IMPACT OF LIMITATIONS ON THE USE OF TAX-ADVANTAGED ACCOUNTS FOR THE PURCHASE OF OVER-THE-COUNTER MEDICATION

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT

OF THE

COMMITTEE ON WAYS AND MEANS

U.S. HOUSE OF REPRESENTATIVES

ONE HUNDRED TWELFTH CONGRESS

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IMPACT OF LIMITATIONS ON THE USE OF TAX-ADVANTAGED ACCOUNTS FOR THE PURCHASE OF OVER-THE-COUNTER MEDICATION

WEDNESDAY, APRIL 25, 2012

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON OVERSIGHT,
Washington, DC.

The subcommittee met, pursuant to call, at 2:30 p.m., in Room 11002, Longworth House Office Building, the Honorable Charles Boustany [chairman of the subcommittee] presiding.

[The advisory of the hearing follows:]

HEARING ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

Boustany Announces Hearing on the Impact of Limitations on the Use of Tax-Advantaged Accounts for the Purchase of Over-the-Counter Medication

Wednesday, April 25, 2012

Congressman Charles W. Boustany, Jr., MD, (R–LA), Chairman of the Subcommittee on Oversight of the Committee on Ways and Means, today announced the Subcommittee will hold a hearing on limitations on the purchase of over-the-counter ("OTC") medication with tax-advantaged accounts such as health care Flexible Spending Arrangements ("FSAs"), Health Savings Accounts ("HSAs") and Health Reimbursement Accounts ("HRAs"). **The hearing will take place on Wednesday, April 25, 2012, in Room 1100 of the Longworth House Office Building, beginning at 2:30 P.M.**

In view of the limited time available to hear witnesses, oral testimony at this hearing will be from invited witnesses only. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing. A list of invited witnesses will follow.

BACKGROUND:

Millions of Americans currently use tax-advantaged accounts to save for medical expenses defined as "qualified" by the Internal Revenue Code (IRC). Contributions to and distributions from these accounts are generally tax-exempt and may be used for unreimbursed medical expenses such as deductibles and co-payments. Approximately 33 million Americans are in families with FSAs, which are offered by 29 percent of small businesses and 85 percent of large employers. An additional 11.4 million Americans are enrolled in an HSA.

Until 2011, these account holders could use their tax-free savings to purchase OTC medication without a prescription. Recent changes to the Tax Code modified the definition of qualified medical expenses, generally prohibiting Americans from using their FSA, HSA or HRA funds for medication not prescribed by a health care provider. As a result, Americans must now purchase non-prescribed OTC medications with after-tax dollars, resulting in a tax increase on American families.

Physician groups have suggested that the OTC medication prescription requirement has imposed an unreasonable administrative burden, resulted in longer waits for appointments, and increased health care costs. The Subcommittee's hearing will examine how these changes have specifically affected patients, consumers, physicians, and health care costs and spending.

In announcing the hearing, Chairman Boustany said, **"Too often in Washington, officials make decisions about health care policy based on abstract theories and budgetary scores. This hearing will focus on how one decision in particular—the limitation on how consumers may use their own FSA, HSA or HRA money—has adversely affected access and affordability for families, physicians, and job creators."**

FOCUS OF THE HEARING:

The hearing will focus on reviewing the rules affecting FSAs, HSAs and HRAs and the impact the rules have on consumers, physicians, and employers.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Please Note: Any person(s) and/or organization(s) wishing to submit for the hearing record must follow the appropriate link on the hearing page of the Committee website and complete the informational forms. From the Committee homepage, *http://waysandmeans.house.gov*, select "Hearings." Select the hearing for which you would like to submit, and click on the link entitled, "Click here to provide a submission for the record." Once you have followed the online instructions, submit all requested information. ATTACH your submission as a Word document, in compliance with the formatting requirements listed below, **by the close of business on Tuesday, May 9 2012**. Finally, please note that due to the change in House mail policy, the U.S. Capitol Police will refuse sealed-package deliveries to all House Office Buildings. For questions, or if you encounter technical problems, please call (202) 225–1721 or (202) 225–3625.

FORMATTING REQUIREMENTS:

The Committee relies on electronic submissions for printing the official hearing record. As always, submissions will be included in the record according to the discretion of the Committee. The Committee will not alter the content of your submission, but we reserve the right to format it according to our guidelines. Any submission provided to the Committee by a witness, any supplementary materials submitted for the printed record, and any written comments in response to a request for written comments must conform to the guidelines listed below. Any submission or supplementary item not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. All submissions and supplementary materials must be provided in Word format and MUST NOT exceed a total of 10 pages, including attachments. Witnesses and submitters are advised that the Committee relies on electronic submissions for printing the official hearing record.

2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. All submissions must include a list of all clients, persons and/or organizations on whose behalf the witness appears. A supplemental sheet must accompany each submission listing the name, company, address, telephone, and fax numbers of each witness.

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202–225–1721 or 202–226–3411 TTD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

Note: All Committee advisories and news releases are available on the World Wide Web at *http://waysandmeans.house.gov/*.

Chairman BOUSTANY. The subcommittee will come to order. I would like to welcome everyone to this afternoon's hearing on the limitations of the Democrats' health care law that places on consumers use of tax-advantaged plans to purchase over-the-counter medication.

Millions of Americans use tax-advantaged plans to save for medical expense. Plans such as flexible spending arrangements, health reimbursement arrangements, health savings accounts allow consumers to set aside funds for out-of-pocket health care expenses such as deductibles, co-payments, and until recently over-the-counter products not typically covered by insurance. Contributions to and distributions from these plans are generally tax exempt and make health care more affordable to well over 40 million families.

Until 2011, families with tax-advantaged plans could use these funds to purchase over-the-counter medications such as allergy

medication, cold and flu remedies, first-aid products without a doctor's prescription. However, to pay for the massive entitlement expansion in the President's health care law the new law required that consumers using tax-advantaged plans must first obtain a doctor's prescription in order to use tax-preferred account funds to purchase over-the-counter medication. This provision alone is a $5 billion tax increase on the American people.

As a result, millions of Americans now first have to visit a physician's office before going to a drugstore to purchase cold medicine with their FSAs, for example. This leads to increased wait times in doctors' offices, greater cost both in time and dollars for consumers and potential delay in obtaining treatment. This policy was not enacted to cure a problem or to promote better health care spending, this was done to raise revenue, pure and simple.

When the new law was first enacted the American Medical Association wrote that the limitations would, I quote, increase cost to the health care system, generate unnecessary physician office visits and place a new administrative burden on doctors, end quote. A Wall Street Journal article from last year quoted one pediatrician as saying, and I quote, I am now doing the IRS's work and that is what I resent most, end quote.

This afternoon's hearing is not designed to be a broad debate about the 2010 health care law. Instead it is to examine one provision in the new health care law and hear from our witnesses how this is affecting consumers, physicians, job creators in the health care sector.

And with that I want to welcome our witnesses here today, and I look forward to a fruitful discussion on this very important topic. Ranking Member Lewis has been detained. He should be here shortly. But I will now yield to my friend Mr. Becerra from California for the purposes of an opening statement.

Mr. BECERRA. Thank you, Mr. Chairman, for holding this hearing today. Health care is an important topic that touches the lives of millions of Americans. The Affordable Care Act will expand comprehensive health insurance coverage to over 30 million Americans and has already insured millions of young adults and people with preexisting conditions. It contains important insurance reforms that will benefit both those who are insured today and those who are not insured.

The Affordable Care Act will reduce the deficit by over $120 billion over 10 years and over $1 trillion over 20. The Act did not add to the deficit and was fully paid for by a number of provisions. One of those provisions is before us today, a provision that affects the tax treatment of reimbursements for over-the-counter medicines from certain tax-favored accounts.

The provision before us today raised about $5 billion. This provision was initially suggested in a 2005 report from the Joint Committee on Taxation as an option to improve tax compliance. The new rule states that over-the-counter medications may no longer be reimbursed from flex spending accounts, health savings accounts or health reimbursement accounts without a prescription from a physician.

I look forward to hearing from the witnesses today. I would like to learn more about how the new rule is affecting taxpayers and

the health care system and how any changes to this provision would interface with the notion and desire for tax reform. Many people, including some on this committee, have said that we should eliminate all tax expenditure programs, which are those specialty programs that affect only certain populations within the Tax Code, and this would fall within the category of one of those tax expenditure programs. And I would be very interested to see what the witnesses have to say about that.

So, Mr. Chairman, I thank the witnesses in advance for their testimony and their willingness to share their experiences. And with that, I yield back the balance of my time.

Chairman BOUSTANY. I thank the gentleman from California. And let me just say that I ask unanimous consent that all members' written statements be included in the record. Without objection it is so ordered. And when Mr. Lewis gets here I will also allow him out of courtesy to give an opening statement since he is ranking member of this subcommittee.

I want to thank our witnesses for being here this afternoon. We will hear from Scott Melville, President of the Consumer Health Care Products Association. Mr. Melville, welcome. We have Dr. Joel Feder, a member of the American Osteopathic Association. Welcome, sir. Steven Taylor of the Sjogren's Syndrome Foundation. Mr. Taylor, welcome. Jennifer Hatcher, who is Senior Vice President of the Food Marketing Institute. Ms. Hatcher, welcome. And Peter Van de Water, Senior Fellow of the Center on Budget and Policy Priorities. Welcome. I want to thank you all for being here today. You will each have 5 minutes to give your statements for the record, but your full written statements will be included in the record of this hearing.

Mr. Melville, we will begin with you. You have 5 minutes.

STATEMENT OF SCOTT M. MELVILLE, PRESIDENT AND CHIEF EXECUTIVE OFFICER, CONSUMER HEALTHCARE PRODUCTS ASSOCIATION, Washington, D.C.

Mr. MELVILLE. Thank you, Chairman Boustany, Ranking Member Lewis, other Members of the Subcommittee. Thank you for holding this hearing and inviting me to testify on behalf of the Consumer Health Care Products Association, the national association representing manufacturers and distributors of over-the-counter medicines and dietary supplements.

OTC medicines are a vital part of our Nation's health care system and often serve as a first line of treatment for many common self-manageable conditions like colds, allergies, heartburn and headaches. OTC medicines are like prescription medicine pharmaceuticals regulated by the Food and Drug Administration. However, OTCs can be purchased by consumers without a prescription because the FDA has determined that the medicine can be safely used by a consumer without the intervention of a doctor or other health care professional.

This broad availability of OTC medicines 24/7 in a wide range of retail outlets, including pharmacies, provides tremendous benefit to both consumers and our health care system. In fact, a recent study by Booz & Company estimated that OTCs provide $102 billion in benefits to our Nation's health care system every year. These bene-

fits are realized first through reduced doctor visits accounting for approximately $77 billion of those savings; and, two, reduced drug costs relative to prescription products accounting for $25 billion. Consumers, public and private payers and the economy all benefit. The authors concluded that each dollar spent on OTC medicine saves the Nation's health care system $6 to $7.

Access to OTC medicines empowers consumers and allows them to take greater control over their health care and their health care spending. So do flexible spending arrangements, or FSAs, which were designed to help Americans afford the portions of health care costs not covered by insurance. In 2003 the Internal Revenue Service first authorized the use of FSAs for the purchase of OTC medicines, confirming their equal status with prescription pharmaceuticals for purposes of FSA eligibility. In subsequent years millions of consumers budgeted for their health care, set aside pretax money and utilized FSA continuance to purchase OTC medicines. Retailers made it a seamless transaction by identifying eligible products and processing the payment electronically through the consumer's FSA accounts.

Unfortunately, for consumers and the health care system that efficient process ended on January 1, 2011. That is when a provision in the Affordable Care Act took effect that requires consumers to seek a prescription for a medicine that doesn't require one if they want to utilize their FSAs to purchase an OTC medicine. There is no medical or regulatory justification for this. It is simply a legal requirement under the new law if they want to use their tax-advantaged FSA.

This leaves consumers with three options. One, to seek an unnecessary doctor's appointment to get a prescription and then submit the purchase for reimbursement under their FSA account. Two, to purchase the OTC medicine out of their own pocket which will raise the cost of the product to the consumer between 10 or 35 percent depending on their individual tax bracket. Or three, go without treatment. None of these options we would suggest are good health care policy, none of these options increase health care access, but they do increase cost to consumers and to our health care system.

According to the Employers Council on Flexible Compensation, the average FSA participant earned approximately $55,000 per year and contributed around $1,400 to their FSA in 2008, the latest data that we were able to access. Clearly FSA accounts benefit a broad cross-section of America. And a recent Neilsen study found that of 19 American households that participated in a FSA program roughly half of them used their FSAs to purchase OTC medicines before the treatment was changed.

Now, our industry is not alone in advocating for restoration of eligibility of OTCs under FSA accounts, and we are pleased there is a growing bipartisan support in Congress to do just that. CHPA is one of the founding members of the Health Choices Coalition, which includes physicians, patient groups and retailers that is dedicated to restoring OTCs to tax-preferred status. The coalition supports legislation sponsored by Representative Lynn Jenkins and Shelley Berkley and also Representative Diane Black, and also supports bills sponsored by Representative Erik Paulsen and co-spon-

sored by you, Chairman Boustany, and Representative Aaron Schock as well. We thank these members for leading the fight. If we are not successful, this unnecessary policy will continue to cost Americans time, money and needless suffering.

Mr. Chairman, thank you again for allowing me the opportunity to testify before this subcommittee, and I will be happy to answer any questions you may have.

[The prepared statement of Mr. Melville follows:]

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
Scott Melville
President and CEO
Consumer Healthcare Products Association

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 2010[1] 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 study[3] 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.

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[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 survey[5] 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.

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[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)

yourhealth AT HAND

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.

CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

- 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.

CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

yourhealth AT HAND

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.

CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

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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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.

CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

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

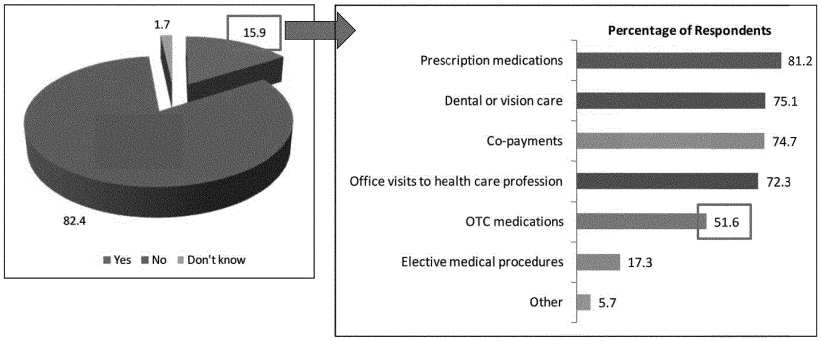
nielsen

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.

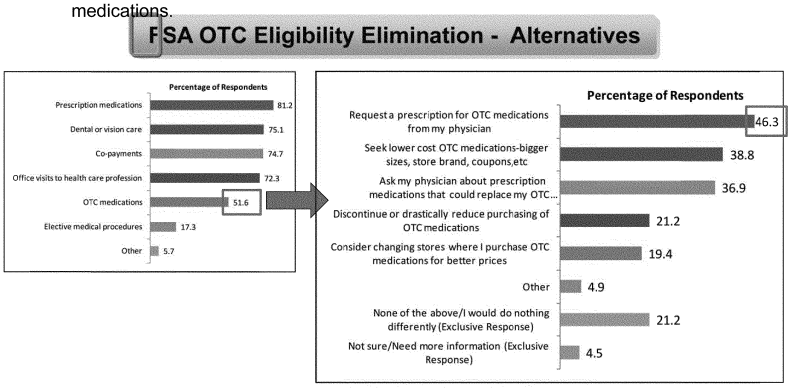
FSA Usage for Eligible Expenses



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.



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%

Chairman BOUSTANY. Thank you, Mr. Melville. Dr. Feder, you may proceed.

STATEMENT OF DR. JOEL M. FEDER, D.O., F.A.C.O.F.P., CAPTAIN MC, USN (RET.), AMERICAN OSTEOPATHIC ASSOCIATION, OVERLAND PARK, KS

Dr. FEDER. Chairman Boustany, Ranking Member Lewis, Representative Jenkins and Members of the Subcommittee, thank you for the opportunity to testify before you today.

As an osteopathic physician board certified in family medicine, I have treated patients for 36 years. The osteopathic profession has a strong and distinguished history of educating, training and placing physicians in underserved communities. Today over 60 percent of all osteopathic positions practice in a primary care specialty.

Over the years I have witnessed efforts to enhance access to quality health care and promote patient centered care. Today I share with you my personal experience of how the new restrictions placed on consumers choosing to use their tax-advantaged account to purchase over-the-counter medications has affected my practice and my patients.

As a physician my paramount concern is developing and preserving a strong relationship with my patients. I along with my colleagues strive to empower patients to make decisions regarding their health while still coordinating their care. In doing so, I aim to put practices into place that allow them to stay out of the office as a result of good health.

In my experience with this new requirement the majority of the patients that request a prescription for an OTC medication are doing so to address a simple cold or allergy. However, this still requires an appointment slot normally allocated for other patient needs. As a result my time available to treat patients with more serious health care needs has reduced significantly. On average I see about 25 patients per day, spending 15 to 20 minutes with each patient, 90 percent of whom visit my office for traditional care ranging across a wide array of health care needs, plus 10 percent who are simply requesting a prescription for OTC medication and in some instances numerous medications.

My practice is a relatively small practice with five providers, including four physicians and one advanced registered nurse practitioner. We have an administrative staff of 10 working in the office who are extremely busy processing paperwork to keep the office running and filing claims for the patient care my partners and I provide. The additional task of processing requests for appointments for OTC prescriptions is an unnecessary burden. This new burden is in addition to the further demands on physician practices, including the adoption of electronic health records and electronic prescribing systems, preparation for coding under ICD–10, implementation of quality measures and adjusting to other changes in the health care delivery system. These additional policies and procedures are important; however, each new requirement can be quite costly to small physician practices.

