

Testimony

for

**House Committee on Ways & Means
Subcommittee on Oversight**

**Impact of Limitations on the Use of Tax-Advantaged
Accounts for the Purchase of Over-the-Counter
Medication**

by

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April 25, 2012

Introduction

Chairman Boustany, Ranking Member Lewis, and distinguished Members of the Subcommittee, thank you for inviting me to discuss the importance of over-the-counter medicines in healthcare. I am Scott Melville, President and CEO of the Consumer Healthcare Products Association (CHPA). CHPA is the 131-year-old trade association representing U.S. manufacturers and distributors of over-the-counter (OTC) medicines and dietary supplements. Every year, millions of Americans rely on OTC medicines as a first response to onset symptoms of mild-to-moderate ailments. Eligibility of these medicines under flexible, tax-preferred accounts, such as Flexible Savings Arrangements (FSAs) and Health Savings Accounts (HSAs), offers significant value to the American consumer.

About CHPA

Founded in 1881, CHPA is a member-based association representing more than 75 manufacturers and distributors of nonprescription, OTC medicines and dietary supplements. Products produced by the member companies of CHPA provide millions of Americans with safe, effective, and convenient therapies for the treatment and prevention of many common ailments and diseases.

CHPA is committed to promoting the increasingly vital role of over-the-counter medicines and dietary supplements in America's healthcare system through science, education, and advocacy. The association provides leadership and guidance on regulatory and scientific issues to Congress; state legislatures; and federal, state, and international government agencies. CHPA shares tools and information with partners across the globe to ensure the safe and responsible use of OTC medicines.

OTC Medicines are a Proven and Vital Part of the Healthcare System

Part of the reason we're here today is to discuss a provision of the Patient Protection and Affordable Care Act (PPACA, P.L. 111-148/P.L. 111-152) that requires holders of tax-preferred healthcare accounts (such as Flexible Spending Arrangements and Health Savings Accounts) to seek a physician's prescription if they wish to use those accounts to purchase an over-the-counter medicine. We believe this requirement is bad policy for both the American consumer and the U.S. healthcare system.

For millions of Americans, OTC medicines are a trusted and affordable way to get well, stay well, and feel well. These medicines have been found safe and effective by the U.S. Food and Drug Administration (FDA) when used as directed, and are used to treat many common, self-manageable conditions like colds, allergies, heartburn, and headaches. Like prescription drugs, OTC medicines are pharmaceutical products regulated by the U.S. Food and Drug Administration (FDA). However, OTCs can be purchased by consumers directly, without a prescription, because the FDA has determined that these medicines can be safely used by consumers without the intervention of a physician or other healthcare professional. As a result, OTC medicines provide benefits to American families and the U.S. healthcare system in a range of ways, including:

- **Access** to conveniently available healthcare options 24 hours a day, every day, for busy families and caregivers through a wide range of retail outlets including pharmacies, supermarkets, and convenience stores;
- **Affordability** for both consumers and the healthcare system;
- **Empowerment** for individuals and families to meet their everyday healthcare needs; and
- **Trust** in safe and effective medicines.

A survey of physicians and consumers CHPA conducted in 2010¹ found that 88 percent of physicians recommend their patients attempt to address minor to moderate ailments themselves through the use of OTC medicines before seeking the care of a professional. Additionally, 89 percent of consumers believe OTC medicines are an important part of their overall family healthcare and just as safe and effective as prescription medicines when taken according to directions. In fact, 81 percent of U.S. adults use OTC medicines as a first response to minor ailments and half of parents reported that an OTC medicine has helped keep their child from missing school.

OTCs are a proven means to keep healthcare costs down and unnecessary visits to the doctor, a significant cause of rising health care costs, at a minimum. The CHPA study concludes that, on average, physicians say approximately 10 percent of office visits result from minor ailments, which could be effectively self-managed by patients, including through the use of OTC medicines. This amounts to more than 40 million appointments each year that could be avoided with effective and responsible self-care. Even eliminating half of these unnecessary appointments could save the healthcare system more than 20 million visits each year, at a savings of more than \$5 billion.² As more and more areas of the country are struggling with reduced medical service due to a shortage in physicians, reducing needless visits to the doctor is vital to the future of healthcare.

