Sjögren's Syndrome Foundation
The Moisture Seekers
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Daniel J. Wallace, MD

An Inside Look at Sjögren's and Overlapping Connective Tissue Diseases

The greatest risk factor for developing an autoimmune disorder is the existing presence of an autoimmune disease. Overlaps are common and often complex. This is why the Sjögren's Syndrome Foundation (SSF) is publishing a series of articles featuring the overlap of Sjögren's with other connective tissue disorders, which include a review of the major features of those disorders and comments on how the presence of the other diseases may impact the expression of Sjögren's and vice versa.

The SSF would like to thank Dr. Daniel Wallace for authoring the second article in this series focusing on the overlap of Sjögren's and lupus. While reading this article, please note the SSF "Sjögren's and Lupus Glossary" on page 7.

Sjögren's and Lupus: Clinical Considerations

by Daniel J. Wallace, MD

Lupus and Sjögren's are frequently overlapping conditions. Many patients with Sjögren's have lupus features, and individuals with lupus (systemic lupus erythematosus [SLE]) often have symptoms of dryness, including dry eyes and dry mouth. Relatively few studies have examined these relationships, and this brief review summarizes our current understanding of these interconnections.

The association of Sjögren's and lupus was first noted in 1959. Small-scale studies suggested the prevalence of Sjögren's in lupus ranging from 7-35%. Five large-scale studies have analyzed the influence of Sjögren's upon lupus. One clinical and laboratory comparison study found 9.2% of 283 Greek lupus patients filled the American-European classification criteria for Sjögren's. In this study, lupus patients with Sjögren's tended to be older, with a

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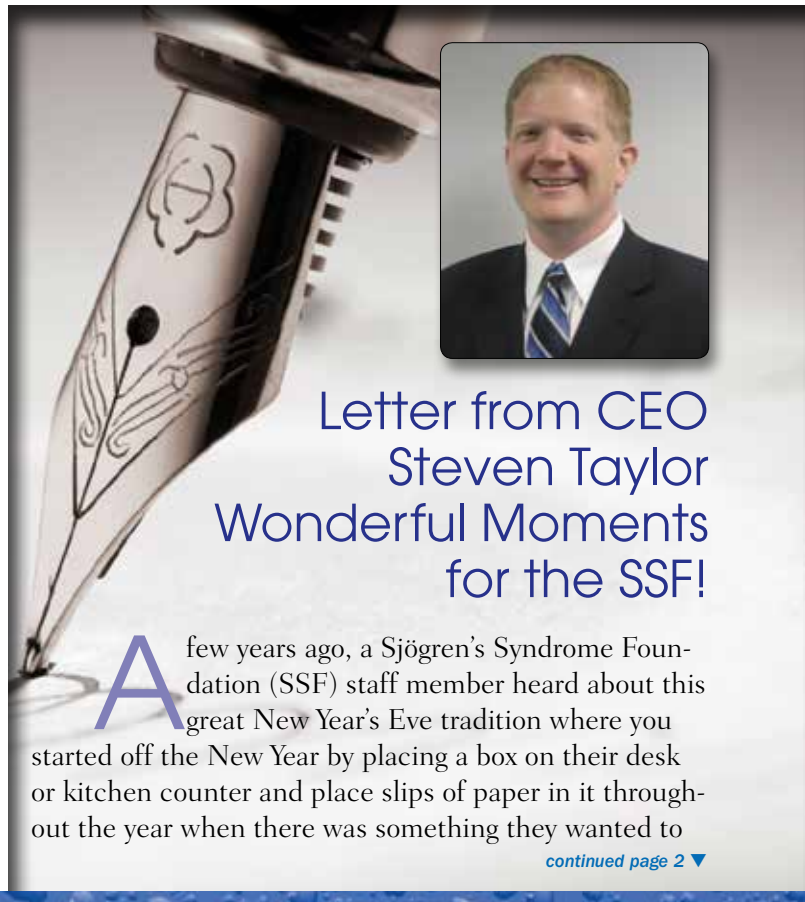

Letter from CEO Steven Taylor Wonderful Moments for the SSF!

A few years ago, a Sjögren's Syndrome Foundation (SSF) staff member heard about this great New Year's Eve tradition where you started off the New Year by placing a box on their desk or kitchen counter and place slips of paper in it throughout the year when there was something they wanted to

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remember at the end of the year. Then throughout the year, you would fill up the jar so that on the next New Year's Eve you could read the slips of paper and remember all the wonderful things that happened during the year! You call them your "wonderful moments."

So this past year in 2015, the SSF started a jar in our office so that we could look back at our year and think about the big and little accomplishments we achieved! We thought, what a great way to look back at the end of the year and celebrate the little things that may have happened over the past 12 months.

Thanks to our amazing volunteers, dedicated staff and our donors, the SSF has achieved so many wonderful things that I am looking forward to reading our jar with the staff on New Year's Eve!