As you know, physicians work hard to establish a trusting relationship with their patients. Generally patients choose to see their physician when they truly believe they need care. And my experience is most patients feel inconvenienced and unhappy with a new prescription requirement and enter my office with that mindset. As a result, I am potentially placed in a difficult and uncomfortable situation with a patient by possibly refusing to provide a prescription, charging for that service and/or recommending the patient purchase a different higher cost alternative. For instance, I do not agree with the practice of using OTC medicines as a source of renewed energy. A patient might then seek to choose another physician who is willing to write their prescription, which further fragments the important physician-patient relationship.

We must remember that the FDA has already deemed these products safe and appropriate for direct over-the-counter sale to consumers, yet after writing the prescription physicians may be subject to new liability for any potential interactions they might

have with other over-the-counter medications my patient has taken which the patient may or may not be willing to disclose.

In closing, restricting consumers who choose to use their tax-advantaged account to purchase OTC medications by requiring them to obtain a prescription from their physician is unnecessary and disruptive to efficient care delivery. This restriction creates an unnecessary burden upon me as a physician, upon my practice and, most importantly, upon my patients.

I would again like to thank you and Members of the Committee for affording me the opportunity to share my experiences and the AOA's perspective regarding this important topic affecting osteopathic physicians and our patients. We appreciate the work that you do to promote policies that advance patient centered quality care that is cost effective for the health care system. We look forward to working with you in the weeks and months ahead to ensure that congressional action fosters strengthening the physician-patient relationship.

Thank you.

[The prepared statement of Dr. Feder follows:]

Statement of Joel M. Feder, DO, FACOFP, Captain MC, USN (Ret)
American Osteopathic Association

Presented to the
House Ways and Means Committee
Subcommittee on Oversight

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

April 25, 2012

Chairman Boustany, Ranking Member Lewis, and Members of the Subcommittee, on behalf of the American Osteopathic Association (AOA), thank you for the opportunity to testify today on the new restriction placed on consumers that choose to use their Flexible Spending Account (FSA), Health Savings Account (HSA), or other tax-advantaged account to purchase over-the-counter (OTC) medications. My name is Joel Feder, I am a retired U.S. Navy Medical Officer and a Board Certified Family Practitioner in Overland Park, KS. I am co-owner and a partner of Overland Park Family Health Partners. My practice includes the full gamut of family medicine services from birth to geriatrics. We are located in a suburban setting serving a significant number of retired and dependent military patients.

I am the past president of the medical staff at Overland Park Regional Medical Center and I am the past president of the Kansas Association of Osteopathic Medicine. I also serve on the adjunct teaching faculty of the University of Kansas School of Medicine, Department of Family Practice and am a clinical preceptor for the Kansas City University of Medicine and Biosciences.

I have treated patients for 36 years. Over the years I have maintained active involvement on numerous medical boards. Today, I am pleased to share with you my personal experience of how the new restriction placed on consumers choosing to use their tax-advantaged account to purchase over-the-counter medications by requiring them to obtain a prescription from their physician has affected my practice. I will also speak to this new restriction being counterintuitive to the concepts of enhancing access to health care and promoting patient-centered care, how it increases costs to the health care system, and how it is a new administrative burden on already over-burdened physicians and their practices.

Background on the Osteopathic Profession

The osteopathic profession has a strong and distinguished history of educating, training, and placing physicians in underserved communities. This commitment began in the late 1800's and continues today. Our academic and training model, while not unique to the osteopathic profession, places an emphasis on preparing osteopathic medical students for careers in general physician specialties such as primary care, obstetrics, general surgery, and emergency medicine. Our academic curriculum,

along with a community-based training model, is the primary reason that the profession has enjoyed great success in the production of primary care physicians and general surgeons. Today, 60.5 percent of all osteopathic physicians practice in a primary care specialty. Currently, one in five medical students in the United States is enrolled in a college of osteopathic medicine. We are one of the fastest growing fields in the health care sector.

Currently, there are 26 colleges of osteopathic medicine operating on 34 campuses. We estimate that 2 to 3 new colleges will open in the next few years. Many of our colleges are located in geographic regions with acute physician shortages, such as western Washington, Arizona, and the full span of Appalachia where we have four schools. This commitment to establishing colleges and training opportunities in areas of need is key to meeting the health care needs of underserved communities and is indicative of the profession's commitment to this cause. The nation's colleges of osteopathic medicine currently graduate more than 3,600 osteopathic physicians. In 2013 that number will grow to 4,700 and by 2015 over 5,000 osteopathic physicians will graduate each year. If current trends remain consistent, by 2020 there will be over 100,000 osteopathic physicians in the United States.

Establishing a Burden for Physicians and Patients

The evolving health care delivery system is aimed at keeping patients healthy while providing them with access to quality and cost-effective care. The AOA believes that this goal can best be achieved through a longitudinal model of coordinated care such as the patient centered medical home (PCMH).

Unfortunately, the new FSA OTC restriction is contrary to ensuring access to quality, affordable, and cost-effective care. It requires additional time on a physician's part as well as that of patients which perversely affects lower cost quality care. In my experience, this new restriction on the purchase of OTC medications has necessitated changes in how I am able to treat my patients on a daily basis. I have been forced to make decisions regarding whether or not to charge patients a co-pay if they wish to obtain a prescription. I have also struggled to best determine how to make the time in an already fully scheduled day to fulfill these requests from multiple patients who previously did not require a face-to-face visit.

As a physician, my paramount concern is developing and preserving a strong relationship with my patients. I along with my colleagues strive to empower my patients to make decisions regarding their health while still coordinating their care and visiting with them when necessary. As I work to coordinate the care for my patients and provide them with important consult on their individual health care needs, I aim to put practices into place that allow them to stay out of the office as a result of good health. Physicians and patients should discuss all medications being used, but a written prescription should not always be necessary. This restriction being placed on consumers and burden being imposed on physicians; however, drives a patient to my office for a simple symptom, a patient who might otherwise be efficient in managing their own health at home needing my oversight only when medically necessary. Consequently, access to care is impacted since patients who really need my care are sometimes unable to schedule an appointment since I am now juggling

additional patient visits just to write prescriptions for OTC medications. Unfortunately, this new administrative burden has unnecessarily disrupted the physician-patient relationship in many instances.

In my experience, the majority of the patients that request a prescription for an OTC medication are doing so to address a simple cold or allergy; however, this still requires an appointment slot normally allocated for other patient needs. As a result, my time available to address patients with more substantive health care needs has reduced significantly. On average, I see about 25 patients per day, spending an average 15-20 minutes with each patient - 20 patients that visit my office for traditional care ranging across a wide array of health care needs plus 3-5 patients who are simply requesting a prescription for OTC medication, and in some instances numerous medications. Research has found that an OTC medication is an effective, affordable, and a convenient way for people to address their own health care needs. According to a study conducted by Booz & Co for the Consumer Health Products Association, the use of OTC medication saves the health care system $77 billion in avoided doctor's visits and diagnostic testing.

Placing a Burden on Physician Practices

My practice is a relatively small practice with five providers including four physicians and one advanced registered nurse practitioner. We have 10 administrative staff working in the office who are extremely busy processing paperwork to keep the office running and filing claims for the patient care my partners and I provide. The additional task of processing requests for appointments for over-the-counter prescriptions is an unnecessary burden. Larger practices might be able to handle this with less disruption; nonetheless, physician practices are negatively impacted by this administrative burden - especially small practices like my own.

Today, physician practices face new demands as required by statute and regulation including the adoption of electronic health records and electronic-prescribing systems, preparation for coding under ICD-10, implementation of quality measures, and adjusting to other changes in the health care delivery system. These additional policies and procedures are important and are primarily beneficial to efficiency as well as to providing improved patient care. However, each new requirement can be quite costly to a physician practice operating as a small business. The accumulated cost and subsequent time spent implementing new systems or procedures has an impact on revenue.

Confusion is occurring amongst physicians, administrative staff, and patients alike because not all over-the-counter medications require a prescription under this restriction. This level of confusion is not helpful in operating a physician practice when a patient calls or arrives to request a prescription. The administrative staff who is often times the first point-of-contact must research the request in order to preliminarily, but not always definitively determine whether a prescription is necessary. A patient may be subsequently turned away or may then visit with a physician only to find that a prescription for that specific OTC medication is not required under this new policy. Ultimately, time and money is lost for the patient, another patient who could have better utilized that time, administrative staff, and by the physician practice as a whole.

In an effort to address this issue, my practice attempted to include all medications requiring a prescription on the same form. Unfortunately, this type of form is not deemed acceptable by tax-preferred accounts to fulfill the requirement under this restriction. We require patients to come in for a face-to-face visit to discuss OTC medications. My practice has determined it is now necessary to begin charging patients a co-pay for this service because of the time it takes away from an ill patient in a given day.

Creating New Medical Liability Concerns

Physicians work hard to establish a trusting relationship with their patients. Generally patients choose to see their physician when they truly believe they need care. This restriction now presents physicians with patients who traditionally would not be seen and who are not accustomed to being seen in order to purchase over-the-counter medications. In my experience, most patients feel inconvenienced and are unhappy with this situation and enter my office with that mindset. As a result, I am potentially placed in a difficult and uncomfortable situation with a patient by possibly refusing to provide a prescription, charging for that service, and/or recommending the patient purchase a different higher cost alternative. For instance, I do not agree with the practice of using OTC medications as a source of energy. A patient might then choose to seek another physician who is willing to write their prescription which further fragments the important physician-patient relationship. The potential friction created in a once trusting relationship can subject a physician to additional liability that has not existed historically.

Although physicians are now typically seeing patients to write prescriptions for products that the Food and Drug Administration (FDA) has already deemed safe and appropriate for direct over-the-counter sale to consumers, the physician is held liable for any potential interactions they might have with other over-the-counter medications my patient is taking which the patient may or may not be willing to disclose. Physicians should make a concerted effort to discuss all medications with patients; however, this sharing of information is delicate and sometimes one-sided. Additionally, the physician is liable for knowing and providing information regarding the potential side-effects or adverse reactions for countless medications that are readily available to any consumer to purchase at will.

Conclusion

In closing, the AOA believes that restricting consumers who choose to use their tax-advantaged account to purchase over-the-counter medications by requiring them to obtain a prescription from their physician is unnecessary and disruptive to efficient care delivery. With that said, the AOA continues to support a patient's ability to utilize tax-advantaged accounts for the purchase of their over-the-counter medications without restriction. Physicians will continue to coordinate quality care for their patients in order to keep patients healthy rather than simply treating them when they are ill. An important element of that coordination is empowering patients to make informed choices benefitting their health without unduly burdening them or their physician.

I would like to thank you and members of the committee for affording me the opportunity today to share my experiences and the AOA's perspective regarding this important topic affecting osteopathic physicians and our patients. The AOA appreciates the work that you do to promote policies that advance patient-centered quality care that is cost-effective for the health care system. We look forward to working with you in the weeks and months ahead to ensure that congressional action fosters strengthening rather than impedes upon the physician-patient relationship.

Chairman BOUSTANY. Thank you, Dr. Feder. Mr. Taylor, you may proceed.

STATEMENT OF STEVEN TAYLOR, CHIEF EXECUTIVE OFFICER, SJOGREN'S SYNDROME FOUNDATION, BETHESDA, MD

Dr. TAYLOR. Good afternoon. Thank you, Chairman Boustany and committee members. I am Steve Taylor, and I am the Chief Executive Officer of the Sjogren's Syndrome Foundation, and I thank you for allowing us to testify.

Sjogren's is one of the country's most prevalent autoimmune diseases striking as many as 4 million Americans, 90 percent of whom are women. Patients largely depend on the use of over-the-counter products to treat their disease and prevent devastating complications. The cost is untenable for patients and their families and with so many products needed for treatment having to go to a physician for a prescription each and every time can present an undue burden on the patient but also on the health care system, the physician and the office staff.

As with most autoimmune diseases, the immune system turns against one's own body. In Sjogren's the moisture producing glands are the primary target, this causing many complications, including internal organ involvement of the lungs, kidneys and pancreas, as well as body systems are affected, such as the musculoskeletal, gastrointestinal, vascular, nervous and reproductive systems.

But today I wanted to elaborate on our hallmark symptoms, dry eye and dry mouth, since these lead to a majority of our patients' over-the-counter purchases. Dry eye can cause pain and lead to frequent eye infections and blurred vision. When left untreated dry eye can lead to corneal ulcers and abrasions as well as potential blindness. The few treatments available, moisture drops and ointments, are expensive.

Dry mouth can lead to rampant cavities, chipped and cracked teeth and ultimately loss of teeth. A lack of saliva to protect the lining of the mouth, throat, tongue and digestive tract leads to chronic burning and pain. In addition, dry mouth can cause difficult swallowing and problems with digestion. Over-the-counter medications, reflux medications, are taking constantly by our patients and treatments for dry mouth such as saliva substitutes, including gels, sprays and liquids, again are all very expensive.

Today only three FDA approved prescription treatments are available for Sjogren's patients. Two help to increase saliva and one to help increase tear production. Not everyone can take these medications, and even for those who can they still need to use over-the-counter products frequently to avoid pain, infection and other complications. Because there are so many products available on the market used by Sjogren's patients we actually publish a directory of products, over-the-counter products, that are available for our patients to use so they can identify ones that might be helpful to treat their disease.

What is astounding is the cost our patients have to bear when buying over-the-counter products. A 2007 patient survey found that the average Sjogren's patient spends $1,300 a year on over-the-counter products to treat their Sjogren's. For many that dollar figure is actually much higher. We solicited patient stories last week for this hearing and those who responded stated that they spend anywhere from $2,000 to $4,700 a year on medically necessary items.

Chris Albright of Minnesota wrote, my son and I both suffer from severe dry eye, which has impacted our lives immensely. Since 2008 we have paid over $41,000 out-of-pocket solely for lubricating eye drops for the two of us.

Rachel Hagan of California wrote, I cannot tell you how many times I have foregone food for myself because I had to pay for over-the-counter treatments for the various life altering horrible side effects of having Sjogren's.

Betty Moss of Georgia wrote, I spend more than $3,000 a year on over-the-counter medications. All of these purchases are necessities to just keep my life bearable and that cost represents 10 percent of my income.

And Kelly Nichols, an optometrist from Texas, wrote, as a practitioner and clinician scientist in the dry eye area, I never truly appreciated the impact of Sjogren's on the quality of life until attending and speaking at the Sjogren's Syndrome Foundation's national meeting. Dr. Nichols encourages Congress to recognize that Sjogren's patients have many expenses, including over-the-counter costs, to help alleviate the symptoms of their horrible disease.

The stories are the reason I am here today. While our foundation is working hard to increase awareness and education, we still have a long way to go. Many physicians still do not recognize or understand all of the over-the-counter medications that are available and needed to maintain one's health. And requiring a prescription only puts undue burden on the office and their office staff but also on the patient who already has enough to do to fight their chronic illness.

In closing, the Sjogren's Syndrome Foundation is glad that patients with diabetes are able to include medically necessary OTC products for their disease in their health savings plans without having to obtain a prescription. But why one single disease? What about the other diseases for which there is a clear medical need? What about the million of Americans who suffer from Sjogren's? We need your help and recognition that Sjogren's patients, too, depend on OTC products to treat their disease and that these expenses create a major burden in their lives.

We appreciate your time this afternoon for this very important hearing, and I will be hear for questions if you have any. Thank you very much.

[The prepared statement of Mr. Taylor follows:]

Written Testimony from Steven Taylor, Sjögren's Syndrome Foundation CEO
House Ways and Means Oversight Subcommittee Hearing:
"The Impact of Limitations on the Use of Tax-Advantaged Accounts for the Purchase of Over-the-Counter Medication"
April 25, 2012

The Sjögren's Syndrome Foundation (SSF) is deeply grateful to the Subcommittee Chairman, the Honorable Charles Boustany, and the subcommittee members for holding this hearing and listening to the needs of the 4 million Americans we represent who suffer from the autoimmune disease, Sjögren's syndrome. Oral testimony is being provided by Steven Taylor, CEO of the Sjögren's Syndrome Foundation, the non-profit 501(c)3 organization serving Sjögren's patients, their families and professional healthcare givers.

Introduction:

Sjögren's syndrome (pronounced SHOW-grens) is one of this country's most prevalent autoimmune diseases, striking as many as 4 million Americans, ninety percent of whom are women. This chronic disease lasts a lifetime, and it can affect any body organ or system as well as cause dryness throughout the body.

Sjögren's patients largely depend on the use of Over-the-Counter drugs and products to treat their disease and prevent devastating complications. The cost is untenable for patients and their families, as OTC treatments are not covered by insurance, are not tax deductible, and are no longer even covered under Health Savings Plans without obtaining a prescription. With so many OTC products needed for treatment, having to go to a physician or dentist for a prescription for each and every one presents an undue burden.

What is Sjögren's Syndrome?

In Sjögren's, the immune system turns against one's own body. Moisture-producing glands are primary targets, resulting in hallmark symptoms of dry eyes and dry mouth. These symptoms alone can be devastating. If not treated, dry eyes can lead to corneal ulcers and abrasions and potential blindness. Even with treatment, dry eyes cause pain and lead to frequent eye infections and blurred vision. The few treatments available – moisture drops and ointments– are expensive.

Untreated dry mouth can lead to rampant cavities, chipped and cracked teeth, and ultimately the loss of one's teeth. Dentures do not work in a dry mouth, so once teeth are lost, patients have to turn to dental implants that involve expensive surgical procedures. The lack of saliva to protect

the lining of the mouth, throat, tongue, and digestive tract leads to chronic burning, pain, and susceptibility to yeast infections that are very hard to treat. Those with dry mouth suffer from difficulty swallowing and talking and constant problems with digestion and reflux. OTC reflux medications are taken constantly by our patients to prevent the pain of reflux and damage to the esophagus. And treatments for dry mouth – such as saliva substitutes, including gels, sprays, liquids, and lozenges, and remineralizing solutions – again are expensive.