To further quantify the value of OTC medicines, CHPA commissioned Booz & Co. in early 2012 to determine the value OTC medicines bring to the healthcare system. To estimate the value of OTC medicine, the study³ assumed a hypothetical world in which OTC medicines did not exist and all consumers had to either use prescription drug alternatives or leave the conditions untreated. This analysis was performed for seven categories of the most common 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). These seven categories were selected 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 and through five case studies of prescription-to-nonprescription switch, which represent real-world examples of making prescription-only medicines available directly to consumers over the counter and thus significantly expanding their use.

The results of the study demonstrate the high value of OTC medicines. Overall, the availability of OTC medicine in the seven categories analyzed provides \$102 billion in annual savings to the U.S. healthcare system relative to alternatives, as well as the unquantifiable benefit of increased access to medicine for all consumers. \$77 billion of that total results from clinical cost savings, including avoided doctor's office visits and diagnostic testing, while the remaining \$25 billion is realized in the drug cost savings associated with lower-cost OTCs versus higher-priced prescription medicines. What this means is that, on average, every dollar spent by consumers on OTC medicines saves \$6 to \$7 for the U.S. healthcare system as a whole.

¹ "Your Health at Hand Survey," Strategy One on behalf of CHPA, June 20, 2011

² "Potential Reduction in Unnecessary Visits to Doctors from Safe and Appropriate Use of OTC Medicines," Paul London and Associates on behalf of CHPA, June 17, 2011

³ "The Value of OTC Medicine to the United States," Booz & Co. on behalf of CHPA, Jan. 31, 2012

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, and at all hours of the day, provides symptomatic relief for an estimated 240 million people across the nation, 60 million of whom would not seek treatment if OTC medicines were not available. If even a small fraction of those ailments were left untreated and became worse, the increase in visits to a physician could be catastrophic for the healthcare system. The annual retail sales of OTC medicines currently consumed by those 60 million people are approximately equal to \$4 billion in the study's target therapeutic categories. This figure is the direct value of increased access provided by OTC medicines.

The study also found OTC medicines 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. By keeping the American workforce healthy and at work, OTC medicines offer \$23 billion in potential productivity benefits from avoided doctor's office visits and time not having to be away from work for medical appointments.

The Affordable Care Act and Tax-Preferred Accounts

In 2003, the Internal Revenue Service expanded coverage of tax-preferred accounts, such as flexible spending arrangements (FSAs) and Health Savings Accounts (HSAs), to include OTC medicines as qualified medical expenses, allowing consumers to purchase OTC medicines with pre-tax dollars. In the subsequent years, millions of consumers budgeted for their annual healthcare expenses, enrolled in an FSA program, set aside pre-tax money, and utilized their FSA accounts to purchase OTC medicines. The retail community made this process as seamless as possible by identifying eligible products and processing the payments electronically through the consumers' FSA accounts.

Unfortunately for consumers and the healthcare system, the efficiencies in processing these transactions ended on January 1, 2011. That is the date that a provision included in PPACA, which requires holders of FSAs, HSAs, and other tax-preferred accounts to first seek a doctor's prescription before purchasing or being reimbursed for purchases of OTC medicines, went into effect. There is no medical justification for this requirement, and as a nation, we want to encourage Americans to make smart, efficient healthcare choices, including through utilizing FSAs for OTC medicine purchases. But instead, the law today discourages efficient choices and sends the wrong signal.

The requirements leave consumers with three options:

- 1) Seek an unnecessary appointment with a doctor to obtain a prescription, and then submit the purchase for reimbursement under an FSA account;
- 2) Purchase the OTC medicine out-of-pocket, increasing the cost to the consumer by 10 percent to 35 percent, depending on the individual's tax bracket; or
- 3) Forego treatment entirely, and suffer from the symptoms of the condition.