But I sneaked a peek at some of what our staff put in the jar – so here is a sneak preview of the SSF's wonderful moments in 2015:

January

"Time to Diagnose Decreasing" – The SSF is still working on decreasing the time it takes to diagnose Sjögren's! We announced in January 2015 that we have lowered the average time from 4.7 years to 3.9 years. And I encourage you to watch this January 2016 as we announce another decrease! It is very exciting!

February

"Received Thank You Letter from a Newly Diagnosed Patient" – the SSF staff, especially our support staff who answer our phones, are busy talking all day with patients. Some are newly diagnosed, some just found the SSF and others have new questions that have arisen at a recent doctor's office! The SSF fields hundreds of calls a week and it is always a great reminder of why we are here! As I have said since the day I was hired, "the SSF was founded by Elaine Harris to help patients, and we will always be here for patient support as long as I am CEO."

April

"National Patient Conference Great Success" - the 2015 National Patient Conference saw nearly 500 patients join us in Tampa, Florida! We had an amazing line-up of physicians and healthcare providers that spoke at the conference and we look forward to Seattle in April 2016.

May

"SSF Clinical Guidelines Published" - the SSF's effort to develop the first-ever clinical practice guidelines for Sjögren's saw great steps forward. Our Ocular guidelines were peer reviewed and published this past Spring

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RESTASIS® ophthalmic emulsion is indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

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RESTASIS® is contraindicated in patients with known or suspected hypersensitivity to any of the ingredients in the formulation.

WARNINGS AND PRECAUTIONS

Potential for Eye Injury and Contamination

To avoid the potential for eye injury and contamination, be careful not to touch the vial tip to your eye or other surfaces.

Use with Contact Lenses

RESTASIS® should not be administered while wearing contact lenses. Patients with decreased tear production typically should not wear contact lenses. If contact lenses are worn, they should be removed prior to the administration of the emulsion. Lenses may be reinserted 15 minutes following administration of **RESTASIS®** ophthalmic emulsion.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In clinical trials, the most common adverse reaction following the use of **RESTASIS®** was ocular burning (17%).

Other reactions reported in 1% to 5% of patients included conjunctival hyperemia, discharge, epiphora, eye pain, foreign body sensation, pruritus, stinging, and visual disturbance (most often blurring).

Post-marketing Experience

The following adverse reactions have been identified during post approval use of **RESTASIS®** Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Reported reactions have included: hypersensitivity (including eye swelling, urticaria, rare cases of severe angioedema, face swelling, tongue swelling, pharyngeal edema, and dyspnea); and superficial injury of the eye (from the vial tip touching the eye during administration).

USE IN SPECIFIC POPULATIONS

Pregnancy

Teratogenic Effects: Pregnancy Category C

Adverse effects were seen in reproduction studies in rats and rabbits only at dose levels toxic to dams. At toxic doses (rats at 30 mg/kg/day and rabbits at 100 mg/kg/day), cyclosporine oral solution, USP, was embryo- and fetotoxic as indicated by increased pre- and postnatal mortality and reduced fetal weight together with related skeletal retardations. These doses are 5,000 and 32,000 times greater (normalized to body surface area), respectively, than the daily human dose of one drop (approximately 28 mcL) of 0.05% **RESTASIS®** twice daily into each eye of a 60 kg person (0.001 mg/kg/day), assuming that the entire dose is absorbed. No evidence of embryofetal toxicity was observed in rats or rabbits receiving cyclosporine at oral doses up to 17 mg/kg/day or 30 mg/kg/day, respectively, during organogenesis. These doses in rats and rabbits are approximately 3,000 and 10,000 times greater (normalized to body surface area), respectively, than the daily human dose.

Offspring of rats receiving a 45 mg/kg/day oral dose of cyclosporine from Day 15 of pregnancy until Day 21 postpartum, a maternally toxic level, exhibited an increase in postnatal mortality; this dose is 7,000 times greater than the daily human topical dose (0.001 mg/kg/day) normalized to body surface area assuming that the entire dose is absorbed. No adverse events were observed at oral doses up to 15 mg/kg/day (2,000 times greater than the daily human dose).

There are no adequate and well-controlled studies of **RESTASIS®** in pregnant women. **RESTASIS®** should be administered to a pregnant woman only if clearly needed.

Nursing Mothers

Cyclosporine is known to be excreted in human milk following systemic administration, but excretion in human milk after topical treatment has not been investigated. Although blood concentrations are undetectable after topical administration of **RESTASIS®** ophthalmic emulsion, caution should be exercised when **RESTASIS®** is administered to a nursing woman.

Pediatric Use

The safety and efficacy of **RESTASIS®** ophthalmic emulsion have not been established in pediatric patients below the age of 16.

Geriatric Use

No overall difference in safety or effectiveness has been observed between elderly and younger patients.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis: Systemic carcinogenicity studies were carried out in male and female mice and rats. In the 78-week oral (diet) mouse study, at doses of 1, 4, and 16 mg/kg/day, evidence of a statistically significant trend was found for lymphocytic lymphomas in females, and the incidence of hepatocellular carcinomas in mid-dose males significantly exceeded the control value.