Because moisture-producing glands exist throughout the body, the impact of dryness extends to the lining of the lungs and gastrointestinal and urinary tracts, the ears, nose, sinuses, throat, vagina, and skin. Inflammation, dysfunction and ultimately atrophy and destruction of tissue occurs.

We also want to mention the systemic nature of this disease, because multiple organ involvement and other complications can add to the expense of this disease, including the cost of healthcare, loss of jobs and quality of life. The liver, kidneys, heart, pancreas and thyroid can be affected as well as the musculoskeletal, gastrointestinal, vascular, nervous, and urinary and reproductive systems in the body. An autoantibody occurring in 70% of those with Sjögren's causes a reaction to the sun and can lead to fetal heartblock in babies born to mothers with Sjögren's. Sjögren's also can result in lymphoproliferative disorders, leading to development of non-Hodgkin's lymphoma at a rate that is 44 times higher than in the general population.

Treatment:

Only three FDA-approved prescription treatments are available for Sjögren's patients – two are oral medications that help increase saliva and one is an eye drop for dry eye that helps increase tear production. Not everyone can take these medications because of side effects, and for those who can, they still need to use OTC products frequently to avoid pain, infection and complications.

Because there are so many OTC products used by Sjögren's patients, we publish a directory on available products so they can identify ones that might be most helpful for their symptoms. Just to name a few, these include:

- Non-preservative moisture drops, gels and ointments for dry eye
- Moisture-chamber glasses to maintain ocular moisture
- Saliva substitutes and stimulants for dry mouth
- Oral cleaning products
- Lip balms for dry lips
- Saline solutions, gels and irrigators for dry nose and sinuses
- Moisturizers for dry, flaking skin
- OTC medications for reflux
- OTC medications to break up excess mucous, especially in the lungs
- OTC medications to help GI problems, such as constipation and motility issues
- Products to help increase moisture, such as humidifiers and neti pots
- Items to protect patients against the sun, including sunscreen and sun protective clothing
- Special socks to help with neuropathic pain
- Joint and other assistive devices

Costs:

A 2007 SSF national survey found that the average Sjögren's patient spends $1,300.00 a year on OTC products to treat their disease. For many people, that dollar figure is much higher. We solicited patient stories last week for this hearing, and those who responded stated that they spend anywhere from $2,000 to $4,700 a year on medically-necessary OTC items to treat their disease. The response from patients was amazing - Within 4 hours after our email request went out, we received more than 40 stories. And, within 48 hours, we received 141 stories from 26 states. This shows the tremendous need of Sjögren's patients and how passionate our patients are about getting something done to help find ways to help with the high cost of their disease!

Just a few excerpts from the many stories our Foundation received follow:

Marilyn Winnie of Illinois:
"I worry about choosing between medical things I can afford and what I cannot. What medication to take, what to skip. Even now, the cost of all out of pocket expenses has been devastating to my financial situation. How will I choose? This isn't about taking advantage of a system. This is about surviving in some degree of comfort."

Chris Albright of Minnesota:
"I was diagnosed with Sjogren's in 2005. The following year, my 20-year-old son developed symptoms of the disease. We both suffer from severe dry eye which has impacted our lives greatly. Since January 2008, we have paid over $41,600 out of pocket solely for lubricating eye drops for the two of us. My son and I will require these treatments for the rest of our lives, as our condition is chronic and will not improve. The cost will continue to go up. It is difficult enough for us to deal with the disease without continually having to struggle to get the services covered."

Anne Economou of Colorado:
"The costs are staggering and the overall burden to our family is very difficult to put into words. Living with Sjogren's is hard enough. The protocol I follow with dozens of OTC products at least helps me cope with this terrible disease."

Shanti Chandrasekhar of Maryland:
"As if facing the challenges of having to deal with this autoimmune disorder is not enough, the added expenses to manage it causes more worry about saving for the future…making the symptoms worse. It's a vicious cycle that we, as patients, cannot break without outside help."

Yvonne Waller of Georgia:
"OTC drugs to treat my Sjögren's are very expensive. I have to use moisturizing drops, which work great, but the cost is $15.00 per box. I go through a box a week if I am conservative, and that one product alone adds up to $780.00 per year. **I could not keep my job** without the aid of the various moisturizers Sjogrens patients MUST have because the pain would just be too intense. So where does the money come from to purchase these? I have good insurance, but that does no good, and I have to find other ways to cover them or do without and suffer the consequences, because these items are literally necessary for survival."

Rachel Hagan of California:
“I was diagnosed with Sjögren’s syndrome almost 12 years ago. I cannot tell you how many times I have forgone food for myself because I had to pay for OTC treatment for the various, life-altering, horrible side effects of having Sjogren's. The effects that ripple through my family due to the cost of just trying to live with this disease are terrible. Sjögren's patients have a medical necessity for OTC products.”

Anne Kassner of Colorado:
“I have had Sjogren’s since I was 32 years old. I am now 45, and it has been a great burden to pay for over the counter tears that I have to put in my eyes 7-12 times a day as well as ointments at night. For my mouth, I have to use mouth sprays and rinses to keep it moistened or I cough all night long. I spend on average $200.00-$300.00 a month on all these products. This is a huge burden to me and my family… Many times the cost dips into our family’s food budget, and it means serving a poor meal in order to have eye drops so I can pry my eye lids open. Yes, all the over the counter meds that I have to have to use hugely affects me and our whole family.”

Stephanie Cantrell from Tennessee:
“I was diagnosed two years ago at the age of 35. There are so many costs that go into maintaining a somewhat normal life while living with Sjogren's. I use a humidifier in every room, constantly use eye drops during the day and ointment at night to keep my eyes moist. I have frequent eye exams in order to monitor any damage to my eyes and frequent dental visits to monitor and treat dental decay. I use mouth lozenges, gel, gum, mouth spray and dry mouth patches (those at $12.00 for a box of 16 that only lasts a few days). It gets expensive! I have mouth sores and cracking. My skin stays so dry that I always have to use lots of lotion. I cannot be in the sun without sunblock.

My mouth and throat feel as if I have eaten sand and my skin feels like sand paper. The neuropathy? Well, it feels like I am being electrocuted. Constant jolts. Heartburn daily. I constantly have an upset stomach. Nosebleeds, which are helped somewhat by using a Neti-Pot.

The cost can become outrageous just trying to maintain life with Sjogren's. I would have never realized how debilitating and expensive Sjogren's can be had I not had it.”

Betty Moss of Georgia:
I spend more than $3,000 a year on OTC medications. All of these purchases are necessities just to keep my life bearable. The cost represents more than 10% of my monthly income. It is truly a struggle every month to pay my bills.”

Gail Azerrad, RDH, of California:
“Consider, please, that those of you on this Congressional panel are reading this or looking at someone reading this through eyes that, hopefully, are not impacted by Sjogren's. That likely means that your eyes are not bothered by the unrelenting glare from the overhead lights in this room. And, none of you probably struggle with the size and color of the font in today's Hearing Agenda, even if you wear eyeglasses. You will be able to read your lunch menu and the street signs when you go home to listen to the TV news since reading newspapers is out of the question. Good thing you don't feel like there is sand in your eyes or that you want to rub your eyes as if it's an Olympic sport. If all that is the case, then none of you have the tell-tale scarred

corneas, dry, burning, blurry eyes of Sjogren's syndrome, a progressive, incurable, anti-immune disease. Consider yourself lucky...

It's a pretty sad state of life that the only 'help' for Sjogren's impacted eyes are over-the-counter lubricants or drops. Welcome to a maddening, limited, frustrating, expensive market of such eye products. The myth that anything O-T-C is cheap, easily affordable and totally optional to use, is just that, a myth."

Melinda Ware of Virginia:
"Most over-the-counter (OTC) drugs and products I depend on to treat Sjögren's symptoms are necessary and not covered by Insurance, Healthcare Flexible Spending Accounts and Healthcare flex allowances plans, Medicaid or Medicare. I spend on average of approximately $3500 a year on OTC products alone to assure a decent quality of life... Sjögren's has changed my life as I once knew it. I was once an active nurse and outgoing woman who liked the outdoors and volunteering in my community. I have had to lower my expectations for my quality of life, my income, my ability to contribute to my family and community."

Molly Clennan of Florida::
"Due to the cost of all the over the counter medications and my limited budget, I have to pick and choose what I can afford and what I can't. I can never buy all of the products needed to help treat my symptoms and give me some reprieve due to the cost."

Rebecca Hunt, Washington, D.C.:
"While the cost of eye-drops or ibuprofen may not seem like a lot, when used daily, several times a day, or every hour, as is the case with many patients living with Sjogren's Syndrome , these costs -- on top of other medical costs associated with living with a chronic disease -- add up. While restoring the "tax-free" purchasing of OTC medical expenditures is not free to taxpayers, everyone wins when individuals living with chronic diseases have easy access to lower-cost medical care."

Kelly K. Nichols, OD, MPH, PhD, of Texas:
"As a practitioner and clinician-scientist in the area of dry eye, I never truly appreciated the impact of Sjogren's on quality of life until attending and speaking at a SSF national meeting. The collective voice of Sjogren's patients, providing support for one another through this difficult disease, and the appreciation of patients when finally diagnosed with the syndrome was overwhelming. This is a multi-faceted condition that does not have a simple solution, requiring many OTC and prescription treatments. I encourage Congress to recognize that Sjogren's patients have many expenses including OTC costs to help alleviate the symptoms that are such a burden in the disease."

Current Requirement to Obtain a Prescription:

While the Sjögren's Syndrome Foundation is working hard to increase awareness and education of Sjögren's, we still have a long way to go. Many physicians still do not recognize or understand all of the OTC products needed to maintain one's health when one has Sjögren's. This adds to the already burdensome and complicated requirement that patients obtain a prescription for their OTC needs.

Closing:

We are glad that patients with diabetes are able to include medically-necessary OTC products for their disease in their Health Savings Plans without having to first obtain a prescription. But why single out one disease? What about other diseases for which there is a clear medical need? What about the 4 million American who suffer from Sjögren's? We need your help and recognition that Sjögren's patients, too, depend on OTC products to treat their disease and that these expenses create a major burden in the lives of so many.

Thank you for the opportunity to present testimony.

The Sjögren's Syndrome Foundation (SSF), a non-profit 501(c)3 organization, serves Sjögren's syndrome patients, their families, and caretakers. The Foundation focuses on education of patients, physicians, and the public; support for patients and families; and research to find better treatments and, ultimately, a cure for this devastating disease.

Reference articles on the cost of Sjögren's and affect on QOL:

Bowman SJ, St Pierre Y, Sutcliffe N, Isenberg DA, Goldblatt F, Price E, Hamburger J, Richards A, Rauz S, Regan M, Rigby S, Jones A, Mulherin D, Clarke AE. Estimating indirect costs in primary Sjögren's syndrome. *J Rheumatol.* 2010 May;37(5):1010-5.

Callaghan R, Prabu A, Allan RB, Clarke AE, Sutcliffe N, Pierre YS, Gordon C, Bowman SJ; UK Sjögren's Interest Group. Direct healthcare costs and predictors of costs in patients with primary Sjogren's syndrome. *Rheumatology (Oxford).* 2007 Jan;46(1):105-11.

Segal B, Bowman SJ, Fox PC, Vivino FB, Murukutla N, Brodscholl J, Ogale S, McLean L. Primary Sjögren's Syndrome: health experiences and predictors of health quality among patients in the United States. *Health and Quality of Life Outcomes* 2009, **7**:46 doi:10.1186/1477-7525-7-46.

Sjögren's Syndrome Foundation April 25, 2012

Chairman BOUSTANY. Thank you, Mr. Taylor. Ms. Hatcher, you may proceed.

STATEMENT OF JENNIFER HATCHER, SENIOR VICE PRESIDENT, GOVERNMENT AND PUBLIC AFFAIRS, FOOD MARKETING INSTITUTE, ARLINGTON, VA

Ms. HATCHER. Thank you, Mr. Chairman and Members of the Subcommittee. I appreciate the opportunity to testify today on behalf of supermarket retailers and wholesalers represented by FMI.

The supermarket industry is committed to providing our customers with a wide range of products, including both food and med-

ical products. The restrictions placed on the purchases of over-the-counter medical products with an FSA debit card beginning January 1, 2011 are a real burden for consumers and the retail community and they make no sense.

I will give you a brief history of the issue from our perspective and our members' investments. In July 2006, the IRS published new guidance that required retailers to develop and implement an information inventory approval system, IIAS, if they wished to continue to be able to accept FSA debit cards for purchases. Under the new IRS requirements a merchant's point of sale system must be able to verify in realtime electronically that the merchandise being purchased with an FSA card is an eligible medical expense. A massive database of all eligible items had to be designed and built. Each merchant point of sale system had to be engineered to identify and flag all eligible products and decline all ineligible products electronically. The system also had to be able to maintain the data electronically to be produced in the event of an IRS audit. Anyone who has ever had the responsibility for an IT project can understand the complexity of this assignment.

In 2007, FMI joined with a group of stakeholders to develop a nonprofit membership organization to build the database part of this project to ensure consistency across all participants. We did not want customer confusion where an item was determined to be eligible at one store and ineligible at another store down the street. At the time of the founding this group, known as the special interest group for IIAS standards, included about a dozen stakeholders and now its membership includes more than 11,000 companies.

The guidance we had from the IRS regarding the eligibility of certain items was extremely limited. I believe it was only about one page in length. We consulted numerous attorneys and the IRS as often as they were willing and had dozens of conference calls to ensure the database was accurate and comprehensive. The hard work to develop the database of products has been successful, and each month an electronic list by UPC code is updated to identify eligible and ineligible products and a link is emailed to each participating company. The April electronic list included 32,182 eligible items.

In addition to the creation of the eligible product database, FMI members were required to also have the merchant side of the system implemented by January 1, 2008 to ensure that the items could be downloaded and flagged and an unflagged item could not be purchased with an FSA card, which was the IRS's ultimate concern. This was a tremendous amount of work to accomplish in this timeframe. Customers, merchants and the IRS seemed to be happy with the new system. It was consistent, efficient, accurate and was created without a single taxpayer dollar.

On March 23, 2010, this all changed. In an attempt to raise revenue for the health care law this provision was modified to say that the expenses associated with OTC drugs or medicines will only be considered to be eligible for reimbursement if they are accompanied by a prescription. OTC medical supplies and equipment can continue to be purchased under the existing IIAS system. This practical effect of this change is to require a $130 office visit for a prescription to purchase an $18 package of Claritin. All of the eligible item lists for all merchant locations had to be updated at the busi-

est time of the year. In total, 16,000 OTC medicines had to be removed from the electronic eligible items list.

Beginning January 1, 2011, the tremendous effort and expense that more than 11,000 companies undertook to comply with the original IRS requirement was negated. The associates in our member companies who invested so much of their time and resources into developing this system were obviously frustrated. Each of our members who responded reported to me more than $100,000 in expenses for the development and implementation of this IIAS system. In government dollars that may not seem like a lot, but with a 1 percent industry profit margin in grocery that equates to more than $10 million in grocery sales just to break even on that expense.

Regardless of how you feel about PPACA, this change is unfair to customers and to retailers and just does not make sense. Bandages and contact solution remain eligible. Claritin and Advil require a prescription.

FMI believes Congress should preserve affordable consumer access to OTC medicines through FSA accounts. We strongly support legislation that many of you have sponsored and cosponsored to make this change.

I will be pleased to answer any questions you have.

[The prepared statement of Ms. Hatcher follows:]

Testimony of Jennifer Hatcher
Senior Vice President, Government and Public Affairs
Food Marketing Institute

Before the House Ways and Means Committee, Subcommittee on Oversight

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

Wednesday, April 25, 2012

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Mr. Chairman and Members of the House Ways and Means Subcommittee on Oversight, my name is Jennifer Hatcher, and I am Senior Vice President, Government and Public Affairs, with the Food Marketing Institute (FMI). Thank you for the opportunity to testify before the Committee on Ways and Means Subcommittee on Oversight on the impact of limitations on the use of tax-advantaged accounts for the purchase of over-the-counter (OTC) medicines.

The Food Marketing Institute[i] represents supermarket retailers and wholesalers. The supermarket industry sells a wide variety of grocery items and other consumer products, including over-the-counter (OTC) medications. More than 68% of supermarkets have pharmacies and both pharmacy and OTC products represent an important component of our overall health and wellness offerings.

Our members use a variety of payment types to purchase OTC products. Until January 1, 2011, when purchases for FSA OTC medicines were cut off for customers using an FSA debit card without a prescription, FMI members were seeing growth in the use of debit cards to make purchases with a Flexible Spending Account. Below is a history of the issue and our members' investments in point-of-sale (POS) equipment.

In July 2006, the IRS published updated health benefit card guidance for FSAs (Flexible Spending Account) and HRAs (Health Reimbursement Account). This IRS guidance required members of FMI and other retailers to develop and implement an Information Inventory Approval System (IIAS) if they wished to be able to continue to accept FSA debit cards for purchases.

Our members are in the business of selling food and other retail products. As you can imagine, developing a system as complex as an IIAS was an enormous task. Under the new IRS requirements, a merchant's point-of-sale system must have the ability to verify in real-time that the merchandise being purchased with an FSA/HRA card is an eligible medical expense. A massive database of all eligible items had to be designed and built. Each merchant POS system had to be engineered to identify and flag all eligible products and decline all ineligible products electronically. An associate had to be assigned to monitor and update this system on a monthly basis. The system also had to be able to maintain the data electronically to be produced in the event of an IRS audit. Anyone who has ever had the responsibility for an IT project can envision the complexity of this assignment.

In 2007, FMI joined with a group of merchants, acquirer processors, issue processors, third-party benefit plan administrators and payment card networks to develop a non-profit, membership corporation to develop the database part of this project to ensure consistency across all participants. We did not want customer confusion where an item was determined to be eligible at one store and ineligible at a store down the street. FMI and the other founding members provided the seed money and staff support to start this project. At the time of its

founding, this group, the Special Interest Group for IIAS Standards (SIGIS), included about a dozen stakeholders and now its membership includes more than 11,000 companies.

