



**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:

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