

# White paper on the benefits of OTC medicines in the United States

## *Report of the Consumer Healthcare Products Association's Clinical/Medical Committee*

### Executive summary

Self-care constitutes the foundation of the healthcare pyramid and allows the health care system to focus its strained resources on the diagnosis and treatment of serious diseases, new research, and innovative services. OTC medicines are an indispensable element of the self-care armamentarium.

Americans rely on over-the-counter (OTC) medicines for the treatment and prevention of many commonly occurring conditions including musculoskeletal pain, headaches, the common cold, allergies, heartburn, dermatitis, obesity, tobacco smoking dependence, and dental caries. This report examines the role of OTC medicines in the U.S. health care system as reflected through professional treatment guidelines, medication use data, as well as clinical and consumer research.

The important role of OTC medicines in the treatment of many conditions is demonstrated by their presence in the treatment guidelines of many leading U.S. medical associations, in the high frequency at which the medicines are recommended by health care professionals, and in the wide use of the products by consumers.

Accessibility and convenience are important features of OTC medicines. Accessibility facilitates the use of OTC medicines for the treatment of conditions that require early intervention to obtain optimal therapeutic effect, such as migraine headaches or cold sores. This "at hand" benefit also is reflected in the recommendations of the Centers for Disease Control and Prevention (CDC) and the American College of Emergency Physicians (ACEP) to stock a variety of OTC medicines, including analgesics, antihistamines, and hydrocortisone cream, in home and travel first aid kits.

Convenience has been recognized

as an important value in health care. This report emphasizes the convenience value offered by OTC medicines, a key benefit of these medications that is seldom addressed in the literature. Like prescription medicines, OTC medicines have intrinsic pharmacological activity that results in medical effects. However, unlike prescription medicines which can only be purchased at pharmacies, OTC medicines are available at a variety of retail outlets including grocery stores, convenience stores, discount department stores, and warehouse outlets. These retailers are often closer to an individual's home or work place than to the nearest pharmacy. Consequently, OTC products provide location convenience. Another convenience offered by OTC products is that they save the patient time since they do not require consultation with a health care provider for a prescription. OTC medicines also provide the convenience value of choice by offering consumers a wide variety of treatment options. While surveys show that many individuals consult a physician or pharmacist about the use of OTC medicines, consumers ultimately have the autonomy to make the final choice regarding the use of OTC medicines.

### Introduction

OTC medicines are essential for maintaining the health of Americans. FDA's Web page on the Regulation of Nonprescription Products states:<sup>1</sup>

"Over-the-counter (OTC) drugs play an increasingly vital role in America's health care system OTC drug products are those drugs that are available to consumers without a prescription. There are more than 80 therapeutic categories of OTC drugs, ranging from acne drug products to weight control drug products. As with prescription drugs, CDER [Center for

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Drug Evaluation and Research] oversees OTC drugs to ensure that they are properly labeled and that their benefits outweigh their risks. OTC drugs generally have these characteristics:

- Their benefits outweigh their risks.
- The potential for misuse and abuse is low.
- Consumer can use them for self-diagnosed conditions.
- They can be adequately labeled.
- Health practitioners are not needed for the safe and effective use of the product."

The findings of a Slone survey of 2,590 adult Americans support the important role OTC medicines have in America's health care system.<sup>2</sup> In this survey, 6 of the 10 most frequently used drugs, including the top 4, were drugs available OTC. Furthermore, among the remaining 30 drugs in the top 40 list were an additional 7 drugs available OTC.

Traditional uses of OTC medicines include the treatment of mild to moderate pain, symptoms of the common cold, hay fever, heartburn, diarrhea, constipation, hemorrhoids, gingivitis, eczema, and acne, as well as prevention of dental caries and sunburn. Indications for which OTC medicines have been recently approved in the United States include smoking cessation, emergency contraception, and weight

management. Outside the United States, OTC medications are available to treat an even wider range of diseases. For example, in the United Kingdom, medications were “switched” from prescription (Rx) to OTC status to facilitate self-treatment of conditions such as hypercholesterolemia, lower urinary tract infections, bacterial conjunctivitis, and benign prostatic hyperplasia.<sup>3</sup>

Currently in the United States, OTC medicines are available in the following broad therapeutic classes:

- Analgesics and antipyretics
- Cold, cough, and allergy products
- Nighttime sleep-aids
- Gastrointestinal products
- Dermatological products
- Other topical products (including vaginal antifungals, anorectal medicines, products for head lice, products for hair loss, ophthalmics, and otics)
- Oral health care products
- Menstrual products
- Nicotine replacement products
- Weight loss aids
- Vaginal contraceptives and emergency contraceptives

The purpose of this report is to examine the role of OTC medicines in the U.S. health care system, particularly the benefits these products provide from a medical, convenience, and economic perspective. While the risks of OTC medicines are addressed, the main focus of this review is on the benefits of OTC products. An emphasis is placed on data from U.S. sources, since many factors relevant to OTC medicines are specific to the local health care environment.

## Health benefits of OTC medicines

### OTC medicines for treatment and prevention of common health conditions

*Frequency of conditions treated with OTC medicines.* OTC medicines are an accepted and often first-line therapy for many of the most common conditions affecting the U.S. population. Attachment 1 describes the high frequency of occurrence for many of the symptoms and conditions for which OTC medicines are used. For example, based on data from the 2008 National Health Interview Survey (NHIS), many Americans suffered from low back pain (more than 61 million), arthritis (more than 51 million), migraines or severe headaches (more than 30 million), sinusitis (more than 30 million), hay fever (more than 18 million), and

chronic bronchitis (more than 9 million).<sup>4</sup> In the same survey, more than 45 million adult Americans were current smokers, more than 74 million were overweight, and more than 59 million were obese. The prevalence of many conditions treated with OTC medicines is within the range of some of the most common conditions which are treated with prescription products; in the 2008 NHIS, the prevalence of hypertension was more than 56 million and the prevalence of diabetes was more than 18 million.