The guidance we had from the IRS regarding the eligibility of certain items was extremely limited. I believe it was only about one page in length. We consulted numerous attorneys and the IRS as often as they were willing and had dozens of conference calls to ensure the database was accurate and comprehensive. The hard work to develop this database of products has been successful and each month an electronic list by UPC code is updated to identify eligible and ineligible products and a link is emailed to each company.

In addition to the creation of the eligible product database, FMI members were required to also have the merchant side of this system implemented by January 1, 2008 in order to continue to accept the FSA/HRA debit cards. Much work had to be done to ensure that the items could be downloaded and flagged and that an unflagged item could not be purchased with an FSA/HRA debit card, which was the IRS's ultimate concern. This was a tremendous amount of work to accomplish in this timeframe, but many of our members met this deadline, and many others were able to bring their systems online just a few weeks after the January 1, 2008 date.

The FSA business increased as customers, merchants and the IRS seemed to be happy with this new system. It was consistent, efficient and accurate and was created without a single taxpayer dollar.

On March 23, 2010 this all changed. In an attempt to raise revenue for the health care law "PPACA" (P.L. 111-148), this provision was modified to say that the expenses associated with OTC drugs or medicines will only be considered to be eligible for reimbursement under an FSA or HRA account if they are accompanied by a prescription. OTC medical supplies and equipment can continue to be purchased under the existing IIAS system. The practical effect of this change is to require a $130 doctor's office visit for a prescription to purchase an $18 package of Claritin. Bandages and contact solution remain eligible without a prescription.

On December 20 and 23, 2010 the IRS finally released guidance on how the change must be implemented and the change had to take place by January 1, 2011. All of the eligible item lists for all merchant locations had to be updated at the busiest time of the year, which for grocery stores is between Thanksgiving and New Year's. In total, 16,000 OTC medicines had to be removed from the SIGIS electronic eligible items list. Beginning January 1, 2011, the extreme effort and expense that more than 11,000 companies undertook to comply with the original IRS requirement by January 1, 2008 for an IIAS was negated. The associates in our member companies who invested so much of their time and resources into developing this system were frustrated.

In gathering information for this testimony, I asked our member companies for an estimate of their expenditures toward the IT necessary for development of their part of the IIAS system and their data retention. Each respondent reported more than $100,000 in expenses. In government dollars that may not seem like a lot, but with a 1% industry profit margin, that equates to more than $10 million in grocery sales just to break even on the expense. Our largest members reported numbers far in excess of $100,000. These expense figures do not even consider the cost and disservice to sick customers of tying up a pharmacist for handling an Advil or Claritin prescription (should one come in) or the $130 doctor's office visit expense to get the prescription that either the individual or insurance company must pay.

Regardless of how you feel about PPACA, this change is unfair to customers and to retailers and just does not make sense. Bandages and contact solution are eligible, but Advil and Claritin require a prescription? FMI believes Congress should preserve affordable consumer access to OTC medicines through FSA accounts. We strongly support legislation to fix limitations on FSA debit card OTC purchases including: H.R. 2010 – the Family and Retirement Health Investment Act of 2011, and H.R. 605 - the Patients' Freedom to Choose Act, both authored by Congressman Paulsen, and H.R. 2529, the Restoring Access to Medication Act, authored by Congresswoman Lynn Jenkins and each of their Senate companions.

Thank you for inviting FMI to testify on this important issue. Our industry is committed to providing our customers with a wide range of products; including both food and medical products. The restrictions on FSA OTC purchases create a real burden for consumers and the retail community, and they will significantly diminish our members' investments unless Congress acts to amend the health care legislation. The elimination of FSA OTC purchases is basically a new tax on consumers who previously could put aside pre-tax dollars to pay for health-related items throughout the course of a year. Moreover, in our opinion, the provisions in PPACA that took away this benefit will not reduce overall health care costs, but will simply shift these costs to other areas of our health care delivery such as physicians, pharmacists and other practitioners. FMI urges the restoration of this important OTC tax-preferred health account benefit.

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[1] Food Marketing Institute (FMI) conducts programs in public affairs, food safety, research, education and industry relations on behalf of its nearly 1,250 food retail and wholesale member companies in the United States and around the world. FMI's U.S. members operate more than 25,000 retail food stores and almost 22,000 pharmacies with a combined annual sales volume of nearly $650 billion. FMI's retail membership is composed of large multi-store chains, regional firms and independent operators. Its international membership includes 126 companies from more than 65 countries. FMI's nearly 330 associate members include the supplier partners of its retail and wholesale members.

Chairman BOUSTANY. Thank you, Ms. Hatcher. Mr. Van de Water, you may proceed.

STATEMENT OF PAUL N. VAN DE WATER, SENIOR FELLOW, CENTER ON BUDGET AND POLICY PRIORITIES, WASHINGTON, D.C.

Mr. VAN DE WATER. Mr. Chairman, Ranking Member Lewis, Members of the Subcommittee, I appreciate the invitation to appear before you this afternoon.

The Affordable Care Act includes a number of spending reductions and tax increases designed to assure that expanding health

coverage does not drive up the Federal budget deficit. Some of these provisions limit the use of tax-advantaged accounts to pay for health related expenses. These limitations make sense both as tax policy and as health policy, and repealing any of them would in my view be unwise.

Only a minority of workers benefit from these tax-advantaged accounts. In 2010 only 39 percent of all workers had any access to Federal spending accounts and only 37 percent of the employees offered an FSA chose to participate. Thus, as a result only about one worker in seven has an FSA, and an even smaller number of workers, rather smaller fraction of workers is enrolled in other tax favored accounts.

Furthermore, people with high incomes benefit disproportionately from these tax-advantaged accounts because they are in higher tax brackets, tend to consume more health care, and can afford to deposit larger amounts in their accounts. Middle and low-income people benefit much less, if at all. For example, someone in the 15 percent income tax bracket who contributed the average of $1,420 to an FSA would save $322 in Federal income and payroll taxes. The typical middle income family, however, probably contributes much less than that and therefore receives even smaller tax savings. Low and moderate income households are unlikely to receive any tax savings because they pay little or no income tax.

These modest tax benefits entail relatively large administrative and compliance costs. Employers must manage the accounts themselves or hire a vendor to do so typically at a cost of about $60 annually per participant. In addition, account holders must spend hours complying with onerous recordkeeping requirements to assure that they are using their accounts only for approved items.

FSAs and other tax-advantaged accounts also encourage the over consumption of health care, which runs directly counter to bipartisan efforts to slow the growth of systemwide health care costs in both public programs and the private sector.

The accounts make people less price sensitive and reduce the effectiveness of cost sharing requirements and controlling health care utilization. Moreover, prior to the restriction on over-the-counter items funds in tax-advantaged accounts could be used to purchase nearly any health care item or service regardless of whether it was medically necessary, cost effective or of meaningful health value.

The staff of the Joint Committee on Taxation included changing the definition of medical expenses for tax-advantaged accounts in a 2005 report, identifying options for improving tax compliance and reforming tax expenditures. The Joint Committee offered several reasons for using the same definition of medical care both for tax favored accounts and also for itemized deductions.

First, having different definitions for different provisions caused similarly situated individuals to receive disparate tax treatment.

Second, purchases of over-the-counter medicines and other items such as pain relievers, cold remedies, and sunscreen constitute routine personal expenses which are generally considered not deserving of a tax subsidy.

Third, the Joint Committee wrote, providing a subsidy for over-the-counter medicines may also result in less compliance as it may

be more difficult to distinguish products that are medical from those that are not.

These reasons still apply today. I think it is important for us to remember, as was noted in Mr. Melville's prepared testimony, that flexible spending accounts and other such accounts were generally not available to be used at all for over-the-counter products prior to 2003. Thus, this provision that we are talking about is relatively new and as far as I can tell the world, the medical system, the tax system, were operating quite well before 2003 and the notion that the situation is deteriorating substantially as a result of this provision I think is implausible.

Moreover, Mr. Melville's testimony notes that the average household spends only—using an FSA spent only $136 on OTC medicines in 2010. The drop-off he says was 12 percent. Converted into dollars that is $15. And even if all of that drop-off were attributable to the provision that we are talking about today, it is truly a de minimis amount for most people. And for people for whom over-the-counter expenses represent a large amount then I believe the exception for medical prescription is justified.

Thank you very much, sir.

[The prepared statement of Mr. Van de Water follows:]

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TESTIMONY OF PAUL N. VAN DE WATER
Senior Fellow, Center on Budget and Policy Priorities

Before the
Subcommittee on Oversight
Committee on Ways and Means
U.S. House of Representatives

Limitations on Tax-Advantaged Accounts

Mr. Chairman, Ranking Member Lewis, members of the subcommittee, I appreciate the invitation to appear before you today.

The Affordable Care Act (ACA) includes a number of spending reductions and tax increases designed to assure that expanding health coverage does not drive up the deficit. Some provisions limit the use of tax-advantaged accounts to pay for health-related expenses. These limitations make sense both as tax policy and as health policy, and repealing any of them would be unwise.

One section of the ACA raises an estimated $13 billion over the 2010-2019 period by limiting contributions to health flexible spending accounts (FSAs) to $2,500 a year. Another raises $5 billion by making the definition of medical expenses for FSAs, Health Savings Accounts (HSAs), and other tax-advantaged accounts conform to the definition used for the itemized income tax deduction for medical expenses. As a result, the cost of over-the-counter (OTC) medications and other OTC items may no longer be reimbursed from an account without a prescription or a letter of medical necessity from a physician. Reimbursements from tax-advantaged accounts are also counted in applying the ACA's excise tax on high-cost health plans.

Only a minority of workers benefits from these tax-advantaged accounts. In 2010, 39 percent of all workers and 56 percent of workers in large firms had access to flexible spending accounts. Only 37 percent of employees offered an FSA in 2010 chose to participate, and the average annual contribution to an FSA was $1,420, well below the new $2,500 limit.[1] Thus, only about one worker in seven has an FSA. A smaller fraction of workers is enrolled in other tax-favored accounts.[2]

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[1] Janemarie Mulvey, *Health Care Flexible Spending Accounts*, Congressional Research Service Report RL32656, January 11, 2012.

[2] Kaiser Family Foundation and Health Research and Education Trust, *Employer Health Benefits, 2011 Annual Survey*.

People with high incomes benefit disproportionately from tax-adantaged accounts because they are in higher tax brackets, tend to consume more health care, and can afford to deposit larger amounts in their accounts. Middle- and lower-income people benefit much less, if at all. For example, someone in the 15-percent income tax bracket who contributed the average of $1,420 to an FSA would save $322 in federal income and payroll taxes. The typical middle-income individual likely contributes much less than the average, however, and therefore receives even smaller tax savings. Low- and moderate-income households are unlikely to receive *any* income-tax savings because they pay little or no income tax. They do receive payroll tax savings, but low-income workers will lose more in future Social Security benefits than they gain in lower payroll taxes, because their Social Security benefits are based on their taxable earnings.[3]

These modest tax benefits entail relatively large administrative and compliance costs. Employers must manage the accounts themselves or hire a vendor to do so — typically at a cost of about $60 annually per participant. Accountholders must spend hours complying with onerous recordkeeping requirements to assure that they are using their accounts only for approved items.

FSAs and other tax-advantaged accounts also encourage the overconsumption of health care, which runs directly counter to bipartisan efforts to slow the growth of system-wide health-care costs in both public programs and the private sector. The accounts make people less price-sensitive and reduce the effectiveness of cost-sharing requirements in controlling health care utilization. Moreover, prior to the restriction on over-the-counter items, funds in tax-advantaged accounts could be used to purchase nearly any health care item or service, regardless of whether it was medically necessary, cost effective, or of meaningful health value.

The staff of the Joint Committee on Taxation (JCT) included changing the definition of medical expenses for tax-advantaged accounts in a 2005 report identifying options for improving tax compliance and reforming tax expenditures. JCT offered several reasons for using the same defintion of "medical care" for both tax-favored accounts and itemized deductions. First, having different definitions of "medical care" for different provisions caused similarly situated individuals to receive unequal tax treatment. Second, purchases of over-the-counter medicines and other items (such as pain relievers, cold remedies, and sunscreen) constitute routine personal expenses, which are generally not considered deserving of a tax subsidy. Third, "providing a subsidy for over-the-counter medicines may also result in less compliance, as it may be more difficult to distinguish products that are medical from those that are not, such as toiletries and products that promote general health."[4] These reasons still apply today.

Finally, the Affordable Care Act extends health coverage to 34 million more Americans and establishes minimum standards for health insurance policies, including an annual limitation on cost-sharing. These and other aspects of health reform further diminish the already weak policy rationale for FSAs and other tax-avantaged accounts for health spending.

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[3] Chuck Marr and Kris Cox, *Curbing Flexible Spending Accounts Could Help Pay for Health Care Reform,* Center on Budget and Policy Priorities, June 10, 2009, http://www.cbpp.org/cms/index.cfm?fa=view&id=2829.

[4] Joint Committee on Taxation, *Options to Improve Tax Compliance and Reform Tax Expenditures*, January 27, 2005, pp. 105-8.

Chairman BOUSTANY. Thank you, Mr. Van de Water. Before we proceed with questioning of the witnesses I would like to extend courtesy to the ranking member of this subcommittee, Mr. Lewis, for a statement.

Mr. LEWIS. Thank you very much, Mr. Chairman. And Mr. Chairman, I want to apologize to you and to other Members of the Committee and to my friend and colleague Mr. Becerra for my getting here. I was held up downtown, but I am here.

Mr. Chairman, thank you for holding this hearing today. I agree that this is an important topic for millions of Americans. I understand that Mr. Becerra gave an opening statement for the Democrats, and I thank you, sir. And I thank you for extending me an opportunity, Mr. Chairman, to speak. I also would like to thank the

witnesses for their testimony I will read, and I am probably going to have some questions, and I yield back.

Thank you.

Chairman BOUSTANY. I thank the ranking member. And I should say we are glad you are here.

Mr. LEWIS. Thank you, sir.

Chairman BOUSTANY. We will now proceed with questions for the witnesses.

Mr. Taylor, I am glad you are here today because you brought a different perspective to all of this. When we talk about over-the-counter items, medications, we are typically thinking of aspirin and cold medicine, but you bring to the table representation for a group of people who have very serious chronic conditions, an autoimmune condition, with very specific needs in the over-the-counter space which is critical to their health. So I want to thank you for bringing that perspective.

Are there other conditions out there perhaps in the autoimmune world or in other areas that are similar to the patients with Sjogren's with similar needs? Could you comment on that?

Dr. TAYLOR. Absolutely. Surely in the autoimmune disease field there are over 80 autoimmune diseases and some of them do have similar conditions and symptoms as Sjogren's, as well as need over-the-counter products for their disease because there isn't pharmacological methods available for them as well. In addition, diseases such as head and neck radiation patients who had head or neck cancer also use a lot of over-the-counter medicines for their dry mouth, which is a serious side effect from having head or neck cancer, in having the treatments as well. So it does extend into other areas besides autoimmune diseases and really does hurt the pocketbook of those patients and their families for sure.

Chairman BOUSTANY. And oftentimes these are specialists who treat these patients, and getting in to see a specialist like a rheumatologist for instance is not always one of those things you can do on the spur of the moment or even within a week or two, it can be difficult to get in to get an appointment, is that true?

Dr. TAYLOR. That is correct. On average it takes between 3 and 6 months to get an appointment with a rheumatologist unless you go through the emergency room or you have a medical emergency that somehow can get an appointment in to see them. And rheumatologists treat all the dry mouth symptoms for Sjogren's. And most of the dry eye products are suggested by an optometrist or an ophthalmologist, but typically an ophthalmologist is who is following them, and they have a very heavy workload as well because they are doing surgery and other things as well. So it is very difficult for them to get into their physician's appointments and then also to be able to get a prescription every time they need to buy an over-the-counter product.

Chairman BOUSTANY. I thank you for bringing that perspective.

Mr. Melville, in 2009 President Obama promised not to support any tax increases on families earning under $250,000 a year. And yet looking back at all of this it seems that that is exactly what has happened now. The ban on over-the-counter purchases without a prescription is estimated to raise taxes on American families to

the tune of about $5 billion. I think we heard that figure mentioned earlier. Can any of the witnesses, starting with you, Mr. Melville, comment on whether families using FSAs, HRAs, HSAs make less or more than $250,000, and let's talk about the impact of this tax increase on those families.

Mr. MELVILLE. Sure. Thank you for the question. And as I mentioned in my testimony, the average income for an FSA holder is $55,000. And on average they set aside about $1,400 of their income to pay for their medical costs that weren't covered by reimbursement. And from that perspective we think that FSAs and HSAs provide the right kind of message to consumers that they are responsible for taking care and having skin in the game on their own health care and that they will spend that money responsibly, and particularly because it is their money, they are setting it aside. And as a result of the change in policy someone who had been doing all of the right things, budgeting for their own health care, seeking an OTC treatment first before perhaps going to see a physician and taking care of it and saving the health care system money, they are doing all the right things, and the effect of this policy is to penalize them by saying you can no longer use your tax-advantaged card, and if you want to use your FSA you have to go to a doctor and get a prescription for a product that doesn't require a prescription.

Chairman BOUSTANY. So is this going to add cost overall, this requirement, to go in and get a prescription each time you need to get over-the-counter type medications?

Mr. MELVILLE. It does not increase the price of the product, it increases the cost to the consumer, because before they were able to use tax-advantaged dollars to purchase these products, now they are using after tax dollars, and you are treating OTC medicines differently than other medicines, prescription medicines. And it really doesn't make a lot of health policy sense because many of these medicines that are now available OTC were previously available by prescription. It is simply that the product and the experience with the product was such that the FDA and the sponsor and manufacturer of the product were able to show that a consumer could use this product safely without the intervention of physicians. So something that was previously available only by prescription and you could use your FSA, if it gets switched to OTC, that same product, you can no longer use your FSA.