In the 24-month oral (diet) rat study, conducted at 0.5, 2, and 8 mg/kg/day, pancreatic islet cell adenomas significantly exceeded the control rate in the low-dose level. The hepatocellular carcinomas and pancreatic islet cell adenomas were not dose related. The low doses in mice and rats are approximately 80 times greater (normalized to body surface area) than the daily human dose of one drop (approximately 28 mcL) of 0.05% **RESTASIS®** twice daily into each eye of a 60 kg person (0.001 mg/kg/day), assuming that the entire dose is absorbed.

Mutagenesis: Cyclosporine has not been found to be mutagenic/genotoxic in the Ames Test, the V79-HGPRT Test, the micronucleus test in mice and Chinese hamsters, the chromosome-aberration tests in Chinese hamster bone-marrow, the mouse dominant lethal assay, and the DNA-repair test in sperm from treated mice. A study analyzing sister chromatid exchange (SCE) induction by cyclosporine using human lymphocytes *in vitro* gave indication of a positive effect (i.e., induction of SCE).

Impairment of Fertility: No impairment in fertility was demonstrated in studies in male and female rats receiving oral doses of cyclosporine up to 15 mg/kg/day (approximately 2,000 times the human daily dose of 0.001 mg/kg/day normalized to body surface area) for 9 weeks (male) and 2 weeks (female) prior to mating.

PATIENT COUNSELING INFORMATION

Handling the Container

Advise patients to not allow the tip of the vial to touch the eye or any surface, as this may contaminate the emulsion. To avoid the potential for injury to the eye, advise patients to not touch the vial tip to their eye.

Use with Contact Lenses

RESTASIS® should not be administered while wearing contact lenses. Patients with decreased tear production typically should not wear contact lenses. Advise patients that if contact lenses are worn, they should be removed prior to the administration of the emulsion. Lenses may be reinserted 15 minutes following administration of **RESTASIS®** ophthalmic emulsion.

Administration

Advise patients that the emulsion from one individual single-use vial is to be used immediately after opening for administration to one or both eyes, and the remaining contents should be discarded immediately after administration.

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 Please allow 8 weeks for delivery of your rebate check. APC84HR14 Certificate expires 12/31/2015

You Stood Up!

You can turn any celebration into an awareness event, which is exactly what Jody did at her wedding with a tribute to her grandmother!

Jody describes her grandmother, Mary Runninger (whom she called Tutu), as one of the most selfless people that she knew, who always put her family and others first. As Jody began planning for her big day, she heard of couples making a charitable donation instead of giving favors and instantly thought of her grandmother, the disease she suffered from and the Sjögren's Syndrome Foundation.

Jody remembers how much the disease affected her grandmother, who was diagnosed with Sjögren's at age 70 and passed away 11 years later, sharing: "I saw how Sjögren's impacted her energy level and enjoyment and love of food. My grandparents traveled the world, but this became tough when her energy level and food choices decreased. I remember my grandparents going on a trip overseas with our church choir. At this time, my grandmother basically could eat very few solid foods due to Sjögren's effect on her salivary glands, so she was surviving on a liquid diet consisting of mostly Ensure. Because of the weight of the Ensure cans, my grandparents had to ask for other choir members to volunteer and carry a couple of cans each in their suitcase. As you can see, my grandmother was rather determined and would do whatever it took to still be able to enjoy life, travel and not let Sjögren's get in her way."

At her wedding, Jody posted a sign honoring her grandmother and letting guests know that in lieu of favors, they would be making a donation to the SSF in her grandmother's memory. The Foundation is moved that Jody used her wedding celebration as a way to honor her grandmother and help raise the critical funds and awareness needed for Sjögren's.

Hosting your own awareness event is a great way to let your friends, family and community become more familiar with Sjögren's. The Foundation is happy to support independent awareness and fundraising activities by supplying brochures and other materials. If you would like to host your own event, contact the Foundation at (301) 530-4420.

◀ *Dr. Jack and Mary Runninger in Sens, France*

"Sjögren's & Lupus" continued from page 1 ▼

higher prevalence of Raynaud's, rheumatoid factor, anti-SSA and anti-SSB, and a high frequency for the DRB1*0301 allele (a variant form of a gene). They had less renal disease, adenopathy, and thrombocytopenia.

In a 2010 John Hopkins study, among the 1531 lupus patient study group, 259 (or 14%) were found to have Sjögren's by clinical evaluation. They were generally older white females with more photosensitivity, oral ulcers, Raynaud's phenomenon, anti-SSA and anti-SSB with less renal disease, anti-dsDNA and anti-RNP antibodies.

A study at Peking Union Medical College discovered that approximately 20% of over 2,000 Chinese lupus also had Sjögren's. Showing significant differences between Sjögren's with lupus, versus without, included older females, sicca symptoms and signs, renal tubular acidosis, and interstitial lung disease. The non-Sjögren's patients had more rashes, nephrosis, central nervous system disease, lower IgG levels, more disease activity and more immune suppressive and corticosteroid use. Here 71% were SSA or SSB positive with Sjögren's/lupus versus the 20% without.