Consumer use of OTC medications reflects the high prevalence of the conditions for which they are used to treat. In a 2001 survey commissioned by the National Council on Patient Information and Education (NCPIE), 598 of the 1,011 adult Americans surveyed (59%) indicated that they had taken an OTC medicine in the past 6 months.<sup>5</sup> Among those who took an OTC medicine, more than three-quarters (78%) did so to relieve pain. Fifty-two percent (52%) of participants reported that they had taken an OTC medicine for a cough, cold, flu, or sore throat; 45% for allergy or sinus relief; 37% for heartburn, indigestion, or other stomach problems; 21% for constipation, diarrhea, or gas; 12% for infections such as athlete's foot or yeast infections; and 10% for skin problems.

*OTC recommendations in clinical practice guidelines.* A search of the National Guideline Clearinghouse database identified numerous clinical practice guidelines from U.S. medical associations or governmental agencies that either explicitly recommend OTC medicines or recommend the use of active ingredients that are available in OTC products (see Attachment 1). OTC medicines recommended in these guidelines include non-narcotic analgesics, antihistamines, proton pump inhibitors, H<sub>2</sub>-antagonists, laxatives, topical hydrocortisone, topical emollient agents, fluoride oral health care products, nicotine replacement therapy products, and weight loss aids.

*OTC medicine use based on health care professional recommendations and self-care decisions.* The use of an OTC medicine can either originate from the recommendation of a health care professional or from a self-care decision. It is estimated that 70% to 90% of all illness episodes are addressed with self-treatment.<sup>6</sup> The decision process between self-medication and professional consultation appears to be affected by many factors, with one of the main issues being perceived severity of

the illness.<sup>7,8,9</sup> Other factors that affect this decision include the effect of the illness on normal behavior, duration of symptoms, understanding of the cause of the symptoms, worry or fear of symptoms, and cultural and socioeconomic factors.<sup>7,8,9,10</sup> In a 2008 survey of 1,005 adults that was commissioned by NCPIE, 650 subjects indicated that they typically self-medicate health conditions such as heartburn, colds, allergies, headaches, cough, and rashes or hives. The main reasons for self-medication were familiarity with how to treat their illness due to past experience (90%), the desire to save time, distance, and/or money (89%), and the belief that the illness isn't serious enough to require consulting a doctor (78%).<sup>11</sup>

A survey conducted in 2000 by Roper Starch on behalf of CHPA examined the extent to which American adult consumers take responsibility for their own health.<sup>12</sup> Based on 1,505 interviews, 40%–54% of respondents indicated they would use an OTC medicine as a first course of action for headaches, skin problems, heartburn/indigestion, common cold symptoms, or allergy/sinus symptoms; 26%–34% reported they would wait to see if the symptoms would go away; and only 4%–13% of participants indicated they would consult a physician first. Conversely, the wait and see approach was the first cause of action taken by the majority of participants (32%–46%) for upset stomach/nausea, constipation/diarrhea, muscle/joint/back pain, minor eye problems, pre-menstrual/menstrual problems, and menopausal problems, followed by the use of OTC medicines (26%–35%), and doctor consultation (9%–19%). Consulting a doctor was the first action the majority of individuals took for teeth and gum problems (36%), followed by the wait and see approach (31%), and OTC medicine use (17%). These findings are generally consistent with an earlier study by Stoller et al.<sup>13</sup> of 667 elderly people living in community settings. The elderly subjects surveyed were much more likely to self-medicate than to consult a physician for headache, runny nose, cough, sore throat, constipation, and diarrhea. In contrast, the same individuals were more likely to consult a doctor than to self-medicate for vision problems and urination disorders.

The use of many OTC medicines in children is usually initiated by parents. In a study in which the mothers of 8,145 pre-school age children were interviewed,

it was reported that more than half of the children (54%) were given an OTC medicine during the past 30 days.<sup>14</sup> The most common medications administered were analgesics/antipyretics and cough/cold medicines. Women without health insurance were significantly more likely to give OTC medicines to their children. An earlier study of 300 mothers of children 6 months to 12 years old showed that the major determinant for keeping OTC medicines handy is the nature of health problems to which mothers perceive their children to be vulnerable.<sup>15</sup> The highest ranked perceived vulnerabilities were scratches on arms or legs (infection), cough for two days, fever of 101°F, and sore throat.

Considering the high prevalence of conditions for which OTC medicines are used and endorsement of their use in clinical practice guidelines, it is not surprising that OTC medicines are widely recommended by physicians. An analysis of data collected from the 1997 to 1999 National Ambulatory Medical Care Surveys (NAMCS) demonstrated that physicians recommended an estimated 88 million OTC products annually during office-based visits; this represents 9.5% of all medications mentioned.<sup>16</sup> In the same study, approximately 65% of non-narcotic analgesics prescribed in office-based practices were OTC products. Data from the 2006 NAMCS showed that 3 of the 20 most frequently mentioned drug names, i.e., ibuprofen, acetaminophen, and omeprazole, were active ingredients available over the counter.<sup>17</sup> An analysis of NAMCS data collected from 1995 to 2000 found that U.S. physicians made an estimated 36 million recommendations for OTC topical skin products.<sup>18</sup> More than half of these recommendations were made by dermatologists and the most frequently recommended products were hydrocortisone preparations, anti-infectives, and skin moisturizers. Shiffman et al.<sup>19</sup> found that following the Rx-to-OTC switch of nicotine replacement therapy products, there was an increase in the number of prescriptions for such products, with more than 10 million physician recommendations in 2004.

There is a paucity of data on physician-patient interactions regarding OTC medicines. A 1995 study of 414 primary care visits at the University of New Mexico Health Sciences Center found that 58% of patients discussed OTC medications with their physicians; 38% of patients discussed analgesics, 10% discussed cold or allergy products, 9% discussed antacids, and 2%

discussed antidiarrheals.<sup>20</sup> In the same study, 37% of physicians asked questions about OTC medications during patient encounters. In a 2006 national survey of 834 office-based physicians regarding the Medicare drug benefit conducted by the Kaiser Family Foundation, physician-patient discussions about the burden of out-of-pocket prescription costs were found to be a trigger in many cases for physician recommendations of OTC medicines.<sup>21</sup> In this study, 38% of physicians reported that they frequently recommend the use of an OTC medicine as a substitute for a prescription medicine in order to assist patients with their out-of-pocket prescription costs. Furthermore, 39% of physicians said that they sometimes recommend an OTC medicine for economic reasons. In a 2003 national survey of 519 cardiologists and internists conducted by researchers from the University of Chicago, physicians reported that the recommendation of an OTC medicine was a likely strategy used to assist patients burdened by out-of-pocket prescription costs.<sup>22</sup>

Consumers frequently consult pharmacists about OTC medicines. According to the American Pharmacists Association's (APhA's) 2008 Annual OTC Product Survey, pharmacists make approximately 31 OTC recommendations per week and an average of 83% of individuals purchase an OTC medicine that their pharmacist recommended.<sup>23</sup> A survey published in 2002 investigated factors influencing pharmacists' OTC product recommendations.<sup>24</sup> Based on responses from 526 pharmacists, formulation or active ingredients, self-use of the product, scientific evidence, and positive consumer feedback were the most important factors influencing their OTC product decisions.