Chairman BOUSTANY. I think we have seen that with peptic ulcer disease. Some of the earlier treatments required prescriptions and now they are over-the-counter as things have evolved. And the ability to get these things over-the-counter probably saves time for the consumer. They don't have to miss work to go to see a doctor and those kinds of things.

Mr. Van de Water, did you want to make a comment.

Mr. VAN DE WATER. Yes, Mr. Chairman. Again, based on the figure in Mr. Melville's testimony the average family with an FSA is spending about $136 a year on OTC medications. That means that the tax advantage to that family is on the order of $30 to $35 a year on it if they could use the FSA to purchase these over-the-counter items. With numbers like that there are going to be very few families for whom it would be advantageous to actually spend

the money to go to the doctor, even with a modest copayment, to look for a prescription to purchase aspirin or a cold medicine. And for the people with very high over-the-counter spending, such as those whom Mr. Taylor has been talking about, Mr. Taylor's own organization on their website recommends that their members talk to their physician about all of the over-the-counter medications they are taking anyway and if these are chronic concerns the prescription could be obtained in the course of a regular visit.

Chairman BOUSTANY. Dr. Feder, do you want to give a physician's perspective on all that?

Dr. FEDER. This restriction on patients requiring prescriptions for over-the-counter drugs, it places a tremendous burden on the family doc. I can tell you that from my practice. And my colleagues will tell you the same thing. You know, right now patients can come in with a list of 15 or 20 over-the-counter medicines, and if we see that some of them aren't appropriate to be taken together the patient reacts unfavorably to that. It puts the provider in a very uncomfortable position. Also, the patient will, in my practice, and I think in most practices, will have to pay for an office visit in terms of the copay.

Chairman BOUSTANY. Thank you. I will now yield to Ranking Member Lewis for questions.

Mr. LEWIS. Mr. Van de Water, in your written statement you stated that 39 percent of all workers have access to flexible spending accounts. About how many workers is that?

Mr. VAN DE WATER. Well, we currently have about 142 million workers, so applying that percentage you get about 55 million with access to flexible spending accounts.

Mr. LEWIS. Well, that is access, but not use, right?

Mr. VAN DE WATER. Correct.

Mr. LEWIS. So does the number of people who have access in total to include workers and their family members?

Mr. VAN DE WATER. Well, we don't have good data on that. Of course some of the work—in some cases some of those 55 million workers could be in the same household as another worker covered by an FSA, in other cases other members of the household might not have access to an FSA through their own employment. So we can't be sure. But one would guess that it could be on the order of one and a half to two times the 55 million number of workers covered.

Mr. LEWIS. Thank you. Dr. Feder, you testified a few moments ago in responding to the chairman's questions that when people come in asking for over-the-counter prescriptions they place a burden on you and other physicians. What can be done to lessen that burden?

Dr. FEDER. The patients, the ones that I have talked to about this, they are upset that they have to come in in the first place and ask for a prescription for an over-the-counter drug because of the cost of their copay or the cost of the visit. And so right away their mindset is somewhat uncooperative with my mindset. And so in order to try to smooth that rift over, you know, I will give them the prescription generally speaking unless I think it is a problem for their health. But the burden on the physician is I could be seeing, you know, some very ill patients, elderly patients that I see

that take me lots of time to see, and instead I am spending my time on these patients writing prescriptions for over-the-counter drugs.

Mr. LEWIS. Now, most of the people that come in, are they sick of some symptoms or are they just—maybe they saw a TV ad or heard something on the radio and said this is good for me and I just need it, I want it, Doctor, please write this prescription?

Dr. FEDER. I think there is two parts to that question, sir. The first part, most of the prescriptions OTC that I give out are for colds, they would be for allergies. For example, the patient in the spring involves having bad allergy symptoms so they need a prescription for Claritin or Allegra or Zyrtec, something like that. And then there are those patients who come in from direct consumer advertising on television and radio that hear about something. Let me just use the example of testosterone because low T has become the big key word today. But that is a prescription item, so that is treated differently. But the over-the-counter drugs—oh, and other conditions would be pain. They might come in to ask for a prescription for ibuprofen or Aleve or something like that.

Mr. LEWIS. Thank you very much. Thank you. Mr. Chairman, I yield back.

Chairman BOUSTANY. Mrs. Black, you are recognized.

Mrs. BLACK. Thank you, Mr. Chairman. And as a health care professional I certainly can see a number of reasons here why this is not a very good idea. First of all, we have got limited dollars that can be spent in health care, to begin with. We already know that it is an area where there is a rising cost to both the patient, the consumer and then also to the physicians in liability. And so as I am sitting here listening to the testimony I was just writing down some of the areas where I see this as really being a negative rather than a positive as we look at trying to get a lower cost of care and also making sure that it is patient centered care. And so I wrote these things down, and I would like any one of the panelists to add to this or correct me in what I am seeing here as being the real problems with this change.

First is the cost of the visit. We all know that with the limited dollars, especially in those families that only have a limited number of dollars to spend on their health care, that the cost of just going to see a physician to get that prescription is going to be an added cost to their already difficulty in paying for the cost of health care.

Number two is something that I don't know that was really mentioned here, in part of my having to slip it in now, but I am not sure that we really mentioned about the time away from the workplace that someone is going to take. I know having been a mother and also a working professional, and if I had to go to the doctors every time I needed something for my children's cough or sniffles or whatever, it is going to be time away from the workplace and we will see that impacting the families in particular.

Number three, there is already a physician shortage. 50 percent of my district is rural. We are having a hard enough time attracting physicians. And if they are using their time to write prescriptions rather than seeing patients that really need to be seen, this is really a problem.

Number four is the liability. And Dr. Feder, I don't know that I really thought about that a whole lot until you mentioned it because now you really can't just say, oh, I will just write that prescription because you have a runny nose or you have an allergy to a spring fever or whatever, you are really going to have to do a full exam. Because if you just write a prescription and somebody has an adverse effect it is going to come back on you. Liability is already high enough and what we are doing is we are adding on top of that where it is going to take your time again and also result in a possible liability issue.

And then the one that I don't know that we have mentioned here as well is patient choice, having enough confidence that people can understand how to take care of some of their own health care needs without running to a health care professional. And I think that that is a sad thing that we say that these are drugs that have been approved by FDA to be over-the-counter when we should be giving our patients enough credibility to say that they can read a box, they can understand an over-the-counter medication that has been approved by FDA.

So I have chronicled five things here that I think are going to drive up the cost of care, as well not move us in the position of having more patient centered care and allowing people to be more involved in their own care. So any one of you all, can you add to that or do you want to correct something that I said? Mr. Melville, let me start with you.

Mr. MELVILLE. Well, I think you really laid out the issue at hand here, which is this creates behavior that reduces access and increases cost. I think everyone in this room on the committee and here in the audience is committed to looking for solutions that reduce health care costs and that increase access to health care. It is something our country is struggling with. And quite frankly, this policy takes us in the wrong direction. Because as Dr. Feder mentioned, the consumer has to pay a copay, but his insurer is paying the balance of that doctor's visit. The copay may be $10 or $20 or $30, the system is paying the $100 or whatever the balance is.

And in addition to that, as you mentioned, the time out of the office as well. Caregiver moms miss twice as many days for taking care of their children than they do for their own health care. And the access 24/7 to an OTC medicine allows parents to treat their children and often allow their children to go to school, allow the parent to go to work. And the cost associated with absence because of these illnesses is tremendous. And it was never really quantified and I am sure was not quantified when the CBO looked at the savings as a result of this change in law.

Mrs. BLACK. I think I am going to run out of time here. I see it clicking. I have got less than 10 seconds left. So if anyone does have additional remarks or comments pertaining to what I said I would ask that you would give it to us in writing.

Thank you very much.

Chairman BOUSTANY. Mr. Becerra, you are recognized.

Mr. BECERRA. Thank you, Mr. Chairman. And thank you all for your testimony. I just want to make sure I understand what we are talking about. We are talking about over-the-counter medicines. So to be clear, over-the-counter medicines are medicines that you or

I or anyone in America, any consumer, could purchase right now by just walking into the pharmacy and plucking it from the counter. This is not a medication that requires a doctor's prescription. So we are talking about your run of the mill flu medication, it could be aspirin or something for a migraine, it could be the alcohol or peroxide, hydrogen peroxide you might use to help heal a wound, things that you can get without having to go to the doctor to get a prescription. Now, because of the law the way it is if you don't have a prescription, you buy that medicine, you can't get a tax write-off for it. If you buy that cold medication with a prescription and buy it off the counter, not going to a pharmacist but right off of the counter, you can write it off from your taxes. And so what we are talking about is the fact that there are Americans who want to take advantage of the fact that by purchasing medicines that any American can purchase that they can get a tax write-off, they can reduce their taxes. And so it is an incentive to call Dr. Feder or any other doctor and say, Dr. Feder, I have got a cold, it is really bad, could you give me a prescription so I can go buy that cold medication. And the inconvenience and so forth that you have explained I think arises from all of that.

This is the concern I have. I can understand why most Americans want to reduce their cost of health care because health care is extremely expensive. But have any of you figured out how we would cover the $7 billion cost of eliminating that provision? Because by giving that select group of Americans who has FSAs or HRAs or HSAs, these flexible spending accounts, these different type of accounts, we are giving a select group of Americans a chance to deduct the cost of that flu medicine from their taxes where the majority of Americans buy the same medicine, buy the same pills but don't get to deduct those costs from their taxes. And so the cost to taxpayers who don't have FSAs or HRAs or HSAs are passed on to the majority of Americans—yeah, the cost of those deductions are passed on to those who don't have these flexible savings accounts. And so if we want to return to the days when a certain segment, the minority of Americans could deduct the cost of that flu medicine from their taxes we have to come up with $7 billion in offsets, because that is what the cost will be over 10 years. Someone pays for that. Other taxpayers have to pay for that, either paying more taxes elsewhere or we deficit spend and borrow the money from China.

So have any of you thought of the solution, because we talked about solutions, what the solution is? How do we pay for the $7 billion cost of reinstituting a program that allowed a minority of Americans to deduct the cost of their over-the-counter medicines from their taxes, which the majority of Americans cannot do?

If you have it paid for, I would love to hear it. Otherwise that is the dilemma we have. I would love to do what you want to do, because I would love to help those Americans, the minority of Americans who can deduct the cost of their over-the-counter medicines from their taxes, but I have to pay for it, I have to find a way to pay for it. And right now we are being told that we have to cut Medicare, we are being told we have to cut Meals on Wheels for seniors, we have to cut funding for our schools because we are in deficit. And on health care we are told, and Dr. Feder probably

knows this very well, we have got to do something about this sustainable growth rate reimbursement for physicians and other providers which is not keeping pace with the cost of inflation for doctors to be able to provide health care. And that is going to cost a ton of money.

Dr. Feder, I don't know if you would rather we cover this but not take care of the SGR doc fix. And so it is easier said than done, and given that these provisions that you would like to see in place are a convenience and help a minority of Americans, and by some estimates the FSAs impact about one in seven workers which means they touch the lives of about 30 million Americans, that is 1/10th, 10 percent of Americans participate in FSAs or are touched by FSAs, that means 90 percent of Americans go to the same pharmacies, purchase those same medicines and they can't deduct them from their taxes. And so it would be helpful if when you come here to tell us to really rethink and restore that program if you help us figure out how we come up with the $7 billion it will cost to reinstitute the program.

Thank you.

Chairman BOUSTANY. I would remind my friend that he just made a good case for the fact that we still have a massive health care problem in the country and it has not been adequately addressed by the passage of a health care law and so we have much more work to do. And I think any of those things that could empower individuals and families to take more control of their health care destiny is probably a good thing in the long run.

Mr. BECERRA. But Mr. Chairman, on that point, a few years ago some years back there was no such thing as deducting the cost of your over-the-counter medicine. It came into play as a result of the creation of the FSAs and so forth. And I think it encourages folks to make sure that they take the medicines they need. But this is the time of austerity and I think, Mr. Chairman, we have to figure out what are the most important things. Is having a consumer go to Dr. Feder and say, Dr. Feder, I need to see you because I need you to give me a prescription so I can buy that cold medicine that I can buy over the counter on my own without a prescription——

Chairman BOUSTANY. We will continue this debate.

Mr. BECERRA. That is the question, that is the question.

Chairman BOUSTANY. Ms. Jenkins, you are now recognized.

Ms. JENKINS. Well, I want to thank the chairman again for holding this hearing and for all of you for testifying today. We have got great bipartisan support in the House and even on this Ways and Means Committee to repeal this provision. And I hope that hearing some of the facts today will encourage even more of our colleagues to support removing this burden on consumers.

Mr. Chairman, I would ask unanimous consent to enter a letter of support into the record. It is from the Health Choices Coalition and it is simply supporting the repeal of this prescription requirement from the health care law.

Chairman BOUSTANY. Without objection.

[The letter follows: The Honorable Lynn Jenkins]

April 25, 2012

The Honorable Charles Boustany, M.D.
U.S. House of Representatives
Washington, DC 20515

The Honorable John Lewis
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Boustany and Ranking Member Lewis:

On behalf of the undersigned groups of the Health Choices Coalition representing physicians, consumers, retailers, manufacturers, pharmacies, pharmacists, pharmacy benefit managers, patients, insurers, small businesses and employers, we write to thank you for holding this hearing today to examine tax-preferred accounts for purchasing over-the-counter products. The coalition is concerned about the impact of the provision in the Patient Protection and Affordable Care Act ("PPACA") that requires holders of tax-preferred healthcare accounts to obtain a physician's prescription in order to use funds from those accounts to purchase an over-the-counter item.

The goal of PPACA was to expand access to affordable care for all healthcare consumers. Unfortunately, the provision that limits coverage of OTC medicines instead increases costs to the health care system and places a new, administrative burden on already over-burdened physician offices.

Consumers depend on OTC medicines as a first line of defense for their families' healthcare needs. OTC medicines provide Americans with an effective, affordable, convenient and accessible means to address their healthcare needs. These medicines save consumers billions of dollars annually through reducing unnecessary doctors' visits, increased productivity at work, and the cost advantages of using OTC medicines as a frontline treatment.

A recent study[1] found that OTC medicines contribute a total of $102 billion each year in savings and cost avoidance in the healthcare system. In other words, for every $1 spent on OTC medicines, the healthcare system reaps $6-$7 in savings. The availability of OTC medicines off-the-shelf and without a prescription provides medicines for an estimated 60 million people who would otherwise not seek treatment. OTC medicines are an essential part of the healthcare system and deserve equal tax treatment with prescription drugs and medical devices.

Furthermore, millions of American families rely on flexible spending arrangements ("FSAs"), Health Savings Accounts ("HSAs"), and other tax-preferred accounts to purchase these cost-effective medications. This issue is of critical importance to the estimated 19 million working Americans who rely on voluntary contributions of pre-tax dollars to FSAs to help meet their basic healthcare needs, including the purchase of safe, affordable OTC medicines. Prohibiting the use of FSA funds to purchase these medicines, or requiring documentation from a doctor that OTCs are being used to treat a medical condition, is already limiting access and greatly reducing the cost-efficiencies associated with these medicines.

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[1] "The Value of OTC Medicine to the United States," Booz & Co. 2012, on behalf of CHPA

A 2010 survey[2] found that more than 90 percent of Americans prefer to seek treatment with OTCs before seeing a healthcare provider. At the same time, nearly 90 percent of the physicians and pharmacists surveyed recommend that patients self-treat with OTC medicines prior to seeing a doctor. As a result, an overwhelming majority of pharmacists and physicians surveyed believe there is already an increased burden on medical professionals because of this provision in the healthcare reform law.

We believe this provision of PPACA limiting the use of tax-preferred accounts has resulted in unintended consequences to both physicians and patients. We thank you for your efforts in repealing this bad policy and remain committed to working with you and others in Congress to restore the ability to pay for OTC medicines with tax-preferred account funds.

Sincerely,

AARP
Aetna
America's Health Insurance Plans
American Academy of Family Physicians
American College of Physicians
American Medical Association
American Osteopathic Association
American Society of Association Executives
Associated Builders and Contractors, Inc.
Bayer HealthCare Consumer Care
Blue Cross Blue Shield Association
Consumer Healthcare Products Association
CVS Caremark
Food Marketing Institute
National Association of Chain Drug Stores
National Association of Manufacturers
National Community Pharmacists Association
National Federation of Independent Business
National Grocers Association
Perrigo Company
Retail Industry Leaders Association
Sjögren's Syndrome Foundation
U.S. Chamber of Commerce
Walgreens
WellPoint

[2] "Your Health at Hand" Survey, CHPA 2010

Ms. JENKINS. One of my constituents back home, Donna, in Fort Scott, Kansas, wrote me at the beginning of this Congress, and this is what she said: My husband and I try to stay very healthy and really enjoy the flexibility of the health savings account as it once was. It was very convenient to be able to buy over-the-counter products to manage our own health care. Americans should choose a healthier lifestyle which could cut down on costs tremendously. I do not know why anybody wants the government to be so involved in the management of the money we have worked so hard to earn. Please work hard to get this part of the health care act repealed.

And I struggled to provide a rational response to this constituent as to why this prescription requirement was even included in the President's health care law in the first place. It doesn't provide better health care for consumers and I can't figure out how it would lead to creating the 4 million jobs that then Speaker Pelosi promised the bill would create. To me the only logical response was that it was a simple line item that provided revenue to help pay for the massive overhaul, which is why we have introduced legislation to repeal this provision.

Ms. Hatcher, you mentioned in your testimony all the work your organization did to comply with the original 2008 IRS guidelines. Then we passed the health care law and you all get new guidance just weeks before you must comply with these new prescription requirements. You mention a company spent about $100,000 to comply with this new provision from the health care law.

Do you know what the average salary is for a full-time employee in your member companies?

Ms. HATCHER. It would depend upon the position. There would be a wide variation between the various positions in the store, but it would be well below that expenditure.

Ms. JENKINS. So you think you could hire at least a couple full-time employees for the cost of just getting the system set up?