A 2013 study found 103 patients participating in a prospective cohort of recent-onset lupus were assessed for fulfillment of the American European Consensus Group criteria for Sjögren's. 18.5% of the group, all female participants, had lupus and Sjögren's. They tended to be older, have anti-SSA antibodies at diagnosis and rheumatoid factor. Overall, Sjögren's patients tend to be more serologically "rich" with higher immunoglobulin levels, rheumatoid factors and circulating immune complexes. In summary, Sjögren's/lupus patients, meeting Sjögren's criteria, comprise about 10% of the lupus population although about twice that many have features of Sjögren's.

Special Considerations

The prevalence of subacute cutaneous lupus erythematosus (SCLE) rashes is increased in Sjögren's patients with the anti-SSA antibody. This rash can coexist with chronic cutaneous (discoid) lupus. Involving the dermis rather than the epidermis, patients tend to be sun sensitive, respond less well to antimalarials, but the rashes do not scar. If a woman with these anti-SSA gets pregnant, this is associated with a 14% risk for neonatal lupus. The 52kd component of anti-SSA crosses the placenta and is associated with a self limited SCLE rash that spontaneously resolves over several weeks to months. In about 2% of cases, congenital heart block can be found on fetal echocardiograms as early as week 18. All pregnant women with the anti-SSA antibody should undergo ultrasound at week 18 and 24 and more often if indicated. A variety of interventions including pacing, betamethasone, antimalarials, apheresis and intravenous immune globulin have been used with varying degrees of success.

Lupus nephritis (a kidney disorder) involves the glomerulus, which is usually spared in Sjögren's. Both disorders involve the interstitium, while Sjögren's alone is associated with renal tubular acidosis. Sjögren's changes in the gastrointestinal tract include atrophic gastritis, biliary cirrhosis, and esophagitis. Sjögren's patients have 2-3 times more interstitial lung disease than individuals with lupus, and most lupus patients with this have a Sjögren's overlap. Inflammatory polyneuropathy is more frequent in Sjögren's patients and is associated with cutaneous vasculitis, as well as severe burning and tingling. The association of Sjögren's with lymphoma is well-known and thought to be present in about 7.5% of patients. The prevalence of lymphoma in lupus is about one in 150 patients. A recent survey of individuals with lupus who also developed lymphoma noted that 16 of 75 (21%) also fulfilled criteria for Sjögren's.

Treatment and prognosis

Whereas half with lupus have organ-threatening disease and require steroids and immune suppressives, the percentage with Sjögren's is about 20%. Studies with these agents for Sjögren's have revealed less robust responses, but metrics used to evaluate them are still in the development stage. Both conditions respond to antimalarials, methotrexate, azathioprine, corticosteroids, mycophenolate mofetil, belimumab and rituximab but in Sjögren's the evidence is largely anecdotal, based on case series, or derived secondary outcomes in the few clinical trials that have been published. Nevertheless, death from Sjögren's complications is rare and patients live close to a natural lifespan. However, there is huge unmet need for improving quality of life.

The next article in this series is a focus on Sjögren's with Rheumatoid Arthritis by Neha Bhanusali, MD, and will be featured in the February issue of *The Moisture Seekers*.

Table: Organ system involvement during the course of Sjögren's and systemic lupus erythematosus

(Sources: The Sjögren's Book *and* The Lupus Book, *edited by Daniel J. Wallace, MD)*

Target organ	% Prevalence Sjögren's	% Lupus
Glandular disease		
Xerostomia	92%	20%
Dry eyes	95%	20%
Parotid enlargement	53%	<1%
Musculoskeletal		
Arthritis/arthralgia	75%	90%
Raynaud's	48%	25%
Myositis	2%	10%
Pulmonary		
Interstitial lung disease	6%	3%
Small airway disease (includes bronchitis sicca)	23%	3%
Pleurisy	15%	44%
Interstitial nephritis or renal tubular acidosis	9%	<5%
Gastrointestinal tract		
Esophageal dysmotility	36%	20%
Autoimmune pancreatitis with high IgG4	2%	<1%
Atrophic gastritis	20%	<5%
Biliary cirrhosis	5%	<2%
Autoimmune hepatitis	2%	<2%
Celiac disease	5%	<2%
Nervous system		
Peripheral neuropathy	5%	2%
Dysautonomia	3%	10%
Central nervous system vasculitis	1%	10%
Cardiac		
Pericarditis	5%	15%
Heart block	1%	<1%
Hemic-lymphatic		
Adenopathy	20%	15%
Cryoglobulinemia/ purpura/vasculitis	5%	2%
Non-Hodgkin's lymphoma	7.5%	<1%

Sjögren's and Lupus Glossary

Adenopathy: A swelling of the lymph nodes. In Sjögren's, this usually occurs in the neck and jaw region.

Anti-RNP: Antibody to ribonucleoprotein. Seen in lupus and mixed connective tissue disease.

Anti-SSA (Ro antibody): Associated with Sjögren's, sun sensitivity, neonatal lupus, and congenital heart block.