#### **'At hand' benefits of OTC medicines**

One of the benefits of OTC medicines is that they can be purchased and kept "at hand" for future use. OTC medicines are recommended for inclusion in home first aid kits, as well as travel kits. The American College of Emergency Physicians (ACEP) recommends that every home have a first aid kit which contains OTC medicines, including analgesics such as acetaminophen, ibuprofen, and aspirin, cough and cold medicines, allergy medicines, hydrocortisone cream, and decongestant tablets.<sup>25</sup> For trips across the country, ocean cruises, and overseas flights the ACEP recommends a traveler's first aid kit which contains analgesics, an antihistamine, antinausea/motion sickness

medication, antibiotic ointment, hydrocortisone cream, calamine lotion, and sunscreen.<sup>26</sup> CDC's recommended travel health kit also includes analgesics/antipyretics, an antihistamine, hydrocortisone cream, and sunscreen, OTC antidiarrheal medicines such as loperamide or bismuth subsalicylate, mild laxatives, antacids, decongestants (alone or in combination with antihistamine medications), as well as cough suppressant/expectorant medications, and throat lozenges.<sup>27</sup> Prepackaged health kits are available commercially or can be assembled by consumers on their own due to the OTC availability of its components.

Consistent with these recommendations, many households store some OTC medications at home for future use. A study of 300 mothers of children 6 months to 12 years found that most mothers keep some OTC medications in the home.<sup>15</sup> The medications most commonly kept in the house were fever remedies (>90% of mothers), cough remedies (>50%), and remedies for skin problems, such as rash or athlete's foot (>30%).

An important aspect of the "at hand" benefits of OTC medicines is that they are readily available for conditions which require prompt treatment. An example in this area is acute headache for which professional treatment guidelines recommend the early use of OTC analgesics to maximize their effectiveness.<sup>28</sup> For example, in patients with migraines, initiation of treatment within 1 hour of pain onset results in a significantly shorter duration of pain than initiation of treatment more than 1 hour after pain onset.<sup>29</sup> Another example of a condition which requires prompt treatment is herpes simplex labialis. For this condition, topical antiviral therapy such as the OTC medication docosanol, must be initiated within a few hours of the appearance of the first symptoms for an effective therapeutic outcome.<sup>30</sup>

#### **Use of OTC medicines to decrease prescription medicine treatment gaps**

The term "treatment gap" refers to the number of people with a condition or disease who need treatment but do not get it. There are many economic, practical, and psychological barriers that prevent patients from receiving medical care and obtaining prescription medicines. In a 2008 nationwide survey of 1,025 adult Americans, 20% of individuals reported that cost of prescription drugs prevented them from obtaining a necessary medical prescription in the past

year.<sup>31</sup> In the same study, 19% of respondents reported that inconvenient office hours prevented them from going to the doctor, 19% experienced difficulty obtaining a medical appointment, 18% reported that the cost of physician visits prevented them from seeing a doctor, and 13% experienced difficulty finding a physician.

OTC medications are not associated with the same barriers to use as prescription medications. Consequently, the treatment gap for a condition may decrease if an OTC therapy becomes available. For example, the 1996 introduction of OTC nicotine replacement therapy products in the United States led to a significant increase in smoking quit attempts. Based on sales data, the number of quit attempts using nicotine replacement therapy products is estimated to have increased from 2.5 million in 1995 (pre-OTC availability) to 5.8 million in 1997 (post-OTC availability).<sup>32</sup> The increased utilization inferred from sales data has since been confirmed in population surveys, which indicate that OTC nicotine replacement therapy is used in 26% of quit attempts.<sup>33</sup> Potential benefits of the increased use of nicotine replacement therapy include fewer smoking attributable deaths, increased life expectancy for current smokers, and significant health care cost savings.

Hypercholesterolemia is a condition for which there is a large treatment gap and no available OTC medicines. Approximately 50% of Americans have a total serum cholesterol concentration of at least 200 mg/dL, the level the National Cholesterol Education Program expert panel considers borderline-high risk.<sup>34</sup> However, approximately 50% of patients with increased cholesterol levels are unaware of their condition, and approximately 60% of men and 70% of women who know they have hypercholesterolemia are not receiving treatment for the condition. In 2007, an FDA advisory committee discussed the possibility of making the lipid-lowering drug lovastatin available OTC in the United States.<sup>35</sup> The committee members who voted in favor of an OTC switch cited public health issues associated with hypercholesterolemia and the large number of untreated individuals as factors supportive of a switch. However, the majority of committee members voted against OTC approval due to concerns about consumers' ability to determine the appropriateness of lovastatin therapy and to the absence of appropriate monitoring

and follow-up in an OTC setting.

### Convenience value of OTC medicines

In Webster's Dictionary, convenience is defined as "anything that adds to one's comfort or saves work; useful, handy, or helpful device, article, service, etc." This definition is consistent with findings from qualitative research in which individuals who were asked to describe convenience situations, used words such as "easy to use," "near at hand," "saves," and "frees-up."<sup>36</sup> When describing convenience situations the individuals also accentuated the importance of time (e.g., saves times, amount of time taken, number of hours a service is available) and space (e.g., saving a trip, locational proximity, one-stop shopping).

Various conceptual frameworks for convenience have been developed.<sup>37,38,39</sup> In general, all of these frameworks address the time and energy or effort consumers spend deciding on, accessing, transacting for, and benefiting from a product or service. Therefore, in simplest terms, convenience can be described as an individual's perception of time and energy (mental and physical) related to purchasing or using products or services. The time dimension may refer to time saved by utilizing a product or service or to the ability to obtain a product or service at a more convenient time.