Ms. HATCHER. Certainly.

Ms. JENKINS. What concerns me most about this investment you all had to make was that it may have come at the expense of your members creating new jobs at a time when that was what we need the most. Could you estimate for me or have you received any anecdotal feedback on how this new requirement is hindering job growth for your members?

Ms. HATCHER. Well, certainly, as you mentioned, the expenditures that were put into the system, and there are ongoing expenditures that it didn't really factor in. Just to add to Congresswoman Black's list, one additional expenditure is the most expensive position and the hardest to fill in the supermarket environment is the pharmacist position, and now we have to have a pharmacist involved in the sale of every OTC product that has a prescription, and it has taken him away from really counseling sick patients, so certainly I would add that to the list of those expenses.

Ms. JENKINS. Okay, thank you. Mr. Melville, you mention a study in your testimony, specifically the fact that every dollar spent by consumers on OTC meds saves six to seven dollars for the U.S. health care system as a whole. Can you elaborate a little more on some of the findings of that study?

Mr. MELVILLE. Sure, thank you. The study looked at a hypothetical world that said if OTC medicines were not available, what would consumers do, and so they polled 3,500 consumers and got a direction from them that many of them would go to see a doctor, many of them would go to an emergency room, many of them would seek a more expensive prescription medicine, all behaviors that add costs to the health care system, not reduce costs, and by looking at that and extrapolating, it came up to about $102 billion in current value today because of OTCs. OTCs keep consumers or patients out of a medical office when they don't need to be there. It allows them to purchase a product on their own without the in-

volvement of a pharmacist per se, no dispensing fee. It is cost-effective health care. It is not appropriate in every situation, absolutely not, but where it is appropriate, it is cost-effective and it should be encouraged, and this study shows the benefits of OTC medicines. It makes it difficult to understand how this provision could be scored at saving money for the health care system when it is causing people to go see doctors.

Ms. JENKINS. Thank you. Mr. Chairman, I yield back.

Chairman BOUSTANY. Mr. Marchant, you are recognized.

Mr. MARCHANT. Thank you, Mr. Chairman. In 2009 the President told the Nation that he was not going to be in favor of raising taxes on any family that made under $250,000, yet looking at the rules of Obamacare, it seems that exactly the opposite will take place. The ban on over-the-counter purchases without a prescription is estimated to raise taxes on families of about $5 billion a year.

Can any of the witnesses each comment on the families that you have experience with that you see are affected by this law? Do they fall in the under $250,000 category or do they fall above the $250,000 category?

Mr. Melville.

Mr. MELVILLE. Well, as I cited earlier, the most recent data we were able to obtain showed that the average FSA participant earned $55,000 a year. As a result of this provision, if they had an FSA account before the provision took effect, their cost for OTC medicines went up 10 to 35 percent after the provision took effect.

Mr. MARCHANT. So that would be a tax increase?

Mr. MELVILLE. It is certainly a cost increase to the consumer.

Mr. MARCHANT. Mr. Feder, Dr. Feder.

Dr. FEDER. I can tell you that, you know, my patients, I practice in the great State of Kansas, and I practice in a fairly affluent county, but I guarantee you these patients make far less than $250,000 a year, and we see indigent patients, we see patients that don't have insurance, we give out samples to patients, and we still cannot keep up with the complaints about they can't afford this and they can't afford that, and this is just one more area that I think we can empower and help our patients in that they don't have to come to the office and spend money to see me to write them a prescription that they can get over the counter.

Mr. MARCHANT. Thank you. Mr. Taylor.

Mr. TAYLOR. Thank you. Well, Sjogren's affects 1 percent of the U.S. population, so surely the majority is going to be earners under $250,000, affects mostly women, but it surely does affect people that don't make $250,000, and the patient choice is so important for our patients, but to understand Sjogren's, our patients use between 10 and 17 products daily for their disease from dry skin lotions all the way up through dry eye options to dry mouth options, et cetera. And so surely with the prescription issue, it would fill the doctors' offices with having them write prescriptions, and it is causing problems for our rheumatologists, our ophthalmologists to write those prescriptions for our patients.

Mr. MARCHANT. Ms. Hatcher.

Ms. HATCHER. I don't have any specific data, but where we have seen the use of FSA cards, it is throughout all income levels

in a community, it is not limited to upper income levels, it is throughout all income levels.

Mr. MARCHANT. Yes, sir?

Mr. VAN DE WATER. Mr. Marchant, it is important to look at not just the tax effect of this particular provision, but of the entire legislation of which it was a part. As Ms. Jenkins correctly noted, the purpose of this provision is not just to raise revenues for the sake of raising revenues but to help finance the major expansion of health coverage that was provided by the Affordable Care Act. Indeed, using the figures and the testimony we heard earlier, there are people, you know, the average person benefiting from an FSA will lose perhaps 30 to 40 dollars a year on account of this limitation on over-the-counter spending. However, the Affordable Care Act is also extending health coverage to 33 million Americans who haven't had it and providing tax credits to low—which are focused on low- and moderate-income Americans. So it seems to me, and I can say that as a person who has this year for the first time a flexible spending account and who earns less than $250,000 a year, I for one am quite happy to pay an extra $30 a year to help provide health coverage to the less fortunate of our citizens who otherwise wouldn't have it.

Mr. MARCHANT. So in your view it is—it was basically a cost shifting from one group of people to another group of people?

Mr. VAN DE WATER. It is not a cost shift. It is a way to raise revenue to pay for a very important program.

Mr. MARCHANT. That would be what we define as a cost shift. Thank you very much.

Mr. TAYLOR. Mr. Marchant, may I please add, we have all these new people going to be going on the health care rolls, and we won't have time to see them in the physicians' offices if people that do have FSAs are taking up time to get prescriptions, and that is the biggest challenge that we have in the health care system. There is only 39 percent on FSAs, but they will be taking up time, important time for other people that could get in, need to get in to see their doctors, which is very important to remember as well.

Mr. MARCHANT. Thank you, Mr. Taylor.

Chairman BOUSTANY. Mr. Reed, you are recognized.

Mr. REED. Thank you so much, Mr. Chairman. Mr. Van de Water, I do appreciate your generosity in giving your money to a segment of the economy, of the population for paying for their health care when they need it, but would you agree that some people may not want to be that generous or that some people feel that the money in their FSA accounts is the money that they earned and it is their money, and they should have the choice whether or not to pay for someone else's health care in America?

Mr. VAN DE WATER. Whether or not to have an FSA is itself a choice. As I said, up to this year I had not exercised an FSA.

Mr. REED. I think, sir, what you said is you appreciated the fact that you had an opportunity because of what you make under your FSA to pay for those people that may be in a situation that can't get health insurance, and I appreciate your generosity. But what my concern is is why in Washington, D.C. do we have an attitude that—you may feel that way, but there is millions of people I am sure that are out there that don't feel like you, and we are direct-

ing them from Washington, D.C. under this provision to say, well, so sorry, so sad, we are going to tell you we are going to take your money.

Would you agree your money in your FSA is your money or is it the government's money? Whose money is it in the FSA? Your FSA in your account, whose money is it? Is it the government's money or is it your money? Did you earn that money?

Mr. VAN DE WATER. The tax benefit is——

Mr. REED. No, no, the money in the FSA, you earned it, right?

Mr. VAN DE WATER. We are not talking, sir, about the money in the FSA per se. My money is my money.

Mr. REED. No, I am talking about the money——

Mr. VAN DE WATER. We are talking about whether I should get a tax benefit for buying a cold remedy.

Mr. REED. But that is your money that you earned in your FSA. Does anybody else have an FSA on the panel? Okay. Do you feel that is the government's money or is your money?

Mr. TAYLOR. It is my money that went in there.

Mr. REED. Yeah. So do you have any problem with us coming in and using that FSA money for something else? Do you appreciate the fact that I, here in Washington, D.C., under the Affordable Care Act am directing that I am going to take that money and put it somewhere else? I mean, that is what I am hearing from the testimony from the panel today. Am I missing something?

Mr. VAN DE WATER. Yes, that is a mischaracterization of my remarks, sir. I can use my money to buy over-the-counter drugs at any time. At issue is the amount of the tax subsidy that I should get, and the tax subsidy, which is what we are talking about, is not my money.

Mr. REED. That $30 is not your money?

Mr. VAN DE WATER. I have no right, God-given right to a tax subsidy for buying cold medicine.

Mr. REED. Am I missing something? Isn't that $30 part of the FSA money that you are—you essentially earned, you are just paying the $30 as a tax on the money you earned even though you—because you are getting the tax benefit from the transaction, you are paying the $30 at the end of the day.

I guess my point, I am just trying to stress the point that there is an attitude here in Washington as a new member that I see that is clearly on display here in that the FSA tax benefit is looked at as if that is Washington's money, not the individual who earned its money, and I have a fundamental disagreement, and I believe you can tell where I come down on that side of the equation.

If I could, I just want to get into a little bit—Mr. Melville, can you give me any medical justification as to why this policy was enacted?

Mr. MELVILLE. There is no medical justification that I am aware of. These are often referred to not only as over-the-counter drugs but nonprescription drugs. By their very nature, they don't require a prescription, so the tax policy is inconsistent with the medical treatment of that product.

Mr. REED. Would anybody disagree with that assessment on the issue?

[Witnesses nodding.]

Mr. REED. Now before this provision was put in the Affordable Care Act, was there any consumer advocates or any professional doctors or hospital organizations that were advocating or suggesting using FSAs and HSAs to purchase OTC medication that was harming patients or represented bad health policy? Was there anybody during that debate raising those concerns? Anybody? Yes, no?

Mr. MELVILLE. No.

Mr. REED. Well, with that, I yield back, Mr. Chairman. I clearly see what the policy was for. It clearly was a revenue—I do appreciate your candor on the statement you made, Mr. Van de Water, for the record, that it was clearly a revenue source to pay for the Affordable Care Act, and I do appreciate that candor.

With that, Mr. Chairman, I yield back. Thank you.

Chairman BOUSTANY. I thank the gentleman. Mr. Paulsen, you are recognized.

Mr. PAULSEN. Thank you, Mr. Chairman. Let me just thank you also for holding this important hearing today. It is something I have certainly taken an interest in personally as well as Congresswoman Jenkins. In fact, her and I today have an opinion piece that has been published in the local Roll Call subscription newspaper, so without—I ask unanimous consent to submit that for the record if we could, Mr. Chairman.

Chairman BOUSTANY. Without objection.

[The article follows: The Honorable Erik Paulsen]

Paulsen and Jenkins: Health Care Provision on OTC Drugs Hurts Consumers

By Reps. Erik Paulsen and Lynn Jenkins
Special to Roll Call
April 25, 2012, 12:01 a.m.

When was the last time you walked into your local drugstore and bought a bottle of Tylenol for your headache or a box of Claritin for your child's allergies? Did you use your health savings account or flexible savings account to purchase those, or similar, medicines?

Like millions of Americans, you probably thought that your choice to put money into your HSA or FSA gave you the right to decide how to spend it. Unfortunately, as of this past January, you would be wrong.

More and more consumers are discovering a provision in the 2010 health care law that went into effect at the beginning of this year that prevents you from buying over-the-counter medicines using your HSA or FSA, without a doctor's prescription. Instead of walking into your local drugstore to use your HSA or FSA, Americans are now forced to first visit a doctor, and pay a standard co-pay, before finally receiving a prescription for simple medicines like Advil. Sound burdensome? That's because it is.

Millions of Americans have elected to use an HSA or FSA. More than 40 million HSAs, FSAs and health reimbursement accounts cover more than 11 million lives. These consumers chose this option for their health coverage because these plans offer flexibility and portability. Increasingly, small-business owners are offering these types of accounts as a more workable option for on-the-go employees. The new health care law changes that and is wreaking havoc on patients and small businesses alike.

Doctors and nurse practitioners frequently urge patients to seek out OTC products as a means to address immediate and long-term health care maintenance. These are the same products that have been deemed safe and appropriate for consumers by the Food and Drug Administration.

A recent study found that OTC medicines contribute a total of $102 billion each year in savings and cost avoidance to the health care system. That means for every $1 spent on OTC medicines, the health care system saves $6-$7. In 2010, polling showed that more than 90 percent of Americans prefer to seek treatment with OTCs before seeing a health care provider.

At the same time, nearly 90 percent of the physicians and pharmacists surveyed recommend that patients self-treat with OTC medicines before seeing a doctor.

Consumer-driven health options like HSAs and FSAs put patients in the driver's seat when it comes to their health needs. They provide an option to access quality health care at an affordable price. The unnecessary prescription requirement limits access and flexibility. Consumers don't like it because it's too restrictive; doctors don't like it because it adds unnecessary office visits and burdensome administrative duties; and employers don't like it because they want to promote simple and easy options for their employees.

That's why we are working to repeal this onerous burden and have both introduced legislation that does so with bipartisan support. Today, the House Ways and Means Committee will hold a hearing on the use of HSAs and FSAs to pay for over-the-counter medicines.

We expect that after hearing the common-sense arguments from the panelists, members of the committee and the whole House of Representatives will agree that we must do away with the prescription requirement. We believe that individuals and families make the best decisions for their health care needs, not the government.

Reps. Erik Paulsen (R-Minn.) and Lynn Jenkins (R-Kan.) are members of the Ways and Means Committee.

Mr. PAULSEN. Thank you. Several members on the committee actually have introduced specific legislation to target fixing this onerous provision for over-the-counter medication. So in addition to Ms. Jenkins' bill, I have got the legislation that was mentioned in the testimony, there is 128 cosponsors, Mr. Reichert has a legislation, there is bipartisan support for this. You know, it is really no wonder when you come up with these types of provisions why the President's new health care law still remains so unpopular. I mean, I know it was targeted mostly towards access, but it doesn't address the cost side of the equation at all, and certainly health care savings accounts, flexible savings accounts, and then these over-

the-counter medications that have grown more popular because they have gone through FDA clearance, they become more readily available, it only makes sense they are going to be more widely used as an opportunity to reduce costs in the healthcare system. We have actually made this new health care law more and more expensive ironically. So it has gone from like $900 billion to like $1.7 trillion, so it has, like, doubled in cost, and so it is no wonder that the law itself is so unpopular.

But what I think is really interesting, though, is that you have got 33 million Americans that are in families that use these flexible spending accounts. They are offered by 29 percent of small businesses and they are offered by 85 percent of large employers as well. So you have got employers that are really pushing out to their employees, hey, take advantage of these accounts because it allows you to use your own health care dollars for your own health care needs, and at the same time Congress comes in and pulls the rug out from under them. I get these calls from these suburban mothers who are really just flabbergasted and ticked off that all of a sudden they can't go get allergy medication for their children unless they go to a doctor for that prescription. So you not only have to have the copay, but then you do have the insurance cost that gets paid, that gets spread out among everybody, so then you are increasing health care costs for everybody. It is going in the opposite direction of the intended effort of health care reform. So the consumers don't like it, the doctors don't like it, and the employers don't like it.

Let me just ask this question because this has not come up in discussion today, but another restriction that is actually in the new health care law is also a restriction on the cap of the amount of money that can be put into these accounts each and every year. As we know, some health care procedures are fairly expensive. I will give you one example in particular, but you have got a $2,500 cap essentially now that has been placed on these accounts, and that starts in January 1st of this next year, so we are going to hear a lot more from consumers that are going to be impacted by this new cap, and I am concerned we are going to see similar problems, so you have got millions of consumers that use these funds, their own health care dollars with more restrictions. How will this—as an example, I will give you an example of how this might restrict dental care. So if you have got a consumer that is now going to be able to—say if they want to use an oral health decision for dental care, and they have got no money really to cover their out-of-pocket expenses, so they go to, say, a surgical dental implant for like a jaw bone implant in Dayton, Minnesota. According to fairhealthconsumer.org, this procedure might cost like $1,221, so a significant amount of money. That is a cost that the consumer is going to directly have to pay after their insurance coverage. Then you add a ceramic retainer, you know, for your child, of course, you are at $900, so you have almost used up the whole cap right there.

Let me just ask this, Mr. Melville or any others that might want to comment, after you have had several of these procedures, you can use up and burn through your whole account right there. You know, in general, I mean, what is going to be the impact on the

consumer with that type of a provision as well? Is that moving us in the wrong direction, Mr. Melville?

Mr. MELVILLE. Well, sir, I have a 14-year-old daughter who is getting braces next year, so I will be able to personally experience that cap in my situation, but, you know, I can't speak broadly towards how FSAs are utilized broadly for health care. I can say that the OTC spend is usually a very small part of the overall amount that a consumer will spend out of their FSA, but it is a significant amount, and I think I have heard today some comments saying it is not much. It is a lot for certain people who perhaps aren't making a lot of money and may have a disproportionate need. Maybe they do take an allergy medicine 12 months a year along with their children, and you add all of that up, 10 to 35 percent of that allergy medicine over the course of the year is real money, and I think it is not fair to characterize it as modest or insignificant. It is really significant to a lot of people.

Mr. PAULSEN. Mr. Taylor—or, Mr. Feder, from a physician's perspective on the cap, I mean, another provision that we are going to hear about from consumers down the road here.

Dr. FEDER. Yeah, I think so. I have patients that I do a physical exam on, they need a colonoscopy, a stress test, they need some other procedures, it can run up into the thousands of dollars, and sometimes they will bundle all these to do in one year because they have got the money to do it, and I see that, you know, that is not unusual to see that. They may be looking at an elective surgery, cataracts, although that is covered, but still there is going to be out-of-pocket expense. Maybe they want lasik surgery, there is just a host of elective procedures that are very expensive, and a cap obviously will affect that.

Mr. TAYLOR. And Sjogren's patients on average spend over $1,500 a year on dental work for their dental issues that they have, so it is very expensive as well.

Mr. PAULSEN. Thank you, Mr. Chairman.

Chairman BOUSTANY. I thank the gentleman. Yes?

Mr. LEWIS. Could I just ask one last question, Mr. Chairman?

Chairman BOUSTANY. Yes.