None of these options is good healthcare policy. None of these options increases access to healthcare. But all three do increase costs for the consumer and to our healthcare system.

According to the Employers Council on Flexible Compensation (ECFC), in 2008, which is the most recent year for which data is available, 35 million Americans participated in an FSA program, earning an average of \$55,000 per year and contributing \$1,386 to their FSA annually. A separate analysis by

Nielsen estimates American households using FSAs for OTC medicines spent approximately \$136 on OTC medicines in 2010, but spent 12 percent less on OTCs in 2011.⁴

An additional survey⁵ conducted by Nielsen found that of the 9.8 million households who have utilized an FSA to purchase an OTC medicine, 46.3 percent—roughly half—would request a prescription for OTC medicines from their physician. 21 percent of respondents said that they would discontinue or drastically reduce purchasing OTC medicines, meaning they would either seek a higher-cost prescription medication or leave their ailments untreated. Either way, the requirement to seek a prescription before an FSA or HSA can be used to purchase an OTC means higher costs to the healthcare system and a logistical burden on the American consumer.

In order to address this issue, CHPA was the principal founder of the Health Choices Coalition, a coalition of physicians, pharmacies, pharmacists, insurers, pharmacy benefit managers, patient groups, retailers, manufacturers, and large employers that is dedicated to restoring OTCs to tax-preferred status. To date, representatives of the Health Choices Coalition have met with most members of the House Committee on Ways & Means, as well as many other members of the House of Representatives at large. Specifically, the Coalition supports the “Restoring Access to Medication Act” (H.R. 2529), which was introduced by Representatives Lynn Jenkins (R-KS) and Shelley Berkley (D-NV), and the “Patients’ Freedom to Choose Act” (H.R. 605), introduced by Representative Erik Paulsen (R-MN). We thank the sponsors and co-sponsors of these two bills, as well as the more than 100 sponsors of these and other bills that include a provision aimed at addressing the treatment of OTC medicines in tax-preferred accounts. Their leadership on this effort has been invaluable and we look forward to continuing to work with them on this important issue.

In conclusion, I reiterate that OTCs are a vital and valuable part of the healthcare system. CHPA and its member companies believe strongly that OTC medicines deserve the same tax treatment as other medical costs, such as prescription drugs or medical devices. We encourage each Member of Congress to examine H.R. 2529 or H.R. 605 and consider signing on as a cosponsor. I thank Chairman Boustany and Ranking Member Lewis for inviting me here today and for holding this important hearing.

⁴ Nielsen/CHPA Correspondence, April 2012

⁵ “Impact of Flexible Spending Account Rule Changes on OTC Purchasing,” Nielsen on behalf of CHPA, January, 2011

Appendix

1. Your Health at Hand – “Perceptions of Over-the-Counter Medicine in the U.S.” Survey Key Findings
2. Your Health at Hand – “The Value of OTC Medicine to the United States” Study Key Findings
3. Paul London and Associates – “Potential Reduction in Unnecessary Visits to Doctors from Safe and Appropriate Use of OTC Medicines” Economic Study Introduction
4. Nielsen - “Impact of Flexible Spending Account Rule Changes on OTC Purchasing” Survey
5. Supplement to Nielsen Survey Data

(These studies can be found in full at <http://www.yourhealthathand.org/resources-and-news>)

KEY FINDINGS: “Perceptions of Over-the-Counter Medicine in the U.S.”

Key Findings: Physicians

- + OTC medicines are an important part of healthcare management.
 - 93% of physicians agree that it is important that medicines for minor ailments be available over the counter.
 - 87% of physicians believe OTC medicines are an important part of overall healthcare.

- + OTC medicines help reduce the burden on medical professionals.
 - On average, physicians say about 10% of office visits result from minor ailments which could be self-managed by patients, including by the use of OTC medicines. This amounts to over 40 million appointments each year that could be avoided with self-care.
 - 89% of physicians agree that responsible use of over-the-counter medicines can help to ease the burden on medical professionals.
 - 76% of physicians agree that the availability of over-the-counter medicines help make managing patient health easier.