Time and energy, or effort, are the main determinants of the following important convenience factors described in the literature:

- **Locational convenience.** Goods or services may be provided at a place that is closer to a consumer's home or workplace, thereby saving him or her time and energy.<sup>37</sup>
- **Access convenience.** Access convenience involves an individual's time and energy expenditures to receive a product or service (being able to get a product or service at the right time at the right place).<sup>37,38,39</sup>
- **Choice.** If a consumer has more than one option for receiving a service or product, he can make choices on the basis of time and effort required to receive these services. Berry et al. use the term "decision convenience" in this context and point out that the first decision an individual has to make is whether to self-perform or purchase the service.<sup>38,39</sup> Consumers also define

convenience in terms of product range.<sup>40</sup>

In a 2003 Gallup study, almost half (48%) of adult Americans reported that they felt short of time, and one-third (33%) reported that they experience stress frequently in their daily lives.<sup>41</sup> Employed individuals and parents of children under 18 years of age were more likely to be pressed for time and stressed than their counterparts who weren't employed and did not have young children. More than 60% of individuals in these subpopulations reported that they are short of time. Based on this data, one can expect that families with children in which both parents are employed are especially short of time. In 1978, all parents in the household were employed in 59% of families with children, while in 1998, this number increased to 75%.<sup>42</sup>

In terms of choice, the phrase "adding to one's comfort" from Webster's convenience definition comes into play. Decision-making requires both time, cognitive efforts in terms of knowledge about the offered products or services, and trust in one's ability to make the right choices.<sup>37,38</sup> If choices are perceived as too complex by a consumer, he or she may feel uncomfortable about them and delegate the decision to somebody perceived as more qualified or more capable in the area of question. This is one of the reasons why health care professionals are frequently consulted about OTC medicines (see Section 3.1.3).

#### Role of convenience in health care

The convenience framework described in the previous section can be readily applied to health care services and products. Convenience factors that can affect satisfaction with health care services include access features such as a convenient location of physician and pharmacy services and the availability of services during non-business hours. Some convenience factors specific to pharmacies include in stock availability of prescribed medications, ability to request refills by telephone, and time required to have prescriptions filled.<sup>43</sup>

Several recent studies examined the importance of convenience in health care. A study conducted at the University of Cincinnati regarding mammography screening services illustrates the importance of location convenience of a health care service.<sup>44</sup> In this study, distance to home or work was the main reason patients cited for choosing to leave the university-based mammography site for a new site. Another

study analyzed the impact of access convenience, in this case home delivery of anti-hyperlipidemics, antidiabetics, and antihypertensives, on compliance, as assessed by the medication possession ratio.<sup>45</sup> After controlling for patient demographics and drug use behaviors, individuals receiving their medicines through home delivery had significantly higher compliance rates than those obtaining these medicines from retail pharmacies.

The convenience of certain dosage forms of medicines has also been shown to affect compliance. Patient convenience is one of the factors that leads to improved medication adherence with depot and modified release formulations versus conventional formulations and improved adherence with fixed-combination medicines versus concurrent use of several equivalent single-ingredient products.<sup>46,47,48</sup> In a study published in 2003, reducing the number of daily doses through use of extended release products was shown to improve adherence, patient quality of life, and patient satisfaction in a number of diseases.<sup>48</sup> A systematic review of studies published in 2007 synthesized the findings of nine studies which compared adherence with fixed-dose combination medications versus the same medications administered as single-drug formulations; two studies were in patients with tuberculosis, four studies were in patients with hypertension, one study was in patients with human immunodeficiency virus (HIV) disease, and two studies were in patients with diabetes.<sup>49</sup> Across the nine studies, combination products reduced the risk of noncompliance with the recommended dosing schedule by 26%.

#### **Domains of convenience and OTC medicines**

The convenience values of OTC medicines are of key importance to consumers. In a 2007 study sponsored by the National Consumers League, individuals who reported that they were more likely to consider taking an OTC product for lowering cholesterol than an prescription medication most often cited convenience as the reason for this selection.<sup>50</sup>

The following section discusses the convenience factors associated with use of OTC medicines.

*Locational convenience.* Unlike prescription medicines, which can only be purchased at pharmacies, OTC medicines are available at various types of retail outlets which do not employ pharmacists,

including discount department stores, grocery stores, and warehouse outlets. While there are only approximately 54,000 pharmacies in the United States, there are more than 750,000 retail outlets that sell OTC products.<sup>51</sup> Consequently, for many Americans, the closest place to purchase an OTC medicine is not the nearest pharmacy, but rather another type of retail outlet. The importance of locational convenience when purchasing medications was demonstrated in a 2001 survey of more than 1,200 consumers across the United States.<sup>52</sup> Forty-four percent of respondents in this survey reported that the main reason they used their regular pharmacy was convenience of location, while 17% chose a pharmacy based on price, and 13% chose a pharmacy based on service.

*Access convenience.* The time savings afforded due to access convenience is another important benefit of OTC medicines. In a 2008 NCPIE survey of 1,005 Americans, 77% of participants reported that they self-medicate with OTC medicines because it saves time.<sup>11</sup> The time savings realized with use of OTC medicines versus prescription medicines is primarily derived from avoidance of the need to consult with a health care provider in order to obtain a prescription. A scheduled doctor office visit, including travel, waiting, and visit time, consumes approximately 2 to 4 hours of a patient's time.<sup>53,54</sup> While most Americans travel less than 30 minutes to see a doctor, 2.5% of the overall population travels more than 1 hour to see their doctor.<sup>55</sup> The poor and near poor are more likely than wealthier individuals to travel longer.