Anti-SSB (La antibody): Almost always seen with anti-SSA.

Circulating immune complexes (CICs): Complexes found in the blood that is associated with autoimmune-diseases such as systemic lupus erythematosus, immune complex glomerulonephritis, rheumatoid arthritis and vasculitis. However, slightly increased serum concentrations of such CICs are sometimes also found in healthy individuals.*

Immunoglobulins (gamma globulins): The protein fraction of serum responsible for antibody activity. Measurement of serum immunoglobulin levels can serve as a guide to disease activity in some patients with Sjögren's.

Lupus (systemic lupus erythematosus[SLE]): An inflammatory connective tissue disease.

Neonatal lupus: A rare autoimmune disorder that is present at birth (congenital). Affected infants often develop a characteristic red rash or skin eruption.

Raynaud's phenomenon: Painful blanching of the fingertips on exposure to cold. This may be seen alone or in association with connective tissue disease such as Sjögren's.

SSA: Sjögren's–associated antigen A (anti Ro).

SSB: Sjögren's–associated antigen B (anti La).

Sicca: Sicca symptoms are common in Sjögren's in which symptoms of dry eye and dry mouth as well as dryness throughout the body are prominent. While sicca symptoms occur in the vast majority of Sjögren's patients, not everyone with these symptoms has Sjögren's.

Sjögren's (SHOW-grins): A systemic autoimmune disease that affects the entire body. Along with symptoms of extensive dryness, other serious complications include profound fatigue, chronic pain, major organ involvement, neuropathies and lymphomas.

Sjögren's antibodies: Abnormal antibodies found in the sera of Sjögren's patients. These antibodies react with the extracts of certain cells, and a test based on this principle can be helpful in the diagnosis of Sjögren's. See also SSA and SSB.

Subacute cutaneous lupus erythematosus (SCLE): A unique set of photosensitive rashes, originally described in patients with lupus. May occur in Sjögren's and common in patients with anti-SSA (Ro) and anti-SSB (La) antibodies).

Thrombocytopenia: Low platelet count.

**Definition from National Library of Medicine*

"Letter from the CEO" continued from page 2 ▼

in the *Ocular Surface Journal*. Our oral guidelines and our first draft of systemic guidelines have been submitted for publication. The SSF is proud of this achievement but, rest assured, we are not finished. We still have additional clinical questions to answer and our staff and volunteers will continue to move forward in expanding guidelines into these additional areas!

July

"Awareness Raised on World Sjögren's Day" – July 23rd marks World Sjögren's Day and I am proud to say that the SSF joined with 17 other Sjögren's organizations in 17 other countries to raise awareness with press releases and media interviews!

November

"Clinical Trials Starting for Sjögren's" - The SSF's focus on getting a drug developed to treat Sjögren's has been fast tracked by a number of pharmaceutical companies. The SSF is working alongside nearly 10 companies that have an interest in entering clinical trials for Sjögren's! Watch in 2016 as we announce various trials that will be starting and we encourage you to learn more about what is involved in taking part in the clinical trial. It will take many of you stepping up to take part so that we can, in the near future, see a drug to treat all of Sjögren's!

And I would be remiss if I didn't say that many of our wonderful moments this past year were about spending time with patients! From hearing your stories over the phone or spending time with you at special events, fundraisers, conferences, on committee calls or at our National Patient Conference – we are humbled by your Sjögren's stories and we appreciate your continued support! Together we are making great strides against Sjögren's and we cannot wait for 2016!!!!

So on behalf of the SSF, Cheers to 2015 and ALL of our wonderful moments!

From your CEO,
Steven Taylor

Thank You

To our SSF Awareness Ambassadors

The SSF would like to thank our Awareness Ambassadors for their time and commitment to spreading the word about Sjögren's among those in their communities! Over the last year our Ambassadors have:

- Visited primary care providers with information
- Posted Sjögren's posters in community areas such as health clubs, churches and colleges
- Sent press releases to local media outlets
- Sent emails to family and friends for World Sjögren's Day
- Visited pharmacists at their community pharmacies

With volunteers in over 45 states across the nation, our Ambassadors play a major role in helping the SSF to spread information on Sjögren's far and wide. Together, we are making a difference!

As 2016 approaches, we are looking to gather our volunteer Ambassadors for next year's campaigns. If you are interested in becoming an Awareness Ambassador for the 2016 campaign year you can easily sign up on our website at www.sjogrens.org under the "Get Connected" tab or contact us by emailing mchampigny@sjogrens.org or calling (301) 530-4420.

The Sjögren's Syndrome Foundation would like to thank you for your continued support and dedication to the fight against Sjögren's. Your generosity and support has helped get us to this point, making our achievements possible.

During this time of year, as we celebrate advancements in Sjögren's research, awareness, and the development of new diagnostic testing, we also look forward to 2016 and keeping this momentum alive.

Your support is greatly appreciated and as 2015 comes to a close, we ask that you consider giving a year-end donation this holiday season.

Wishing you a joyous holiday season and happy New Year.

