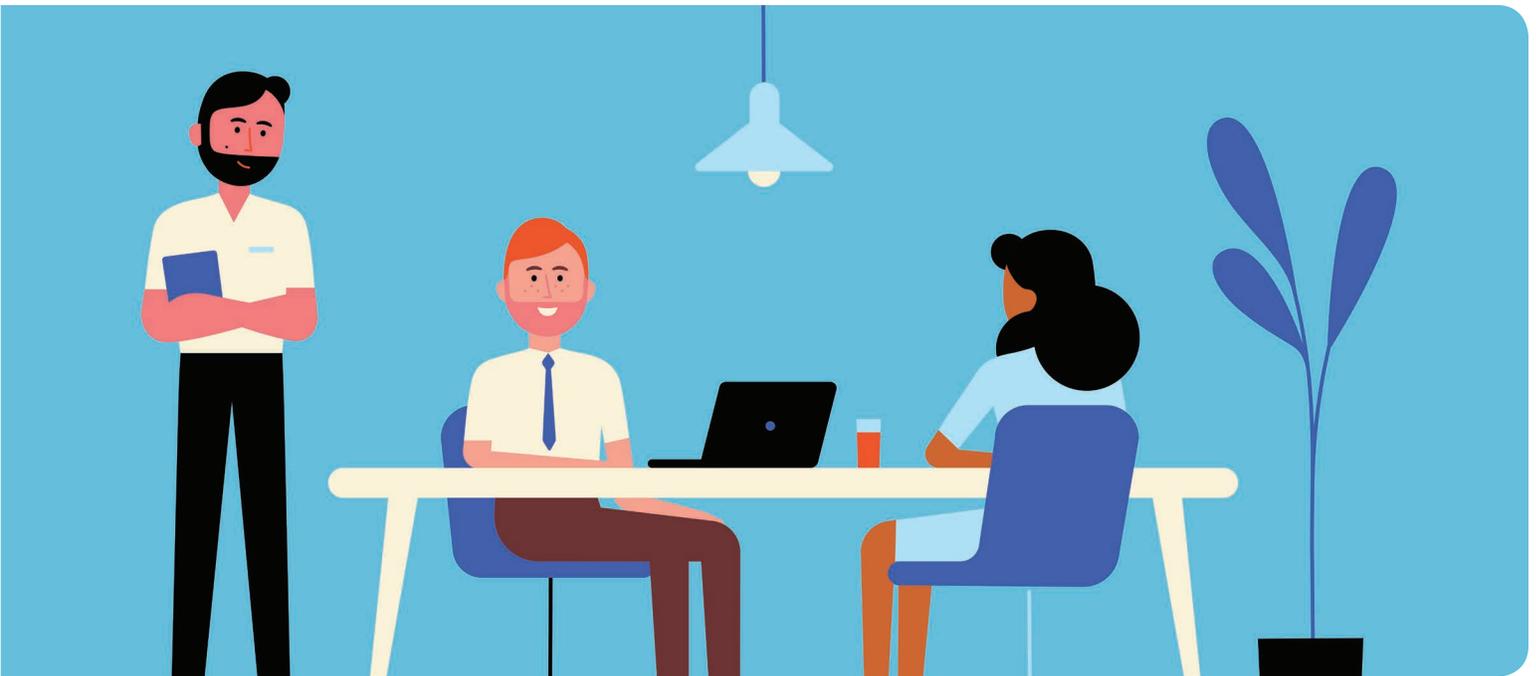
In a scenario where OTC medicines are not available in the marketplace, a patient would have to visit a physician to get treatment or diagnosed during normal working hours, causing them to miss work. With an estimated two hours of lost work on average to get treatment or obtain a prescription through a visit to a physician (including travel time, wait time, and the clinician interaction in the physician's office), a scenario in which OTC medicines were no longer available would incur significant costs.

Based on the number of visits to physician offices and average GDP per day, it is estimated that OTC medicines produce an additional savings of approximately \$34 billion in potential productivity benefits annually.

CONTRIBUTION BY CATEGORY

This study analyzed nine OTC categories. Cost savings were estimated for each of the nine categories individually and then aggregated to produce an overall value of \$146 billion to the U.S. healthcare system.

Three categories, Medicated Skin, Lower GI, and Upper GI, comprised 61 percent of the total OTC savings. The cost savings in these categories are driven primarily by the price difference between OTC products and their Rx counterparts. In other OTC categories analyzed in this study, the primary source of the savings were due to clinical visits to seek treatment.



Savings in categories such as Cough/Cold/Flu are generated 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 contribute to a substantial number of incremental physician visits.

In the allergy category, in addition to the added cost of Rx medicines, the savings are driven by the fact that there is a large number of individuals with chronic allergies who would have to seek a visit to obtain a prescription if OTC medicines were not available.