- + Physicians trust OTC medicines to help consumers safely and effectively care for their minor ailments.
 - 92% of physicians believe OTC medicines are effective and 91% believe these medicines are safe.
 - 88% of physicians agree that they recommend patients try to address minor ailments with self-care interventions, including the use of OTC medicines, before seeking professional care.
 - Physicians are more likely to recommend over-the-counter medicines as a first response treatment option for adult’s minor ailments than options like calling a physician or scheduling a doctor’s appointment.

Key Findings: Consumers

- + 80% of consumers have used an over-the-counter medicine in the last year.

- + OTC medicines provide consumers with affordable, accessible and convenient healthcare.
 - 86% of U.S. adults believe responsible, over-the-counter medicine use helps lower healthcare costs for people like them.
 - 68% of U.S. parents have given their child an OTC medicine late at night to help treat a sudden medical symptom.

- 46% of U.S. adults who believe OTC medicines are important believe so because they do not need a doctor’s visit to use them.
- + Consumers trust over-the-counter medicines to provide relief for minor ailments.
 - 89% believe over-the-counter medicines are an important part of their overall family health care.
 - 81% of U.S. adults use OTC medicines as a first response to minor ailments.
 - U.S. adults believe over-the-counter medicines are just as safe and effective as prescription medicines when taken according to directions.
- + Over-the-counter medicines empower consumers to take charge of their own health.
 - 96% of U.S. adults believe over-the-counter medicines make it easy for individuals to care for minor medical ailments.
 - 93% of U.S. adults prefer to treat their minor ailments with over-the-counter medicines before seeking professional care.
 - 86% of U.S. adults agree that medical visits for minor ailments are unnecessary because of the availability of over-the-counter medicine.
 - 85% of U.S. parents prefer to treat their children’s minor ailments with an OTC medicine before seeking professional care.

About Your Health at Hand

- + “The Value of OTC Medicine to the United States” is a part of CHPA’s *Your Health at Hand* initiative. For millions of Americans, OTC medicines are a trusted and affordable way to get well, stay well, and feel well. Families reach for OTC medicines to relieve symptoms associated with common, everyday ailments associated with pain, cold, allergies, heartburn, and various skin conditions, among others. In today’s healthcare environment, it is important that consumers—as well as healthcare professionals, policymakers, and researchers—appreciate and promote the value and solutions OTC medicines provide. In June 2011, CHPA launched *Your Health at Hand* to highlight the benefits of OTC medicines, including:
 - Access to conveniently available healthcare options 24/7 for busy families and caregivers;
 - Affordability for both consumers and the healthcare system;
 - Empowerment for individuals and families to meet their everyday healthcare needs; and
 - Trust in safe and effective healthcare options.
- + For more information on *Your Health at Hand*, please visit: www.YourYealthAtHand.org.

The Consumer Healthcare Products Association (CHPA) is the 131-year-old-trade association representing U.S. manufacturers and distributors of over-the-counter medicines and dietary supplements. www.chpa-info.org.



KEY FINDINGS: “THE VALUE OF OTC MEDICINE TO THE UNITED STATES”

Over-the-counter (OTC) medicines: Providing solutions for America’s healthcare challenges