Mr. LEWIS. Can I do somewhat of a poll? How many of you favor or see health care reform as good in itself, that it is affordable, accessible when we have more than 50 million of our citizens without any health insurance, they cannot afford to see a doctor, many never see a doctor because they cannot afford it. I would just like to get—I know you are very smart, you have been working in this area, some of you, for quite a while. Dr. Feder?

Dr. FEDER. I can address that, if I might. Yes, sir, I represent the American Osteopathic Association, and we are on record as supporting the Affordable Care Act. However, we do feel with any law there is room for improvement and revision, and I support that position.

Mr. LEWIS. Others?

Mr. TAYLOR. Well, the Sjogren's Syndrome Foundation is on the record as well of supporting the Affordable Care Act. I think the challenge is in any disease—I have worked in nonprofit health care my entire career, American Heart Association and now Sjogren's Syndrome Foundation—is access to health care and we need to do

something about it, and this will definitely change that. The challenge with what we are talking about today is we will be filling those doctors' waiting rooms with people just needing prescriptions for their FSAs instead of getting those new people that finally have insurance into their doctors. And there is even statistics on colonoscopies. People that have higher incomes tend to go for more colonoscopies and fill colonoscopy rooms, when people that actually have symptoms that need the colonoscopies can't get in. The same thing will happen with rheumatologists and opthalmologists, if Sjogren's patients start filling, and they have been, filling waiting rooms trying to get prescriptions, taking away from people that really need those appointments because they have a real medical need for them just to get a prescription for eye drops or saliva substitutes or et cetera. Access to care is wonderful, but we need to make room for those people to get into the doctors' offices as well.

Mr. LEWIS. Thank you. Ms. Hatcher, do you have a point of view here?

Ms. HATCHER. Sure. I mean, just in general in terms of affordable care, obviously there is some work that needs to be done. This particular provision we have been against all along. We did a lot of work to put an advance system in place, and we just felt like the rug was taken out from underneath us. When the IRS asks you to do something, you usually jump and try to do it, and we did, and then we feel like, you know, all of our work was kind of useless, and so I think that is the frustration from our member standpoint is more of the investment they put into this to try to make this work and make the system work and then have it taken away.

Mr. VAN DE WATER. Mr. Lewis, I think that the Affordable Care Act represents a wonderful achievement on the road to reducing the number of people in this country without coverage. As I said before, another one of the Act's remarkable achievements is that it does include provisions to pay for the health care expansion. Unlike, for example, the expansion of, you know, the provision of Medicare drug coverage back in, you know, the previous decade, which was not fully paid for, the Affordable Care Act by CBO's estimation will actually modestly reduce the deficit because it does include other spending reductions and tax changes to pay for it. This provision is clearly one of the less popular provisions, but I do think that it has a strong policy justification, as I have explained earlier.

Mr. LEWIS. Thank you.

Mr. MELVILLE. Mr. Lewis, my association did not take a position for or against the Affordable Care Act. We certainly support the goals of increasing access and reducing cost. We would agree with Dr. Feder that the law itself can be tweaked and improved, and this is an area that we think can be improved because with the expansion of coverage, it will put more pressure on physicians, and the last thing physicians need would be people coming in asking for prescriptions for medicines that don't require one.

Mr. LEWIS. Thank you. Thank you, Mr. Chairman.

Chairman BOUSTANY. I thank the ranking member. I would just conclude by saying that this hearing was focused on this particular provision, first of all, a provision that is going to add cost

to the health care system, and it certainly has a hassle factor associated with it, as we have heard from many of you.

On the broader picture of the health care law that passed, we know obviously, yes, there was increased coverage, but does coverage really mean real high quality access when you consider that a significant amount of that expanded coverage is in the form of Medicaid where we have doctor shortages and physicians who currently are not seeing Medicaid patients or trying to markedly curtail their Medicaid exposure because of the very poor reimbursement that doesn't meet costs. We are going to be simply pushing all of these individuals into the emergency room, and so while you can talk about expanded coverage, does it mean high quality access? And at the same time we do know that costs are going up and accelerating at a rate, according to the CBO, even faster than if we had done nothing.

So there are significant problems remaining, and while I think this was a very valuable hearing to focus on this one provision which is causing a lot of consternation on the part of families across this country and adding to cost, we have clearly much more work to do in health care, and so with that I want to thank the witnesses for being here today and for your testimony. I want to remind you that members may have some additional questions they may submit in writing to you, and those questions and your answers would be made part of the official record. So, again, thank you for being here today, and that concludes our hearing.

[Whereupon, at 4:00 p.m., the subcommittee was adjourned.]

[Submissions for the Record follow:]

The Honorable Wally Herger

The Honorable Wally Herger

Statement for the Record

House Ways and Means Subcommittee on Oversight

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

April 25, 2012

Chairman Boustany and Ranking Member Lewis, thank you for the opportunity to submit testimony regarding the definition of qualified medical expenses with respect to flexible spending accounts (FSAs), health savings accounts (HSAs), and health reimbursement arrangements (HRAs). In an era of ballooning deficits and skyrocketing healthcare costs, we need to be doing everything we can to support individuals and families that are making an investment in their own well-being through these accounts. Participating in an HSA, FSA or HRA is an excellent way to save money on medical expenses by using tax-free dollars to pay for healthcare products and services. In addition, these accounts help individuals and families to take responsibility for their own healthcare, and they encourage Americans to make wise decisions in their healthcare spending.

Unfortunately, arbitrary restrictions on the types of medical expenses for which FSA, HSA, or HRA funds may be used can prevent hard-working American families from spending their own money for legitimate medical expenses. I share the concerns raised by many physician and patient groups regarding the new limitations on the purchase of over-the-counter medications. While these restrictions were put in place by Congress as part of the 2010 health care overhaul, I would encourage the Subcommittee to also review other limitations that have been imposed by the Internal Revenue Service through rulemaking or informal guidance.

One expense I care particularly about that is currently excluded from these accounts is umbilical cord blood banking.

Umbilical cord blood is a rich and non-controversial source of stem cells for current and emerging therapies. Stem cells from umbilical cord blood have been used in more than 15,000 transplants worldwide during the last 20 years to treat a wide range of serious diseases in both adults and children, including many forms

of cancer, blood disorders, and immune diseases. In addition, clinical trials are currently underway to study use of a child's own cord blood stem cells to treat traumatic brain injury, cerebral palsy and hearing loss. However, because umbilical cord blood stem cells require processing and storage before use, many families choose the services of private cord blood banks to store their child's cord blood for future medical therapy.

When I learned about this emerging medical field, I wrote to the IRS, along with 12 of my colleagues, to ask that umbilical cord blood banking be defined as a qualified medical expense so that families could use HSAs, FSAs, or HRAs to pay for cord blood banking services. Regrettably, the IRS has taken the position that these costs are not qualified medical expenses because they do not address an "existing or imminently probable" medical condition, despite the fact that Section 213(d)(1)(A) of the Internal Revenue Code explicitly includes "prevention of disease" in the definition of medical care. There are clear medical expenses associated with processing and storage of umbilical cord blood at the time of birth and during storage, as well as at the time of a future transplant, and these expenses should be eligible to be paid from tax-advantaged health care accounts.

As a result, Congressman Ron Kind and I introduced the Family Cord Blood Banking Act in 2009 and reintroduced the legislation in 2011 to clarify that umbilical cord blood banking is a qualified medical expense for tax purposes. I am grateful to Ranking Member Lewis and the other members of the Ways and Means Committee who have cosponsored our legislation. My sincere hope is that this issue can be resolved, either administratively by the IRS or through legislation, in the very near future so that families with HSAs, FSAs, and HRAs can have access to this exciting new frontier in personalized medicine.

The Honorable Dave Reichert

WRITTEN STATEMENT FOR THE RECORD FROM

CONGRESSMAN DAVE REICHERT (WA-08)

BEFORE THE

U.S. HOUSE OF REPRESENTATIVES
WAYS AND MEANS OVERSIGHT SUBCOMMITTEE

HEARING ON THE IMPACT OF LIMITATIONS ON THE USE OF TAX-ADVANTAGED ACCOUNTS FOR THE PURCHASE OF OVER-THE-COUNTER MEDICATION

APRIL 25, 2012

Chairman Boustany, Ranking Member Lewis, and my colleagues on the Committee – thank you for the opportunity to testify today during this important hearing on the impact of limitations on the use of tax advantaged accounts for the purchase of over-the-counter medications. I am proud to have introduced legislation, the *Restoring Assistance for Families' and Seniors' Health Expenses Act* (H.R. 450), to repeal the provision within the health care overhaul law that prohibits holders of Flexible Savings Accounts (FSAs), Health Savings Accounts (HSAs) and Health Reimbursement Accounts (HRAs) from using money from their accounts to purchase over-the-counter (OTC) medications. H.R. 450 also restores the medical expenses deduction to 7.5% of taxable income and repeals the $2,500 cap placed on FSAs beginning in 2013.

While I have found there to be many troublesome provisions within the health care overhaul, the limitations put on the purchase of OTC medications is one of the most egregious given that many Americans rely on easy access to OTC medications to assist with common ailments such as headaches and the common cold.

Personal choice is a key factor in all health care decisions. FSA's, HSA's, and HRA's empower individuals to take control over their personal health care costs. Approximately 40 million Americans choose to use these accounts to give themselves flexibility to make their own medical decisions and save for future medical expenses. The health care overhaul gives Americans two options – get a prescription for the needed OTC medication or choose to purchase them out-of-pocket, increasing the cost of medication. In other words, not only will this provision increase costs, but it also places an unnecessary burdensome requirement on the individual to schedule an unneeded doctor's appointment.

Physician groups have also expressed concerns related to the OTC limitation provision. The American Medical Association wrote that the limitations would "increase costs to the healthcare system, generate unnecessary physician office visits, and place a new administrative burden" on doctors. Physicians are supportive of the use of OTC medications as a way to treat common illnesses and conditions. Often times, the use of an OTC medication can reduce the time an individual is ill and also prevent more serious ailments that would result in higher health care costs and more doctors visits. A recent study concluded that the use of OTC medication saves the health care system $102 billion annually. The study deduced that these savings came from early treatment of ailments.

It's also important to note the impact the health law has on employers. An astounding 89% of large employers offer tax-advantaged health accounts to their employers because of the flexibility and predictability these accounts offer to an individual's health care costs. The National Federation of Independent Business applauded the legislation I introduced stating, "This legislation will help provide greater economic certainty and predictability for small business…Options like FSA's and HSA's encourage consumer awareness on how they can best spend their health care dollars."

I would like to thank the Chairman and Ranking Member for holding this hearing and allowing me the opportunity to submit testimony. I applaud the efforts of my fellow Committee Members, Representatives Paulsen and Jenkins, who have also introduced measures related to the OTC requirement. It is my hope that this Committee can work together on a bipartisan basis to repeal this onerous and burdensome provision.

Statement

of the

American Medical Association

to the

Committee on Ways and Means
Subcommittee on Oversight
U. S. House of Representatives

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

April 25, 2012

25 Massachusetts Avenue, NW, Suite 600
Washington, DC 20001
Division of Legislative Counsel
202-789-7423

STATEMENT

of the

American Medical Association

to the

Subcommittee on Oversight

of the

Committee on Ways and Means

United States House of Representatives

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

April 25, 2012

On behalf of our physician and medical student members, the American Medical Association (AMA) appreciates the opportunity to submit a statement regarding today's hearing on the Impact of Limitations on the Use of Tax-Advantaged Accounts for the Purchase of Over-the-Counter Medication. We commend Chairman Boustany for holding this hearing to consider the consequences of a provision in the Patient Protection and Affordable Care Act (ACA) that restricts the use of tax-advantaged accounts, such as flexible savings accounts (FSAs) and health savings accounts (HSAs), for the purchase of over-the-counter (OTC) drugs.

Millions of Americans currently rely on tax-advantaged accounts, such as FSAs and HSAs, to save for "qualified" medical expenses as defined by the Internal Revenue Code. Approximately 33 million Americans are in families with FSAs, which are offered by 29 percent of small businesses and 85 percent of large employers. An additional 11.4 million Americans are enrolled in an HSA. Contributions to and distributions from these accounts are generally tax-exempt and may be used for unreimbursed medical expenses, such as deductibles, co-payments, and co-insurance.

In 2003, as several popular drugs moved to OTC status, the Internal Revenue Service changed the regulations on these accounts to allow them to be used for the purchase of nonprescription medications and other health care products. Consumers depend on OTC medicines as a first line of defense for their families' health care needs. OTC medicines, such as aspirin, acid reflux medications, allergy medications, vitamins, and eye drops,

provide Americans with effective, affordable, convenient, and accessible means to address their health care needs. These medicines save consumers billions of dollars annually by reducing unnecessary physician visits, minimizing time lost from work due to illness, and allowing patients to benefit from the cost advantage of OTC medicines, which tend to be less expensive than prescription medications. A survey conducted by the Consumer Healthcare Products Association in 2010 found that more than 90 percent of Americans prefer to seek treatment with OTCs before seeing a health care provider. At the same time, nearly 90 percent of the physicians surveyed recommend patients try to address minor ailments with self-care interventions, including the use of OTC medicines, before seeking professional care.

As a way to offset costs associated with the ACA, Congress revisited the guidelines governing the use of tax-advantaged accounts to purchase OTC medications. However, as an alternative to returning to the pre-2003 limits, Section 9003 of the ACA allowed consumers, beginning in 2011, to continue purchasing OTC medications with pre-tax dollars, but only with a prescription. We believe this change has resulted in several unintended consequences. Under U.S. Food and Drug Administration rules governing drug safety and efficacy, OTC medications do not need a prescription; yet, now, because of Section 9003, patients have to get a prescription solely to use their tax-advantaged accounts. This requirement makes no sense from a drug safety or patient safety perspective since OTC drugs, by definition, do not require prescriptions in order to be purchased.

This new OTC requirement has placed new administrative burdens on already overburdened office-based physicians, particularly small primary care practices. We believe it will result in increased office visits, increased physician and staff time talking to patients over the phone (usually not reimbursed), and increased costs and inconvenience to patients.

Physicians face many new challenges as they begin to implement the numerous reforms included in the ACA and incorporate health information technology into their practices. Rather than improving access and saving money, however, this particular ACA provision may instead increase overall health care spending by forcing patients to schedule office visits with their physicians solely to obtain prescriptions for OTC medications. While some practices may have the resources to handle prescription requests over the phone, others may not. Many physicians require patients to schedule an appointment before prescribing any medication, so that they can examine the patient, determine whether a medication is appropriate, and counsel the patient about possible side-effects and drug interactions. This increased demand on their time means less time and attention to other patients with more urgent treatment needs, and results in increased costs to patients, who are charged for an office visit.

To maintain office productivity, other physicians may decide not to issue prescriptions that simply are not needed for the purchase of OTC medications, and could find themselves with unhappy patients who may decide to leave the practice, thus disrupting long-standing patient-physician relationships. Furthermore, since a prescription for an

OTC product must be treated as any other prescription, record keeping requirements are increased for physicians who must document in patient medical records that a prescription for an OTC drug or vitamin has been ordered.

The AMA has long-standing policy supporting HSAs and FSAs. Last year, the AMA strengthened its position on this issue by adopting policy to support repeal of the federal restriction on the use of tax-advantaged accounts to buy OTC medications without a prescription. We support the legislation, "Restoring Access to Medication Act," that was introduced in the U.S. House of Representatives by Representatives Lynn Jenkins (R-KS) and Shelley Berkley (D-NV), as H.R. 2529 and as S. 1368 in the Senate by Senators Pat Roberts (R-KS) and Ben Nelson (D-NE).

Key advantages of assigning OTC status to drugs that once were available only by prescription are ease of access and reduced costs. The new restrictions effectively eliminate these advantages. We urge Congress to pass this legislation to repeal these new restrictions and once again allow consumers to use tax-advantaged accounts to purchase OTC medications. By so doing, Congress can help to remove the additional burdens and costs imposed on physicians and their patients by this new provision.

Center for Fiscal Equity

Comments for the Record
House Committee on Ways and Means
Subcommittee on Oversight
Hearing on the Impact of Limitations on the Use of Tax-Advantaged Accounts for the Purchase of Over-the-Counter Medication

April 25, 2012, 2:30 PM

by Michael G. Bindner
The Center for Fiscal Equity

Chairman Boustany and Ranking Member Lewis, thank you for the opportunity to submit my comments on this topic. We largely agree that limiting tax advantaged plans is not a good move for cost cutting, provided that use of these accounts do not adversely affect access to care. Sadly, there were problems with these vehicles even before passage of the *Affordable Care and Patient Protection Act.* While the Center is in favor of undoing these limits as part of reform, it is unwise to simply undo the act to return to a bad status quo.

The real danger to the success of the Act is the possibility of the failure of private insurance generally. The key issue for the future of health care consolidation is the impact of pre-existing condition reforms on the market for health insurance. Mandates under the Affordable Care Act (ACA) may be inadequate to keep people from dropping insurance - and will certainly not work if the mandate is rejected altogether for constitutional reasons.

If people start dropping insurance until they get sick – which is rational given the weakness of mandates – then private health insurance will require a bailout into an effective single payer system. One way to stop this from happening is to enact a subsidized public option for those with pre-existing conditions while repealing mandates and pre-existing condition reforms. Another alternative is to pass single-payer catastrophic insurance featuring both Health Savings and Flexible Spending Accounts – however these should be used in concert, with one card (in former days called a Health Security Card) accessing both the catastrophic plan, the HSA and the FSA.

Flexible spending accounts, especially self financed ones, can be used to end the debate over services that some insurers or religious employers do not believe in funding, from acupuncture and cranio-sacral therapy to contraception and abortion, as well as over the counter medications and even medical marijuana in states where it is legal (which is a growing number). Of course, these accounts could also be limited to the gap between the catastrophic deductible, the available HSA balance and needed costs, although once you reopen the door to OTC medications, it will be hard to stop others from piling on.