*Choice of products.* While many consumers consult health care professionals about the use of OTC medicines, consumers have full autonomy regarding OTC product purchases and use. In most therapeutic drug categories, consumers can select from a variety of OTC products, including products with different active ingredients and products with similar active ingredients, but with different formulations, package sizes, and prices.<sup>56</sup> In a 2000 survey of 1,505 Americans, 80% of participants responded that having a range of choices of OTC medicines helps them treat and prevent health conditions on their own.<sup>12</sup>

### **Health care system benefits of OTC medicines**

#### **Societal perspectives**

The OTC availability of medicines facilitates

self-care, which is the foundation of the health care pyramid. A National Institutes of Health (NIH) guide defines self-care as an area that "includes positive steps taken by individuals to either prevent disease or promote general health status through health promotion or lifestyle modification; medical self-care for the identification or treatment of minor symptoms of ill-health or the self-management of chronic health conditions; and steps taken by laypersons to compensate or adjust for functional limitations affecting routine activities of daily living."<sup>57</sup> Consumer surveys reveal that there is an increasing trend for individuals to seek more active involvement in matters pertaining to their own health as well as the health of other family members. In an internet survey conducted in 2004 by the National Lipid Association, more than half of the participants who were not being treated for increased cholesterol but were at moderate risk for coronary artery disease stated that they make more health decisions on their own now than they did in the previous 5 years.<sup>58</sup> These findings are consistent with those of a 2000 survey in which 59% of Americans reported that they were more likely to treat their own health conditions currently than they were a year ago.<sup>12</sup>

The availability of OTC medicines reduces the need for many physician visits, including those that physicians would find trivial or unnecessary. In a 1972 study of 1,458 primary care physicians in the United States, 64% of physicians estimated that at least 10% of their patient visits were trivial, unnecessary, or inappropriate.<sup>59</sup> In a more recent study conducted in the UK, general practitioners considered 6% of adult doctor visits and 15% of children doctor visits to be unnecessary.<sup>60</sup> The most common causes of visits categorized as unnecessary were skin problems and musculoskeletal symptoms. If OTC medicines were not available, the number of trivial physician visits would likely increase. For example, if only a small percentage of individuals who currently self-treat their headache or backache would chose to visit a physician instead of self-medicating with an OTC analgesic, this would result in millions of extra doctor visits each year.

A 2008 study of heartburn sufferers estimated that if OTC medications were not available, there would be an annual increase of approximately 6 million heartburn-related doctor office visits.<sup>61</sup> Temin reported that in 1989 there were 1.65

million fewer doctor visits for colds than in 1976, a difference attributed to FDA approving the switch of cold medicines from Rx to OTC status during this time period.<sup>62</sup> The total resources saved due to this decrease in office visits was estimated at \$70 million per year, an amount which includes the total costs of doctor visits, the costs of transportation, and the costs of time spent travelling and waiting. A study by Lipsky and colleagues demonstrated that the majority of cost savings from taking OTC medications results from improving work productivity and reducing unnecessary physician visits.<sup>63</sup> The study found that the use of OTC medicines to treat upper respiratory infections results in an average cost savings of \$9 per episode. Assuming that adult Americans have an average of three upper respiratory infection episodes per year, OTC cough and cold medicines provide a potential annual savings of \$4.75 billion per year.

Since OTC medicines are generally not covered by health plans, from the perspective of health insurance companies, Rx-to-OTC switches reduce costs for drugs as well as costs for doctor visits. Analyses conducted by various health insurers demonstrated decreases in drug costs and physician visits after H2 antagonists, loratadine, omeprazole, and vaginal antifungal products became available OTC.<sup>64,65,66,67,68,69,70</sup>

#### Consumer perspectives

OTC medicines are generally priced much lower than prescription products. An analysis published in 2005 reported that the average retail price of an OTC medicine in America was \$7, whereas the average price of a name-brand prescription medicine was \$96, and the price of a generic prescription medicine was \$28 USD.<sup>71</sup> At the time of their introduction to the OTC market, Alli (orlistat), Zantac (ranitidine), and Miralax (polyethylene glycol), were all priced between 50% and 90% lower than the original branded prescription medicines.<sup>72</sup> Similarly, the cost of a 30-day supply of Claritin (loratadine) was \$96 when the drug was available by prescription and \$22 following the switch to OTC availability.<sup>71</sup> Due to the economic advantage of OTC medicines, physicians are likely to recommend the use of an OTC medicine as a substitute for an prescription medicine to assist patients who are burdened with out-of-pocket prescription costs.<sup>73</sup>

By using OTC medications, consumers not only save on drug costs, they also

save the out-of-pocket costs for doctor visits (including insured consumer's co-payments) and transportation, as well as the cost of time spent traveling and waiting at the doctor's office. Using the U.S. June 2010 average hourly wage rate of \$22.53, the 2 to 4 hours that a patient saves from avoiding a doctor's visit would result in an average savings of \$45 to \$90.<sup>53,54,74</sup> Temin combined three factors to assess the economic implications of the OTC availability of topical hydrocortisone: price of the drug, cost of the doctor visit to get the prescription, and value of the time used to go to the doctor.<sup>75</sup> He estimated that consumers saved more than \$200 million the first year after topical hydrocortisone was switched from prescription (Rx) to OTC status and more than \$400 million the second year after the switch. In a study concerning the switch of heartburn medications from Rx to OTC status, Mansfield et al. found that consumers saved approximately \$160 in out-of-pocket drug costs and \$14 in physician visit costs annually.<sup>61</sup>

#### Conditions for safe and effective use of OTC medicines

The benefits of OTC medicines can only be realized if consumers use them safely and effectively. Intentional or unintentional nonadherence to the usage instructions of medicines in terms of incorrect dosing and duration of treatment or failure to heed warnings and precautions is a challenge which applies to all medicines, OTC as well as prescription products. Furthermore, misconceptions about medicines such as "if 1 pill is good then 2 pills should be twice as good" and the inability to understand directions on the label can also occur with both OTC and prescription medicines.<sup>76,77,78,79</sup> However, since users of OTC medications are less likely than users of prescription medications to consult with a health care professional prior to product use, it is particularly imperative that consumers, including those with low reading comprehension levels, be able to read and understand the product labeling.