- + The availability of OTC medicines creates significant value for the U.S. healthcare system – \$102 billion in annual savings relative to alternatives. OTC medicines provide two key sources of avoided cost:
 - \$77 billion in clinical cost savings (avoided doctor’s office visits and diagnostic testing); and
 - \$25 billion in drug cost savings (lower-priced OTCs versus higher-priced prescription medicines).
- + For every dollar spent on OTC medicines, the U.S. healthcare system saves \$6 to 7.
- + The total value of OTC medicines is captured throughout entire U.S. healthcare system:
 - \$52.7 billion in value for employer sponsored health plans
 - \$27.5 billion in value for government programs (Medicare and Medicaid)
 - \$21.7 billion in value for self-insured and uninsured populations
- + The availability of OTC medicines – off the shelf, without a prescription – provides symptomatic relief for an estimated 60 million people who otherwise would not seek treatment.
 - The annual retail sales of OTC medicines to these 60 million consumers are \$4 billion. This figure is the direct value of increased access provided by OTC medicines.
- + Without affordable and accessible OTCs, underserved populations would depend more heavily on the highest-cost medical care for minor ailments.
 - 1 in 4 Medicaid patients and 1 in 10 uninsured individuals would seek treatment in an Emergency Department as their first recourse for treatment.
 - Additional Emergency Department visits, primarily by patients on Medicaid and uninsured individuals, will drive up nearly \$4 billion in healthcare costs to the system each year.
- + By keeping the American workforce healthy and at work, OTC medicines offer \$23 billion in potential productivity benefits from avoided doctor’s office visits and time not having to be away from work for medical appointments.
- + “Caregiver moms” miss twice as many days of work annually to care for sick children as they do to care for themselves. This number would be higher if parents did not have OTC medicines to help children avoid missing school.
- + Nearly one-third of the \$102 billion in annual savings is for consumers treating cough/cold and flu symptoms.

About the Study

- + This study examines the value of OTC medicines in seven categories relative to potential alternatives, such as consultations with healthcare professionals for self-recognizable symptoms and/or prescription medicines.
- + The seven categories include the most common acute and chronic, self-treated conditions representing the majority of OTC medicine purchases: allergy, analgesics, anti-fungals, cough/cold/flu, lower and upper gastrointestinal, and medicated skin.
- + In addition to consulting published data sets and economic modeling, the study firm surveyed 3,200 consumers on how they would treat symptoms if OTC medicines did not exist.
- + This study was conducted by Booz & Co. and funded by the Consumer Healthcare Products Association (CHPA).

About Your Health at Hand

- + “The Value of OTC Medicine to the United States” is a part of CHPA’s *Your Health at Hand* initiative. For millions of Americans, OTC medicines are a trusted and affordable way to get well, stay well, and feel well. Families reach for OTC medicines to relieve symptoms associated with common, everyday ailments associated with pain, cold, allergies, heartburn, and various skin conditions, among others. In today’s healthcare environment, it is important that consumers—as well as healthcare professionals, policymakers, and researchers—appreciate and promote the value and solutions OTC medicines provide. In June 2011, CHPA launched *Your Health at Hand* to highlight the benefits of OTC medicines, including:
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Paul A. London and Associates;

**Paul A. London, PhD
Daniel Shostak, MPH/MPP**

June 17, 2011

Potential Reduction in Unnecessary Visits to Doctors from Safe and Appropriate Use of OTC Medicines Could Save Consumers and Taxpayers Billions Annually

The cost of healthcare in America is staggering. Healthcare expenditures in the United States (U.S.) surpassed \$2.3 trillion in 2008, more than three times the \$714 billion spent in 1990. Greater use of safe and effective over-the-counter (OTC) medicines, those available without a prescription, could help Americans cut healthcare costs while meeting their everyday healthcare needs.

The aim of this paper is to estimate savings that could be achieved by reducing unnecessary visits to primary care physicians for patients who can address symptoms with appropriate use of OTC medicines. For the purpose of this research, we defined primary care physicians as including pediatricians, internists, and general practitioners based on definitions from the Centers for Disease Control and Prevention (CDC). The Your Health at Hand survey referenced throughout also included pediatricians and internists in its definition of primary care physicians. Our research makes the following important points:

- Primary care physicians (including internists and pediatricians) have estimated that 10 percent or more of visits to their offices were unnecessary and could have been avoided by self-management of healthcare, including the use of OTC medicines for minor ailments.¹
- Patients made 1.5 billion visits to medical offices in 2008, including 992 million visits where they saw a doctor.²
- Of the 992 million visits to doctors, approximately 525 million were visits to primary care physicians.³
- The average total payment for a visit where the patient saw a doctor was \$199, including \$28 in out-of-pocket (OOP) costs.⁴
- If one-half of the visits that primary care physicians report as unnecessary could be avoided by greater self-management of healthcare including more use of OTC medicines, it would save consumers and taxpayers \$5.2 billion annually.
- The shortage of primary care physicians in the United States is becoming increasingly problematic. Reducing unnecessary visits from 10 percent to 5 percent (by 26.3 million visits annually) would save overburdened doctors almost a half hour per day, allowing them to focus on more urgent patient needs.