❑ Enclosed is my gift of $ _____ to support the Foundation's initiatives and programs.

❑ I am interested in learning more about how to make a stock donation.

❑ Please send me information about listing the SSF in my will.

Thank you for your support of the Sjögren's Syndrome Foundation.

Mail to SSF, BB&T Bank · PO Box 890612 · Charlotte, NC 28289-0612 or Fax to: 301-530-4415

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The Sjögren's Patient and Social Security Disability: It's a Marathon, Not A Sprint!

by Crysti D. Farra, Attorney at Law

Social Security, as a program, began in 1935; however it took more than 20 years before Disability Insurance (SSDI) was added under the Eisenhower administration. Even still, those in the population who were younger than 55, or without significant work history were not covered for disability until 1974, when the Supplemental Security Income (SSI) component of the act was implemented under the Nixon administration.* Although SSI and SSDI are two separate programs, with different criteria to be met at the outset, the definition of disability is largely the same under both (except in children). The following information is designed to give an overview of the steps necessary to be successful at being awarded disability, staying on disability, and maintaining your benefits if you choose to work. This article will only address the programs associated with Social Security, as criteria under private disability policies differ greatly. With that in mind, the three following questions will be addressed:

- What should my first steps be in filing for Social Security Disability with Sjögren's?
- Am I eligible for Social Security Disability if I don't have a formal diagnosis?
- Can I still work if I am on Social Security Disability?

What should my first steps be in filing for Disability with Sjögren's?

Before you file for disability, you should speak with your healthcare professional(s) to ensure you have their support for your SSDI or SSI claim. This is the first and most important step. Your doctor's assistance will be integral in proving that your condition is disabling. You will need to gather the medical evidence to submit to Social Security, which shows that your condition meets their definition of disability. This will include diagnostic records (blood panels, Cat Scans, Magnetic Resonance Imaging studies, etc.) as well as clinical notes from your treating sources. If you are unable to gather this information for yourself, Social Security will assist you. You must provide them with a full and complete list of all doctors you have seen in the previous 12 months and sign a "Consent for Release of Information" form (SSA-827).

For SSDI, you can complete your initial application online by visiting www.ssa.gov and clicking on "Apply for Disability" on the Home Page. If you are applying under the SSI program (if you have no significant work history or are applying for a child), that application currently is not available online, and you will be required to visit your local Social Security field office to complete in person. You can find your local Social

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"Social Security" continued from page 11 ▼

Security field office online or you can call 800-772-1213 for assistance in determining which field office would service your claim. For this type of claim you also need to provide financial information to prove that you have a financial need for assistance under this program. This may include: bank statements; ownership of stocks, bonds or retirement fund accounts; proof ownership or partial ownership in any real property; or any resources at your disposal that can essentially be converted, with some ease, to cash.

Am I eligible for Social Security Disability if I don't have a formal diagnosis?

According to the Social Security Website:*

"Disability" under Social Security is based on your inability to work. We consider you disabled under Social Security rules if:

- You cannot do work that you did before;
- We decide that you cannot adjust to other work because of your medical condition(s); and
- Your disability has lasted or is expected to last for at least one year or to result in death.

This is a strict definition of disability. Social Security program rules assume that working families have access to other resources to provide support during periods of short-term disabilities, including workers' compensation, insurance, savings and investments.

Having a diagnosis does not necessarily mean you have a disability under Social Security Rules and Regulations (SSR), though it will often be helpful in your overall case. Social Security does have a pre-defined list of conditions that the Administration recognizes can be severe enough to prevent you from doing any gainful activity. However, to actually meet the listing is difficult and rare; most cases do not fall within a listing and are proven by the alternate procedures discussed below.

Remember where I mentioned that you will need the support of your treating physicians? This is because with Social Security Disability, it is NOT only about a diagnosis; it is how that diagnosis affects YOU as an individual. The Social Security Regulations use a standard of Substantial Gainful Activity to determine if you are disabled. This means; how limited are you in your ability to function, and with those limitations, what jobs are available to you in the local or national economy? In raw numbers, Substantial Gainful Activity is defined as earning $1,090 ($1,820 for blind individuals) per month or more. So, if your limitations would still allow you to work at a job where you could earn $1,090 per month, with few accommodations, then under the Social Security rules, you are NOT disabled.

Social Security will look to your medical records to provide proof of your inability to sustain substantial gainful activity. This is achieved by taking note of your limitations performing work-like activities that your physician has listed in his/her clinical notes. For example, you complain to your doctor that after only a short walk, you are so exhausted that you must lay down to rest for at least 30 minutes before you can do further activities. Or, you cannot sit or stand for more than 15-20 minutes at a time without experiencing pain which causes you to constantly shift positions. These are some examples of "Activities of Daily Living". If you have proven you have severe limitations in performing your activities of daily living, and this is borne out in the credible medical evidence, then you could be found disabled even absent a formal diagnosis.

Can I still work if I am on Social Security Disability?

Under SSDI, the short answer is yes, under very limited circumstances. There are provisions within the Social Security Regulations that allow someone who is receiving SSDI or SSI to work, but again, the programs vary in standards, therefore I will be speaking only to the SSDI program here.