Unlike prescription container labels which do not have a standardized format, all OTC medicines must have a standardized label that provides instructions for safe and effective use. This standardized label, known as the OTC Drug Facts format, was established by FDA in 1999.<sup>80</sup> According to the conclusions of a 2008 Institute of Medicine workshop, the cur-

rent OTC product labeling standards are considered as a reference for future standardized prescription medicine labeling since they "have already been developed with health literacy considerations in mind, utilize a standard format, and have been marketed to the public, increasing their familiarity and usability."<sup>81</sup>

Two separate studies, each of which included more than 1,000 adult Americans, found that 90% to 95% of consumers read the Drug Facts label when they use OTC medicines.<sup>5,12</sup> However, the same studies also found that consumers read the label selectively and often pay insufficient attention to the active ingredients and the safety information. Even if patients read the label, they may not comprehend it. Poor label comprehension is particularly concerning in individuals with low literacy and those in whom English is not their first language.<sup>81,8</sup>

Several government and nongovernment organizations have developed programs that use various forms of communication to educate consumers about the safe and effective use of OTC medicines. Ongoing consumer education initiatives include FDA's Web pages on "Consumer Information: Safe Use of Over-the-Counter Drug Products,"<sup>84</sup> the American Academy of Family Physicians' (AAFP's) Web site, [www.FamilyDoctor.org](http://www.FamilyDoctor.org), which is in English and Spanish and contains a comprehensive OTC Guide;<sup>85</sup> APhA's patient brochures addressing self-treatment of selected common conditions, which are available in English and Spanish;<sup>86</sup> and CHPA's Web site, [OTCsafety.org](http://OTCsafety.org),<sup>87</sup> which includes the Treat with Care campaign on the safe use of OTC cough and cold medicines in children. In order to engage more consumers in OTC medicine education efforts, many organizations are currently examining ways to use social networking sites and nontraditional media. One example of this is CHPA's StopMedicineAbuse campaign which includes a Facebook page<sup>88</sup> and a Twitter account.<sup>89</sup>

#### Discussion

Evidence-based treatment guidelines, health care professionals' recommendation patterns, and consumer usage data demonstrate that OTC medicines are an indispensable part of the U.S. health care system. These products alleviate or prevent conditions that affect millions of Americans, including headaches, musculoskeletal pain, the common cold, heartburn, diarrhea, dermatitis, heartburn, allergies,

obesity, tobacco addiction, and tooth caries.

Numerous studies that have examined consumers' decision-making regarding the use of OTC medicines demonstrate the three main reasons consumers use OTC medicines: (1) they are familiar with how to self-treat a particular condition due to past experience, (2) they have concluded that their illness is not serious enough to warrant a doctor's visit, and (3) it saves money and time when they self-medicate with an OTC medicine. The latter aspect reflects the convenience value of OTC medicines. Although convenience is recognized as being an important parameter of health care services, there is limited medical literature addressing the importance of convenience as it relates to OTC medicines. The information presented in this report establishes the convenience of OTC medicines. OTC medicines offer locational, access, and choice convenience. The ease with which OTC medications can be accessed enables patients to quickly initiate therapy for conditions which respond best to early intervention. Patients who perceive a doctor's visit as inconvenient, and therefore do not seek out prescription medications, may use an OTC medicine which can be obtained locally without a prescription.

The healthcare system benefits from the OTC availability of medicines due to the reduction of unnecessary use of healthcare services. These services include consultations by primary care physicians, nurse practitioners, community clinics, and urgent care centers which are the first contact for most people looking to receive treatment for cough and cold symptoms. Furthermore, OTC medicines save health plan spendings on provider reimbursement and prescription medicines.

In order for the benefits of OTC medicines to be realized, they must be used safely and effectively. Since these products may be purchased without the guidance of a health care professional, it is important that consumers be educated about the benefits and risks of these medicines. Many public and private organizations have developed tools to enhance the safe and effective use of OTC medicines.

In conclusion, OTC medicines are a common part of people's daily lives. Without them, the health of Americans would likely decline.

## **Attachment 1: Therapeutic agents available in OTC products recommended by U.S. national medical associations and frequencies of selected conditions treated with OTC medicines**

The guidelines listed below were identified through a search of the National Guideline Clearinghouse database (NGC; www.guideline.gov), a public resource for evidence-based clinical practice guidelines provided by the Agency for Healthcare Research and Quality (AHRQ), U.S. Department of Health and Human Services.

The guidelines either explicitly recommend OTC agents or recommend medications without specifying their prescription or OTC status, but the active ingredients are available in OTC products. In the latter scenario, relevant information on the agents' OTC status has been added in brackets.

### **Analgesics**

#### **American College of Physicians &**

**American Pain Society** (2007 evidence-based guideline on low back pain):

- Acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs) are recommended as first-line medication options for most patients suffering from low back pain. [Acetaminophen and several NSAIDs are available OTC.]<sup>90</sup>
- Frequency of low back pain: 61.7 million people  $\geq$  18 years of age report they had back pain in the past 3 months<sup>4</sup>

**American College of Rheumatology** (2000 evidence-based guideline on hip and knee osteoarthritis):

- Acetaminophen is recommended as an initial therapy option for the relief of mild-to-moderate joint pain in patients with hip and knee osteoarthritis. NSAIDs are recommended as an alternate therapeutic approach in patients with knee or hip osteoarthritis with mild to severe pain. [Acetaminophen and several NSAIDs are available OTC.] Topical analgesics, e.g., methylsalicylate or capsaicin cream, are recommended as either adjunctive treatment or monotherapy in individuals with knee osteoarthritis who have mild to moderate pain, do not respond to acetaminophen, and do not wish to take systemic therapy.

[Several topical analgesics are available OTC.]<sup>91</sup>

- Frequency of arthritis diagnosis: 30.3 million people  $>$ 18 years of age report they were told by a doctor or other health professional that they have some form of arthritis<sup>4</sup>

**National Headache Foundation** (2004 guideline on primary headache; conclusions reflect clinical experience and most recent medical literature):

- OTC aspirin, acetaminophen, or NSAIDs such as ibuprofen, naproxen, and ketoprofen are recommended as first-line therapy for episodic tension-type headache. If treatment with single-ingredient products fails, OTC medicines containing acetaminophen and/or acetaminophen with the addition of caffeine are recommended as options.<sup>92</sup>
- Frequency of migraines or severe headaches: 30.2 million people  $\geq$  18 years of age report they had migraines or severe headaches in the past 3 months<sup>4</sup>

**American Academy of Pediatrics & American Academy of Family Physicians** (2004 guideline on acute otitis media):

- Acetaminophen and ibuprofen are recommended as effective analgesic treatment for mild to moderate otalgia. These medicines are described as the readily available mainstay of pain management for acute otitis media. [Acetaminophen and ibuprofen are available OTC.]<sup>93</sup>
- Frequency of acute ear infections: 21.8 million people of all ages and 11.0 million children under 5 years of age had acute ear infections in past 12 months<sup>94</sup>