There are other economic advantages that would come with greater self-management of certain health conditions and minor ailments, including through efficient, effective use of OTC medicines. These advantages include time and monetary gains for consumers and employers if less time was spent in doctors' offices, but these are not evaluated in our savings estimates.

Introduction

OTC medicines are an affordable and effective first-line treatment for a variety of common minor conditions.⁵ (See section below on *Conditions Amenable to Treatment with OTC Medicines*.) A survey of primary care physicians and consumers (the “Your Health at Hand survey”) conducted by StrategyOne in November 2010 for the Consumer Healthcare Products Association (CHPA) confirms this: 92 percent of doctors surveyed agreed that OTC medicines are effective in this first-line treatment role.⁶

The Your Health at Hand survey also found that doctors believe a significant number of office visits – about 10 percent according to the primary care physicians – are unnecessary and could be reduced with more self-management of healthcare by patients with minor conditions, including reliance on OTC medicines. If unnecessary visits could be reduced from 10 to 5 percent (that is by approximately 26.3 million per year) it would save the healthcare system \$5.2 billion annually. The body of this paper examines these and other costs, and describes how we arrive at the estimates of potential savings from reducing unnecessary visits.

Unnecessary Visits that Could Be Avoided by Greater Self-management of Healthcare and OTC Medicines

A significant number of Americans, despite evidence of the safety and effectiveness of OTC medicines, choose to visit a doctor’s office or an emergency room (ER) with minor ailments. Primary care physicians, including internists and pediatricians, interviewed in the Your Health at Hand survey estimated that about 10 percent of visits to their offices could be avoided if more patients managed minor ailments through self-management of healthcare including the use of OTC medicines.^{7,8}

Unfortunately, time wasted during unnecessary doctor visits has a significant cost associated with it. This includes the primary care physicians’ time and that of their staffs, unnecessary tests and procedures as well as labor and resources used to treat patients during visits to ERs and clinics, all of which are far more expensive than the costs of the OTC medicines that in some and perhaps many cases could be tried first. Data from the Medical Expenditure Panel Survey (MEPS) – part of the Agency for Healthcare Research and Quality (AHRQ) of the U.S. Department of Health and Human Services (HHS) – put the mean cost of a non-surgical visit to a doctor’s office at \$199, of which \$28 represents out-of-pocket (OOP) costs to patients.

Impact of Flexible Spending Account Rule Changes on OTC Purchasing

Dennis Callahan
Director, Health Panel Services

January, 2011

The Nielsen logo is located in the bottom right corner of the slide. It consists of the word "nielsen" in a lowercase, sans-serif font, with a series of seven dots underneath it. The logo is contained within a white circular shape that overlaps the blue background and the grey footer.