A Trial Work Period allows a disabled individual who is currently receiving benefits to work above a certain level (currently $780 per month) for 9 months and still maintain their SSDI benefits. These do not have to be consecutive months, but rather any 9 months over a rolling 60 month time period. So, you can work and earn $780 for 2 months now, and then 4 months next year and you will have exhausted only 6 of your 9 trial work months. If your earnings from work do not exceed $780 (currently) per month, then you will not trigger a trial work month and your benefits will continue without interruption. This is, however, provided you are not working a substantial amount of time to earn those low wages. If you are working 6-8 hours per day, 4-5 days per week, then you are not likely to still be considered disabled by Social Security, regardless of how little money you are earning. It is not how much a particular

**www.ssa.gov provides the source of information for most references in this article.*

job pays as much as it is a question of whether you are physically able perform that job?

Claimants receiving SSDI or SSI should also be mindful of Social Security's rules regarding Continuing Disability Reviews. This is a mechanism used by Social Security to ensure that those receiving disability benefits remain disabled under the regulations. In order to prove your ongoing disability, it is important that you continue treatment with your physicians. This will allow you to show that your condition exists, and persists with the same (or worsening) limitations as it was at the time you were originally awarded your SSDI or SSI benefits. Absent this proof, your benefits could be in jeopardy, and in some cases, you could even be charged with an overpayment of benefits. If you do receive notification from the Social Security Administration that your case is up for review or that you are being charged an overpayment, it is highly recommended that you seek the assistance of an attorney who has experience in handling these types of cases.

In closing, it is important to understand that the Social Security Act is one of the most lengthy and complicated pieces of legislation ever passed into law. This process for filing for either Social Security Disability or Supplemental Security Income is rarely a fast experience. You should plan on 6 to 8 months before an initial decision is rendered by Social Security, Navigating this system usually takes the assistance of a professional. Always consult with an attorney who concentrates in the area of law that your situation calls for. Social Security Disability attorneys must be registered through the Social Security Administration and licensed in the state in which they practice. Attorneys/Representatives are not permitted to charge a fee for their services unless they are successful at helping you win or keep your benefits, and they must receive approval from the Social Security Administration before charging/collecting a fee. For a referral to a reputable attorney in your geographic area, contact your local bar association, or the National Organization of Social Security Claimant Representatives at 800-431-2804. They will be happy to provide you a list of seasoned attorneys near you.

Ms. Farra is an attorney licensed to practice in New York and Connecticut, as well as nationally through registration as an appointed attorney representative before the Social Security Administration. For further information, please visit her website at www.crystifarralaw.com.

Announcing the SSF's Newest Research Grant Recipients

Marit Hoeyberg Aure, PhD

Alan Nathaniel Baer, MD

Maria C. Edman, PhD

Markus Hardt, PhD

Petros Papagerakis, DDS, PhD

The Sjögren's Syndrome Foundation (SSF) strives to foster research that will have the greatest potential impact on Sjögren's patients, ensuring new therapeutics are developed and a cure is found. One important way in which we strive for change is to promote innovative research that will inspire new ideas by encouraging investigators to take risks by developing novel concepts that could lead to major breakthroughs in Sjögren's. The SSF is pleased to announce our newest research grant recipients.

This year, the SSF awarded five research grants in Sjögren's that its Research Review Committee deemed the most worthy of funding. New projects include using genetic models to directly follow cell replacement and regeneration in the lacrimal glands; defining new autoantibodies specific for Sjögren's to help with earlier diagnosis; utilizing analytical technologies to gain unique insights into the disease process and to help identify patients in the early stage of Sjögren's.

The number of researchers proposing new projects in Sjögren's continues to increase annually, and the caliber of proposals was exceptionally high this year. The Research Review Committee placed a priority on the following three specific areas when reviewing this year's grants:

- Innovation, which is critical for finding new approaches to treatment.
- Novel diagnostics, which is important for helping reach the SSF 5-*Year Breakthrough Goal* of reducing the time to diagnosis by 50% in 5 years and for improving clinical trial designs.
- Junior investigators, to encourage new researchers to focus their careers on discovering breakthroughs in Sjögren's.

This year's Research Award Recipients are:

Marit Hoeyberg Aure, PhD
Postdoctoral fellow, Center for Oral Biology, University of Rochester

Research Project Title

Cell lineage analysis in lacrimal gland maintenance and repair

Lay Abstract

Repair of the lacrimal gland would be a major triumph for therapeutic treatment of dry eye disease. But to do this, there are basic questions that need to be answered: How are cells in healthy lacrimal glands normally maintained? Does it depend on stem cells? How do lacrimal glands regenerate after injury? In a recently completed study, we have established how secretory cells are normally replaced in the salivary glands. Our results challenge the current dogma and indicate that stem cells do not play a major role in maintaining a healthy gland. Based on the similarities between salivary and lacrimal glands, we propose that lacrimal glands may rely on the same mechanisms. We propose to use genetic models to directly follow secretory acinar cell replacement and regeneration in the lacrimal glands. The outcome of this study will provide a framework on which cell based therapy can be modeled.