### **Cold, cough, and allergy products**

**American College of Chest Physicians** (2006 evidence-based guideline on cough suppressants and pharmacologic protussive therapy):

- Dextromethorphan is recommended for short-term symptomatic relief of coughing in adult patients with chronic bronchitis. A combination of brompheniramine and pseudoephedrine is recommended for treatment of cough due to the common cold in adults. [Dextromethorphan, brompheniramine, and pseudoephedrine are available OTC.]<sup>95</sup>

- Frequency of cough: 26.7 million doctor visits annually due to cough<sup>96</sup>
- Frequency of chronic bronchitis: 9.8 million people ≥ 18 years of age report they were told by a doctor or other health professional in the past 12 months that they had a chronic bronchitis<sup>4</sup>
- Frequency of common cold: American population experiences an estimated 1 billion colds each year<sup>97</sup>

**American Academy of Allergy, Asthma and Immunology & American College of Allergy, Asthma and Immunology** (2008 evidence-based guideline on allergic rhinitis):

- Oral second-generation antihistamines are recommended over first-generation antihistamines for treatment of allergic rhinitis. Oral and topical decongestants and intranasal cromolyn sodium are recommended as treatment options. [Agents from all classes mentioned are available OTC.]<sup>98</sup>
- Frequency of hay fever: 18 million people ≥ 18 years of age report they were told by a doctor or other health professional in the past 12 months that they had hay fever<sup>4</sup>

**American Academy of Allergy, Asthma and Immunology & American College of Allergy, Asthma and Immunology** (2005 evidence-based guideline on sinusitis):

- Topical and oral nasal decongestants are recommended for treatment of acute or chronic sinusitis. [Agents from these two classes are available OTC.]<sup>99</sup>
- Frequency of sinusitis: 30.6 million people ≥ 18 years of age report they were told by a doctor or other health professional in the past 12 months that they had sinusitis<sup>4</sup>

**Gasrointestinal products**

**American College of Gastroenterology** (1997 evidence-based guideline on acute infectious diarrhea in adults):

- Loperamide is recommended as the drug of choice when nonspecific therapy is desired for diarrhea. Bismuth subsalicylate is recommended as the preferred agent when vomiting is a major manifestation of enteric infection. [Loperamide and bismuth subsalicylate are available OTC.]<sup>100</sup>
- Frequency of diarrhea: an estimated 99 million adults experience acute diarrhea or gastroenteritis each year<sup>100</sup>

- Frequency of indigestion, nausea, and vomiting: 8 million people of all ages report they had of indigestion, nausea, and vomiting during the last 12 months<sup>94</sup>

**American College of Gastroenterology** (2005 evidence-based guideline on gastroesophageal reflux disease):

- Antacids, proton pump inhibitors, and H2-antagonists are recommended for patient directed therapy for heartburn and regurgitation. Proton pump inhibitors and H2-antagonists are recommended as mainstay of gastroesophageal reflux disease therapy. [Antacids, proton pump inhibitors and H2-antagonists are available OTC.]<sup>101</sup>
- Frequency of gastroesophageal reflux disease: estimated lifetime prevalence of 25% to 35% of the population<sup>102</sup>
- Frequency of heartburn/gastroesophageal reflux disease: annual prevalence is estimated at 60%<sup>104</sup>

**American Gastroenterological Association** (2008 evidence-based guideline on gastroesophageal reflux disease):

- Proton pump inhibitors and H2 antagonists are recommended as treatment for patients with gastroesophageal reflux disease. Antacids are acknowledged as the most rapidly acting agents whose efficacy can be sustained by combining them with a proton pump inhibitor or an H2 antagonist. [Proton pump inhibitors, H2 antagonists, and antacids are available OTC.]<sup>105</sup>
- Frequency of gastroesophageal reflux disease: see above

**American Gastroenterological Association** (2000 guideline on constipation):

- Fiber and saline agents such as milk of magnesia are recommended for the initial management of constipation followed by bisacodyl, lactulose, and polyethylene glycol. [Except lactulose all ingredients mentioned are available OTC.]<sup>106</sup>
- Frequency of frequent constipation: 3.1 million people of all ages report they had frequent constipation during the past 12 months<sup>94</sup>

**Dermatological products**

**American Academy of Dermatology** (2004 evidence-based guideline on atopic dermatitis):

- Topical corticosteroids and emollients are recommended as standard of care for atopic dermatitis. Coal tar recognized as a treatment option. [Topical

hydrocortisone, emollient agents, and coal tar are available OTC.]<sup>107</sup>

- Frequency of dermatitis: 8.2 million people of all ages report they has dermatitis during the past 12 months<sup>94</sup>
  - Frequency of atopic dermatitis (eczema): 10%–20% of infants and young children, 1%–3% of adult population<sup>108</sup>
- American Academy of Dermatology** (2007 evidence-based guideline on acne vulgaris):

- Benzoyl peroxide is recommended as effective topical therapy of acne vulgaris. Salicylic acid is recognized as a treatment option. [Benzoyl peroxide and salicylic acid are available OTC.]<sup>109</sup>
- Frequency of acne: 5 million people of all ages<sup>94</sup> and an estimated 80 percent of all people between the ages of 11 and 30<sup>110</sup>

**American Academy of Dermatology** (2009 evidence-based guideline on psoriasis):

- Topical corticosteroids, including over-the-counter hydrocortisone preparations, are recommended as a cornerstone of treatment for the majority of patients with psoriasis, particularly those with limited disease. Emollients are recommended as standard adjunctive therapy. Salicylic acid and coal tar are recognized as treatment options. [All ingredients mentioned are available OTC.]<sup>111</sup>
- Frequency of psoriasis: 2.9 million people of all ages report they had psoriasis during the past 12 months<sup>94</sup>

**American Academy of Allergy, Asthma and Immunology; American College of Allergy, Asthma and Immunology; & Joint Council of Allergy, Asthma and Immunology** (2004 evidence-based guideline on atopic dermatitis):

- Emollients available in form of lotions, creams, and ointments are recommended as first-line therapy of atopic dermatitis. Topical corticosteroids, applied to area of eczema, are recognized as effective treatment. [Emollients and topical hydrocortisone are available OTC.]<sup>112</sup>
- Frequency of atopic dermatitis: see above