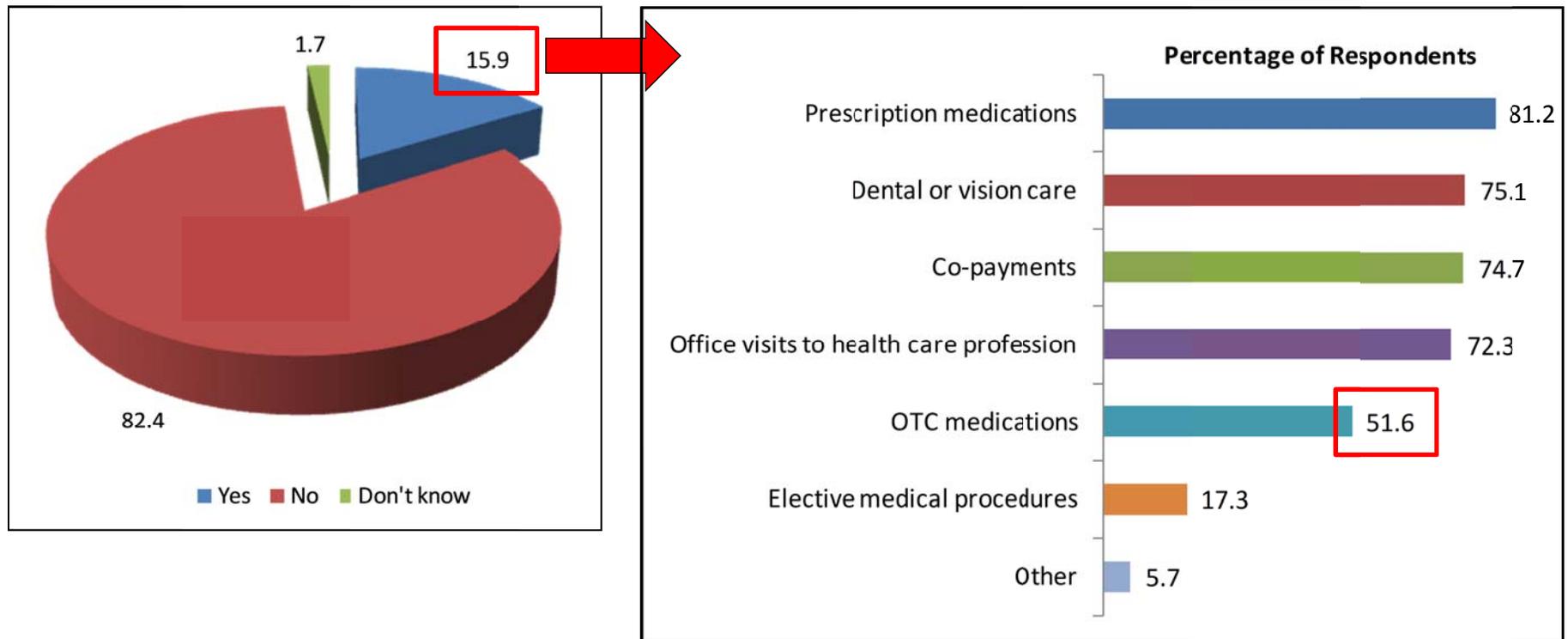
nielsen

FSA Rule Changes

Slightly over half of the FSA enrollees covered the costs of their OTC medications with FSA funds in the past 12 months.

- This equates to 9.8 million US households.