VALUE BY INSURANCE SEGMENT

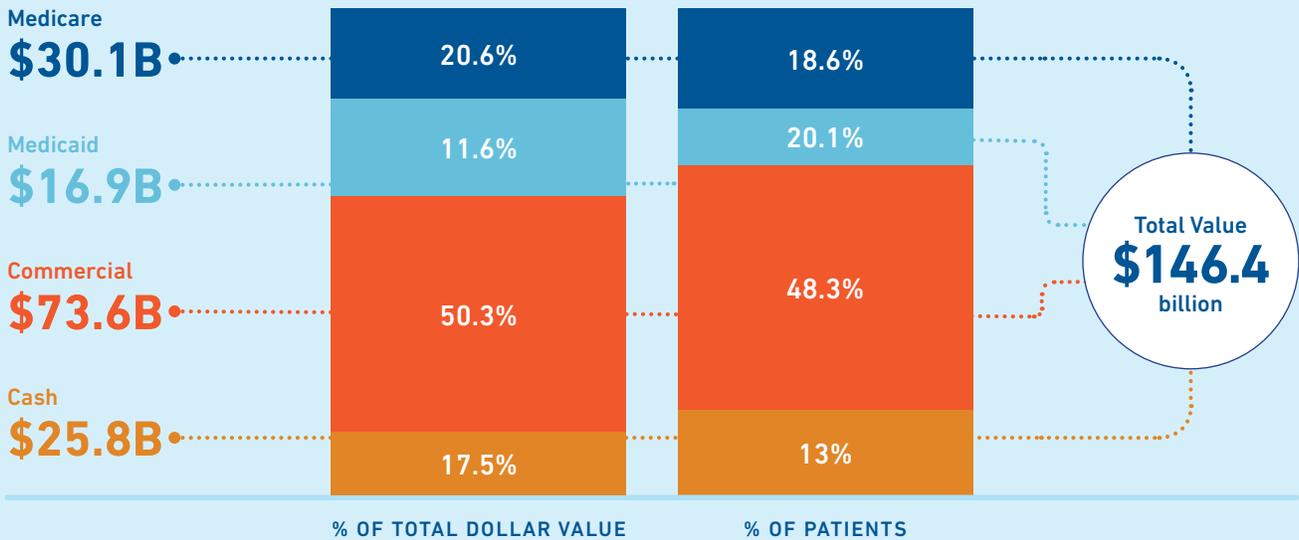
Across the four categories of insurance segments within the healthcare system (cash, commercial, Medicaid, and Medicare) nearly half of the \$146 billion in value was generated within the commercial market. Approximately \$73.6 billion, or 50.3 percent of total savings, were captured by commercial plans. Commercial plans include a plurality of consumers, with a 48 percent share of consumers, while cash, Medicaid, and Medicare plans comprise 13 percent, 20 percent, and 19 percent of the market respectively.

EXHIBIT 5 OTC SAVINGS BY PRODUCT CATEGORY⁴

OTC Category	% of OTC Savings
Allergy	12.9%
Analgesics	18.6%
Antifungals	5.5%
Cough/Cold/Flu	13.7%
Lower Gastrointestinal	11.8%
Medicated Skin	17.5%
Sleep	6.9%
Smoking Cessation	1.1%
Upper Gastrointestinal	12.0%
Total (All OTC Savings)	100%

EXHIBIT 6

HEALTHCARE SYSTEM VALUE BY INSURANCE SEGMENT⁴

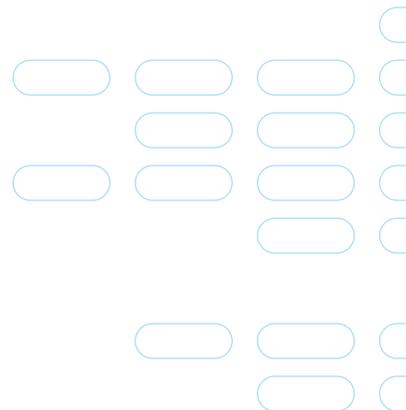


SAVINGS FROM MEDICAL DEVICES

In addition to the \$146 billion in savings provided by OTC medicines, OTC medical devices also generate significant additional value to the healthcare system, totaling \$7.7 billion annually for treatment and testing. Medical devices for treatment purposes include products for pain relief (braces, electronic devices, etc.), foot comfort and care, heat/ice packs, muscle simulators, asthma inhalers, etc. Medical devices for testing purposes include products such as pregnancy tests, blood glucose monitor, blood pressure monitor, etc.

The availability of OTC medical devices for treatment of a condition generates approximately \$4.8 billion in cost savings for consumers who, in a scenario where such devices were not readily available, would instead seek physician visits. According to the results of the survey, this segment includes 46 million consumers.

Furthermore, medical devices available for testing purposes provide approximately \$2.9 billion in additional savings, resulting from the 28 million consumers who would instead seek physician visits without these products.



Sources

1. Information Resources, Inc, 2018
2. 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)
3. The Value of OTC Medicine to the United States, Booz & Co., Jan 2012
4. IRI/NCP Consumer Survey, CHPA OTC Value Study, Oct 2018. IRI Market Advantage POS Data Ending Oct 2018, Symphony Health Pharmaceutical Audits, FairHealth.org/Internet Literature Research
5. IRI survey of U.S. Households, January, 2013

For infographics, video, and other materials regarding this research, visit www.overthecountervalue.org