**Other topical products**

**American Academy of Dermatology** (1996 guideline on superficial mycotic skin infections):

- Topical treatment with antifungal

products is recommended for noninflammatory tinea corporis, tinea cruris, tinea faciei, tinea manuum, and tinea pedis. [Topical antifungals that are available include clotrimazole, ketoconazole, miconazole, terbinafine, and tolnaftate.]<sup>113</sup>

- Frequency of mycotic skin infections: Tinea pedis (athlete's foot) is estimated to occur in up to 15% of the population<sup>114</sup>

**Infectious Diseases Society of America** (2005 evidence-based guideline on skin and soft-tissue infections):

- Topical bacitracin and neomycin are mentioned as options for the treatment of impetigo. Mupirocin is considered the best topical agent for impetigo. [Bacitracin zinc and neomycin are available OTC, mupirocin is available by prescription only.]<sup>115</sup>
- Frequency of impetigo: affects approximately 1% of children<sup>116</sup>

**Infectious Diseases Society of America** (2009 evidence-based guideline on candidiasis):

- Six topical antifungal agents are recommended for treatment of vulvovaginal candidiasis. [Four of the recommended agents are available OTC, i.e., clotrimazole, miconazole, butoconazole, and tioconazole].<sup>117</sup>
- Frequency of vaginal yeast infection: Nearly 75% of adult women have at least one vaginal yeast infection in their life time<sup>118</sup>

**American Gastroenterological Association** (2004 evidence-based guideline on hemorrhoids):

- Topical corticosteroids are recognized as useful medical therapy for managing perianal skin irritation and topical analgesics are recognized as useful for symptomatic relief of local pain and itching. [Topical hydrocortisone and topical analgesics are available OTC.]<sup>119</sup>
- Frequency of hemorrhoids: 8.5 million people of all ages report they had hemorrhoids during the past 12 months<sup>94</sup>

**American Academy of Ophthalmology** (2008 evidence-based guideline on dry eye syndrome):

- Aqueous enhancement using artificial tear substitutes, gels and ointments is recommended for mild dry eye syndrome. [Topical products for dry eye syndrome are available OTC.]<sup>120</sup>
- Frequency of dry eyes: 4.9 million people aged  $\geq 50$  years<sup>121</sup>

**American Academy of Ophthalmology** (2008 evidence-based guideline on conjunctivitis):

- Topical OTC antihistamine/vasoconstrictor agents are recommended for the treatment of mild allergic conjunctivitis.<sup>122</sup>
- Frequency of episodes of watery, itchy eyes (most likely allergy-linked): 40% of adult population<sup>123</sup>

**American Academy of Otolaryngology—Head and Neck** (2008 evidence-based guideline on cerumen impaction):

- Cerumenolytic agents, including carbamide ear drops, are acknowledged as a treatment option. [Carbamide ear drops are available OTC.]<sup>124</sup>
- Frequency of earwax impaction: 12 million people annually<sup>123</sup>

**American Academy of Pediatrics** (2002 guideline on head lice):

- Topical permethrin is recommended as the treatment of choice for head lice in children. Pyrethrin plus piperonyl butoxide is acknowledged as an alternative treatment option. [All ingredients mentioned are available OTC.]<sup>125</sup>
- Frequency of head lice infections: Among children 3 to 12 years of age approximately 6 to 12 million have head lice each year.<sup>124</sup> One large study showed that 3.6% of elementary school children had nits without head lice and 1.6% had lice.<sup>126</sup>

**American Academy of Dermatology** (1996 guideline for androgenetic alopecia):

- Topical treatment with minoxidil 2% solution is recommended as an effective therapeutic option. [Minoxidil is available OTC.]<sup>127</sup>
- Frequency of androgenetic hair loss: 50% of men<sup>128</sup> or 35 million men<sup>129</sup>

**Oral healthcare products**

**American Academy of Pediatric Dentistry** (2008 evidence-based guideline on fluoride therapy):

- Fluoride toothpaste twice daily is recommended for in home use as a primary preventive measure. Fluoride mouth rinses or brush-on gels are recommended as a prevention option for school-aged children at high risk for caries. [Fluoride toothpastes, gel and rinses are available OTC.]<sup>130</sup>
- Frequency of caries in permanent teeth: 42% of population aged 6–19 years<sup>131</sup>
- Frequency of coronal caries: 91% of population aged  $\geq 20$  years<sup>130</sup>

- Frequency of root caries: 18% of population aged  $\geq 20$  years<sup>130</sup>

**American Academy of Periodontology** (2001 evidence-based guideline on plaque-induced gingivitis, chronic periodontitis, and other clinical conditions):

- Topical antibacterial medications including products containing a combination of thymol, menthol, eucalyptol, and methyl salicylate [available OTC], products containing triclosan [available OTC], and products containing chlorhexidine gluconate [available prescription-only] are recommended as therapy options for treatment and prevention of plaque-induced gingivitis.<sup>132</sup> The guideline refers to a voluntary seal standard established by the American Dental Association (ADA) for the assessment of the safety and effectiveness of dental products.<sup>133</sup> A number of OTC products containing a variety of active ingredients (including triclosan, stannous fluoride, and essential oils) have been awarded the ADA seal for an indication of prevention of plaque and gingivitis.
- Frequency of gingivitis: more than 50% of adults have gingivitis on an average of 3–4 teeth<sup>134</sup>

**Smoking cessation products**

**Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, et al.** (2000 evidence-based guideline on tobacco use and dependence):

- Nicotine gums, patches, and lozenges are recommended as first-line therapy options which reliably increase long-term smoking abstinence rates. [All products mentioned are available OTC.
- Frequency of current smokers: 46 million people  $\geq 18$  years of age report they have smoked at least 100 cigarettes in their lifetime and still currently smoke<sup>4</sup>

**Weight loss products**

**American College of Physicians** (2005 evidence-based guideline on obesity in primary care):

- Orlistat is recommended for obese patients who choose to use adjunctive drug therapy. [Orlistat is available OTC.]<sup>135</sup>
- Combined frequency of overweight and obesity: 68% of Americans  $\geq 20$  years of age<sup>136</sup> or 134 million adults 18 years and older<sup>4</sup>

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