FSA Usage for Eligible Expenses

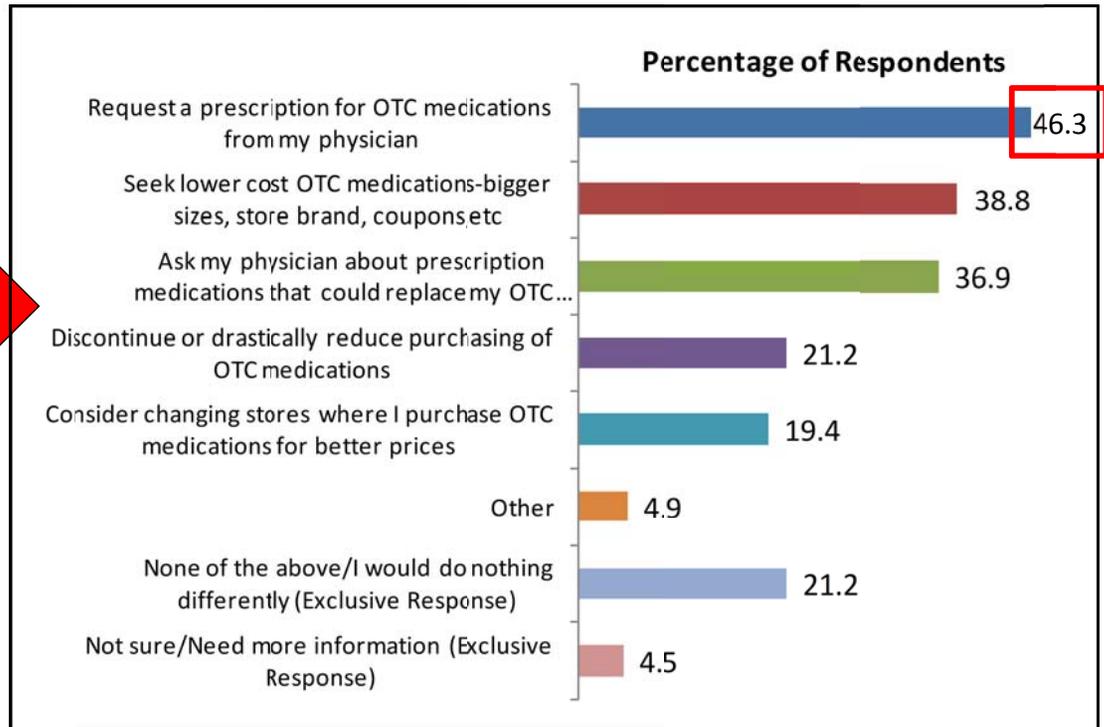
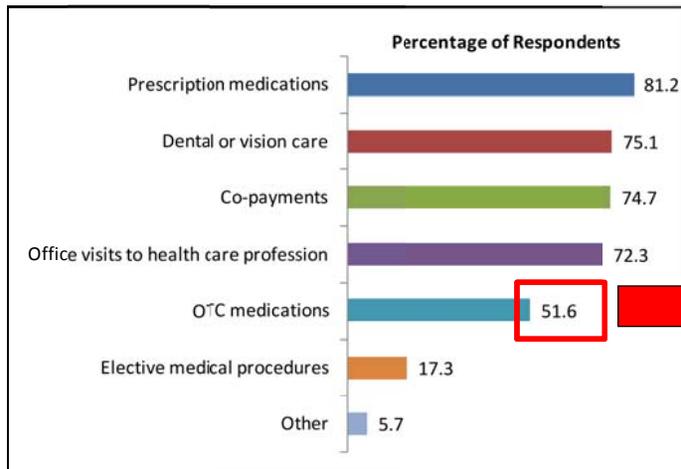


For which of the following eligible health care expenses have you or other household members used Flexible Spending Account (FSA) funds to cover costs during the past 12 months? Please select all that apply.

Faced with losing FSA funds to pay for OTC, consumers will likely be resilient. Physicians will likely play a key role as healthcare utilization patterns change.

- 21% said they would discontinue or drastically reduce purchasing of OTC medications.

FSA OTC Eligibility Elimination - Alternatives



If non-prescription/over-the-counter medication costs were no longer eligible to be paid for with FSA funds which of the following, if any, would you most likely do differently? Please read all the response options and then select all that apply.

Supplement to Nielsen Survey Data

	Total US				Used FSA Funds for OTC in 2010*		
	12/27/09 - 12/25/10	12/26/10 - 12/24/11	% CHG		12/27/09 - 12/25/10	12/26/10 - 12/24/11	% CHG
Total OTC	\$121.92	\$119.35	-2%		\$135.88	\$120.07	-12%
Cough and Cold Remedies	\$41.06	\$42.51	4%		\$47.69	\$46.43	-3%
First Aid	\$16.71	\$15.90	-5%		\$18.90	\$16.21	-14%
Acne Remedies	\$14.34	\$14.42	1%		\$14.63	\$13.95	-5%
Antacids/Anti-gas	\$28.17	\$25.67	-9%		\$28.44	\$21.95	-23%
Laxatives	\$23.32	\$24.24	4%		\$21.78	\$18.74	-14%
Pain Remedies	\$23.38	\$22.80	-2%		\$20.11	\$20.96	4%