Ideally, the system should fund both a public option for people who cannot get care because of cost or pre-existing conditions, allowing others to keep their employer provided care and covering the remainder with a low cost single-payer catastrophic plan provided by the government, with employers funding the HSA and employees funding the FSA. Of course, this level of convenience takes some of the impetus away from cost savings, however as health care is not a normal good that responds to market pressures, this is probably a good thing.

People will obtain health care upon doctor recommendations, regardless of their ability to pay. Providers will then shoulder the burden of waiting for health savings account balances to accumulate – further encouraging provider consolidation. Existing trends toward provider consolidation will exacerbate these problems, because patients will lack options once they are in a network, giving funders little option other than paying up as demanded.

Shifting to more public funding of health care in response to future events is neither good nor bad. Rather, the success of such funding depends upon its adequacy and its impact on the quality of care – with inadequate funding and quality being related. For example, Medicare provider cuts under current law have been suspended for over a decade, the consequence of which is adequate care. By way of comparison, Medicaid provider cuts have been strictly enforced, which has caused most providers to no longer see Medicaid patients, driving them to hospital emergency rooms and free clinics with long waiting periods to get care.

Ultimately, fixing health care reform will require more funding, probably some kind of employer payroll or net business receipts tax – which would also fund the shortfall in Medicare and Medicaid (and take over most of their public revenue funding). We will now move to an analysis of funding options and their impact on patient care and cost control.

The committee well understands the ins and outs of increasing the payroll tax, so I will confine my remarks to a fuller explanation of Net Business Receipts Taxes (NBRT). Its base is similar to a Value Added Tax (VAT), but not identical.

Unlike a VAT, an NBRT would not be visible on receipts and should not be zero rated at the border – nor should it be applied to imports. While both collect from consumers, the unit of analysis for the NBRT should be the business rather than the transaction. As such, its application should be universal – covering both public companies who currently file business income taxes and private companies who currently file their business expenses on individual returns.

The key difference between the two taxes is that the NBRT should be the vehicle for distributing tax benefits for families, particularly the Child Tax Credit, the Dependent Care Credit and the Health Insurance Exclusion, as well as any recently enacted credits or subsidies under the ACA. In the event the ACA is reformed, any additional subsidies or taxes should be taken against this tax (to pay for a public option or provide for catastrophic care and Health Savings Accounts and/or Flexible Spending Accounts).

This option would be particularly attractive to small businesses. It would essentially broaden the tax credit in the ACA. The current tax regime does not serve to encourage use of the Small Business Tax Credit, which in any case should be merged with the health insurance exclusion as part of an NBRT collected on all businesses, regardless of filing status.

The key to utilization is to increase the tax rate enough to encourage use and requiring such tax benefits for health care and our proposed expanded and refundable Child Tax Credit before any other exclusion are taken, including any zero rating of exports (which is why zero rating is not recommended for this tax).

The NBRT can provide an incentive for cost savings if we allow employers to offer services privately to both employees and retirees in exchange for a substantial tax benefit, either by providing insurance or hiring health care workers directly and building their own facilities, although we expect that only larger businesses will go to those lengths. Employers who fund catastrophic care or operate nursing care facilities would get an even higher benefit, with the proviso that any care so provided be superior to the care available through Medicaid. Making employers responsible for most costs and for all cost savings allows them to use some market power to get lower rates, but no so much that the free market is destroyed.

This proposal is probably the most promising way to arrest health care costs from their current upward spiral – as employers who would be financially responsible for this care through taxes would have a real incentive to limit spending in a way that individual taxpayers simply do not have the means or incentive to exercise. While not all employers would participate, those who do would dramatically alter the market. In addition, a kind of beneficiary exchange could be established so that participating employers might trade credits for the funding of former employees who retired elsewhere, so that no one must pay unduly for the medical costs of workers who spent the majority of their careers in the service of other employers.

The NBRT would replace disability insurance, hospital insurance, the corporate income tax, business income taxation through the personal income tax and the mid range of personal income tax collection, effectively lowering personal income taxes by 25% in most brackets.

Note that collection of this tax would lead to a reduction of gross wages, but not necessarily net wages – although larger families would receive a large wage bump, while wealthier families and childless families would likely receive a somewhat lower net wage due to loss of some tax subsidies and because reductions in income to make up for an increased tax benefit for families will likely be skewed to higher incomes. For this reason, a higher minimum wage is necessary so that lower wage workers are compensated with more than just their child tax benefits.

Thank you for the opportunity to address the committee. We are, of course, available for direct testimony or to answer questions by members and staff.

Contact Sheet
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Subcommittee on Oversight
Hearing on the Impact of Limitations on the Use of Tax-Advantaged Accounts for the Purchase of Over-the-Counter Medication
April 25, 2012, 2:30 PM

All submissions must include a list of all clients, persons and/or organizations on whose behalf the witness appears:

This testimony is not submitted on behalf of any client, person or organization other than the Center itself, which is so far unfunded by any donations.

Henderson Brothers

If there is any concern for controlling the cost of health care, it was not part of the discussion on this change. Nexium continues to be one of the top five prescribed drugs when we review employer plan drug claims. Nexium's monthly cost is generally between $140 and $180 per month. The chemical formulation of Prilosec OTC or simply Omeprozole OTC varies only slightly from Nexium, and the active ingredient is the same. Prilosec/Omeprozole OTC is generally less than $24 per month.

Any reasonable physician, who would be told by a patient that Nexium was too expensive, would clearly recommend the OTC alternative. Their natural presumption is that the OTC is not covered and Nexium is. Requiring an Rx from the consumer simply places a barrier in the way of the consumer who is trying to purchase the best value.

I have heard from individuals that, when a person arrives with an Rx for an OTC drug, pharmacists literally take a bottle or package of an OTC medicine off the counter, open it and distribute it in a container like an FDC controlled package. One indicated that they filled only one month's supply and put the rest of the product on the shelf for the next person with that Rx – but charged the individual the full shelf price.

As a benefits consultant for 44 years, I view the changes for OTC medicines as having one valuable benefit. It was a sufficient trade-off for the drug companies in exchange for their early buy-in to the administration's health care reform platform.

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April 20, 2012

Committee on Ways and Means
Subcommittee on Oversight
ATTN: The Honorably Charles Boustany (R-LA), Subcommittee Chairman
1102 Longworth House Office Building, Room 1100
Washington D.C. 20515

Re: Comments for April 25, 2012, Hearing on the Impact of Limitations on the Use of Tax-Advantaged Accounts for the Purchase of Over-the-Counter (OTC) Medication

To Whom It May Concern:

Thank you for the opportunity to provide comments to the Subcommittee.

Based in Coldwater, Michigan, Infinisource, Inc. is a payroll and benefit administrator that provides administrative services related to payroll, tax-advantaged accounts (including Health FSAs, Health Reimbursement Arrangements [HRAs] and Health Savings Accounts [HSAs]), COBRA and HIPAA. Our client base numbers more than 18,000 employers nationwide. All told, we have more than 800 Health FSA clients, over 250 HRA clients and some 30 HSA clients.

As you are well aware, Section 9003 of the Affordable Care Act (ACA) has had a significantly negative effect on tax-advantaged accounts since January 1, 2011. In assisting employers, patients and consumers with these benefits every day, we have seen first-hand the burdens and inefficiencies of this provision.

We see at least six reasons why Congress should consider repealing Section 9003:

- The OTC restriction forces people to pay for OTC medication with after-tax dollars.
- The OTC restriction provides an exception to the rule that adds cost to the health care system.
- Participants around the country have already commented on the hardships that result from Section 9003.
- The OTC restriction essentially amounts to a tax on the working class of America.
- Tax-advantaged accounts serve a vital purpose for a significant segment of society, and limiting their application frustrates that purpose.
- Physicians are already overburdened by the amount of time they spend on non-reimbursable activities, and Section 9003 simply adds to that burden.

1. The OTC restriction forces people to pay for OTC medication with after-tax dollars.

In late 2003, the IRS issued Revenue Ruling 2003-102, which permitted tax-advantaged accounts like Health FSAs to reimburse OTC items. For years, this ruling empowered

consumers to use pre-tax dollars to purchase OTC medication. This is significant because an increasing number of drugs are now available over-the-counter and because prescription drugs (even generics) are an expensive health plan cost. Section 9003 simply eliminates this right, requiring consumers to obtain a prescription for non-prescription medication. Most consumers will not do this because it requires involvement with a doctor, which will likely entail an office visit. As a result, many consumers simply purchase the medication with after-tax dollars.

Good public policy should encourage and facilitate the use of OTC medication whenever possible. The Consumer Healthcare Products Association recently issued a study, *"The Value of OTC Medicine to the United States."* A major finding was that the U.S. health care system saves $6 to $7 every time an OTC drug is purchased, providing over $100 billion in value each year. Section 9003 significantly restrains the ability of OTC drugs to provide maximum benefit to the U.S. health care system.

"When you consider that every dollar spent on an OTC medicine saves our system 6 to 7 dollars in avoided cost, it is paramount that our policymakers do all they can to encourage consumer access to OTC medicines for self-treatable conditions," CHPA President and CEO Scott M. Melville said.

2. The OTC restriction provides an exception to the rule that adds cost to the health care system.

One exception to the OTC restriction is that prescribed OTC medications are reimbursable under a Health FSA, HRA or HSA on a pre-tax basis. However, this entails involvement from the physician. This adds time and cost for the consumer. Typically, instead of self-medicating a health condition (e.g., cold, flu, allergies), the consumer now must pay an office visit co-payment, and the health plan must pay for the balance of that office visit, which in some geographic areas can exceed several hundred dollars. The consumer has to wait for an appointment and take time away from work. Before Section 9003, the consumer had the freedom to obtain the OTC medication at any time of day or night, use an electronic payment card at the point of sale, and have the expense auto-adjudicated immediately.

Another option is for the consumer to try to obtain a prescription over the phone without an appointment. This is very difficult and time-consuming to do because physicians are very busy. Many physicians will refuse to accommodate these requests for reasons explained below.

In addition, if a consumer does obtain a prescription from the physician and makes an OTC purchase, that transaction is not auto-adjudicated. The consumer must provide written documentation to the claims administrator to receive reimbursement, which typically occurs several weeks later.

3. Participants around the country have already commented on the hardships that result from Section 9003.

A website, called www.savemyflexplan.org, has documented several testimonials about the hardships of Section 9003. The following are samples:

- **Audrey - Kentucky:** The new requirement means I can no longer use flex spending money for OTC medications without a doctor's visit. Going to the doctor for these things costs me money--both in the co-pay as well as time away from work. This reduces productivity in the workforce and wastes my doctor's time slotting an appointment to write me a prescription for Tylenol instead of attending to patients who have more serious medical needs. Moreover, it is an unnecessary doctor's visit, which will artificially inflate health care expenses. Please work to repeal this rule and allow OTC medications back in flex spending as they used to be--without a prescription! After all, isn't that the definition of OTC?!

- **Laura - Utah:** It is horrible to not be able to purchase OTC medications on my flex card, specifically because I have a child who has Febrial Sezures [sp] if she gets a high fever. This is something that is very easily treatable with Tylenol or IB. Before when I knew she was getting sick, I would run to the store, and be able to by the medicine. Now, not only do I have to obtain a prescription for it, I also have to pay for it out of pocket and wait for a reimbursement. In these times, I just don't have the extra money to put away, and wait for someone to pay me back later, since it is already taken out of my paycheck. When these charges come up, I shouldn't need a prescription, and I should be able to use my flex card like I did in the past.

- **Lisa - Nebraska:** My spouse uses OTC allergy medicine which is just as effective for him as an allergy medication obtained with a prescription. Prior to 2011, we were able to use our FSA debit card to obtain this OTC medication. With the new regulation, we had to pay for a doctor visit just to be able to submit this for reimbursement. In doing so, we are still not able to use our FSA debit card, but must pay cash, submit a paper claim form along with the prescription, and wait for a check to be issued to us. Not only is this inconvenient for us, it is costing us more money to visit the doctor, is wasting the doctor's time, is costing our health plan more for an 'unnecessary' visit to the doctor, and is costing the FSA plan administrator more to process the paper claim. We would appreciate being able to go back to getting OTC meds as we have in the past saving all of us much needed time and money.

4. The OTC restriction essentially amounts to a tax on the working class of America.

Surveys have shown that the average Health FSA participant earns about $55,000 per year and that Health FSAs benefit about 35 million Americans. HRA and HSA participants number in the several millions as well. Most of these health care consumers are working class Americans, struggling to make ends meet, especially with escalating health care costs. The pre-tax advantage of tax-advantaged accounts is very important. The fact that OTC medication is now presumptively post-tax amounts to a tax on many who cannot afford it.

Paying for benefits on a post-tax basis means that you use after-tax dollars, which employees receive after federal and state income tax and FICA withholding. This essentially eliminates at least a 25 percent discount on OTC medications that was previously available to consumers.

5. Tax-advantaged accounts serve a vital purpose for a significant segment of society, and limiting their application frustrates that purpose.

Tax-advantaged accounts play an important in controlling health care costs. They empower consumers to pay for out-of-pocket expenses (e.g., co-payments, co-insurance, prescriptions and deductible expenses) with pre-tax dollars. Families also use tax-advantaged accounts to defray the cost of dental treatments and vision expenses. Tax-advantaged accounts pay for chronic conditions (e.g., high blood pressure and asthma). When these benefits undergo a serious restriction, this causes health care costs to rise.

Tax-advantaged accounts are not misused. Current law requires that every Health FSA and HRA expense must be verified by an independent third party as medically necessary before it is reimbursed on a pre-tax basis. Most consumers run out of money before the end of the year. Those who don't often purchase needed OTC medications toward the end of the year. This option is no longer available because of Section 9003.

6. Physicians are already overburdened by the amount of time they spend on non-reimbursable activities, and Section 9003 simply adds to that burden.

When Section 9003 took effect, it caught many physicians and pharmacies by surprise. One news report told the story of a Roseville family practice physician who said that her office received calls from three or four patients per week, sometimes wanting 5-10 prescriptions at a time for OTC medications.

Another health care professional has pointed out that physicians already spend a good amount of time on activities that are not reimbursed by patients or insurance. Examples from one physician who tracked such activity on a daily basis were as follows:

- Over 20 phone calls
- Over 16 e-mails
- Over 19 lab reports reviewed
- Over 12 prescription refills

None of these were reimbursable. To compound the problem, a physician undertakes liability every time he or she writes a prescription, even if it is for OTC medication. Physicians are reluctant to do this without examining the patient in an office visit. After all, OTC medications can have side effects as well.

We want to thank the Subcommittee for this opportunity to comment on the impact of limitations on the use of tax-advantaged accounts for the purchase of OTC medication. If you have any questions or concerns, please feel free to contact me or Connie Gilchrest, our Research and Compliance Specialist, who assisted with these comments, at 800-300-3838 or via e-mail at rglass@infinisource.com or cgilchrest@infinisource.com.

Thank you for your consideration.

Respectfully Submitted,

Rich Glass, JD
Chief Compliance Officer
Infinisource, Inc.

Via e-mail (sent to waysandmeans.submissions@mail.house.gov)

cc: The Honorable Dave Camp (R-MI), Chairman of the Committee on Ways and Means

National Business Group on Health

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Creative Health Benefits Solutions for Today, Strong Policy for Tomorrow

May 2, 2012

The Honorable Charles W. Boustany, Jr., M.D.
Chairman
Ways and Means Subcommittee on Oversight
1102 Longworth HOB
Washington, DC 20515

Dear Chairman Boustany:

The National Business Group on Health applauds the Subcommittee's efforts to review the Patient Protection and Affordable Care Act's (ACA) ban on using Flexible Spending Accounts (FSAs), health reimbursement arrangements (HRAs), and health savings accounts (HSAs) to pay for over-the-counter (OTC) medications, except for insulin, unless people have a prescription.

The National Business Group on Health represents approximately 342, primarily large, employers (including 67 of the Fortune 100) who voluntarily provide health benefits and other health programs to over 55 million American employees, retirees, and their families.

As you know, the National Business Group on Health supports H.R. 605, the Patient's Right to Choose Act, a bill that you co-sponsored with Representative Erik Paulsen (R-MN) that would remove both the ACA's ban on using health accounts for OTC medications without a prescription and the $2,500 annual maximum employee contribution limit for FSAs.

The ACA made OTC nonprescription drugs more expensive and taxable. Ironically, this change has likely added to health care costs by creating incentives to use more expensive prescription drugs even when OTC drugs would work just as effectively in many cases. It has also likely raised health care costs and waste by encouraging additional visits to doctors solely to obtain prescriptions for OTC medications. Unnecessary visits will make it even more difficult to schedule appointments with providers when the ACA expands coverage to an additional 28 million people in 2014[1] in the face of a 45,000 primary care physician shortage.[2]

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[1] Congressional Budget Office. Updated Estimates of the Insurance Coverage Provisions in the Affordable Care Act. March 13, 2012, http://cbo.gov/sites/default/files/cbofiles/attachments/03-13-Coverage%20Estimates.pdf

[2] American Association of Medical Colleges. Physician Shortage to Worsen Without Increases in Residency Training. September 30, 2010, https://www.aamc.org/download/150584/data/physician_shortages_factsheet.pdf

Reducing the amount that people are able to contribute to their FSAs will make it particularly harder for people with chronic diseases to pay for their current health care expenses. FSAs are invaluable for diabetics and asthmatics to help pay for maintenance medications and testing supplies. Many others use FSAs to help pay for needed medical care. Accordingly, we also support your continuing efforts to remove the cap on FSA contributions that is scheduled to take effect in 2013 to help lower out-of-pocket health care spending for Americans and their families.

For those reasons, the National Business Group on Health strongly supports your efforts to remove the restrictions on the use of health accounts for OTC drugs without prescriptions and the cap on FSA contributions. Please contact me or Steven Wojcik, the National Business Group on Health's Vice President of Public Policy, at (202) 558-3012, if you would like to discuss our comments in more detail.

Sincerely,

Helen Darling
President