The SSF Research Review Committee commented that Dr. Aure is a "young investigator with experience in methodology and a true interest in Sjögren's."

Alan Nathaniel Baer, MD
Associate Professor of Medicine, Department of Medicine (Rheumatology), John Hopkins University School of Medicine

Research Project Title

Comprehensive analysis of antibodies in Sjögren's using phage immunoprecipitation sequencing

Lay Abstract

The development of better tools to enable earlier diagnosis of Sjögren's is a key goal of the Sjögren's Syn-

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in memoriam

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Mr. and Mrs. Russell
Rhode Island Association of Fire Chiefs Honor Flight Club

In Memory of Anastasia "Bonnie" Goldsmith
Rosalind Cozanitis

In Memory of Elaine Halpern
Eleanor Verbin
Shelley and Jeremy Brott

In Memory of Diane St. Cyr
Gary and Lynn Cavin
Trudy Martin
Betty and Bruce St. Cyr
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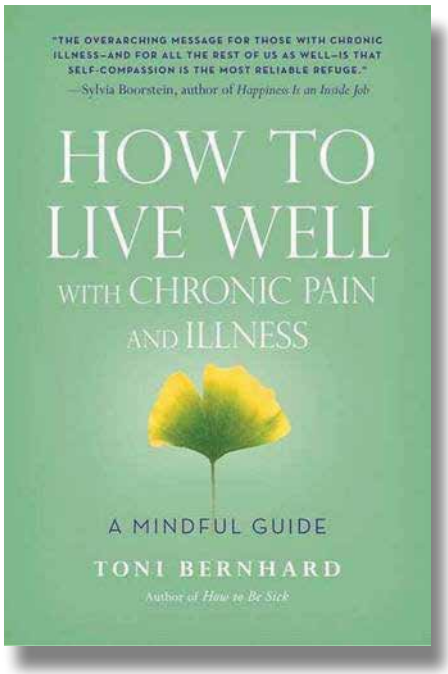

New Book!

How to Live Well with Chronic Pain and Illness – A Mindful Guide

by Toni Bernhard

How to Live Well with Chronic Pain and Illness – A Mindful Guide by Toni Bernhard addresses challenges that chronic illness creates, using practical examples to illustrate how mindfulness, equanimity, and compassion can help readers make peace with a life turned upside down.

This book can be purchased using the order form below, online at www.sjogrens.org or by contacting the Sjögren's Syndrome Foundation office at 800-475-6473.

	Non-Member Price	Member Price	Qty	Amount
How to Live Well with Chronic Pain and Illness – A Mindful Guide by Toni Bernhard	$17.00	$14.00		
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Shipping and Handling: US Mail: $5 for first item + $3 for each additional item Canada: $14 for first item + $3 for each additional item Overseas: $22 for first item + $3 for each additional item				
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"Research Grantees" continued from page 11 ▼

drome Foundation. Earlier therapeutic intervention in Sjögren's has already been shown to lead to better outcomes. Autoantibodies are proteins produced by immune cells that bind to an individual's own tissues on structures called "autoantigens." Autoantibodies are present in the blood and also in certain body fluids, such as saliva. Some autoantibodies are specific for a given autoimmune disease and help in diagnosis while others define disease subsets with unique clinical features. In this project, the entire repertoire of antibodies to autoantigens and human viral proteins will be characterized in each of 45 Sjögren's patient samples using a powerful new technology, called phage immunoprecipitation sequencing. Our goal is to define new autoantibodies specific for Sjögren's, which could be used for earlier diagnosis and to increase understanding of its causes.

The SSF Research Review Committee noted that Dr. Baer's research could potentially "…result in new biomarkers for diagnosis and follow up of Sjögren's patients."

Maria C. Edman, PhD
Research Associate, Department of Pharmacology and Pharmaceutical Sciences, University of Southern California, School of Pharmacy

Research Project Title

Tear fluid and serum levels of Cathepsin S and its endogenous inhibitor Cystatin C as biomarkers for Sjögren's

Lay Abstract

Sjögren's is an autoimmune disease that affects the glands that produce tears and saliva, causing dry eye, dry mouth, fatigue, and other symptoms that reduce quality of life. It takes ~3.9 years for a Sjögren's diagnosis, largely due to the lack of a simple, reliable method for its early detection. We recently found in preliminary studies that one protein in tears from Sjögren's patients was increased, while another related protein was decreased, suggesting their potential use for early identification of Sjögren's patients. We propose to expand these studies by collecting tears and sera to see if there is a local versus a systemic change in the same proteins in Sjögren's patients versus patients with other autoimmune diseases and healthy people. These measurements may represent a new diagnostic tool for Sjögren's patients and also enable more effective treatment by quantifying the extent of local (exocrine gland) versus systemic disease.

The Committee described Dr. Edman as an "excellent young investigator candidate …early in her career."

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"Research Grantees" continued from page 17 ▼

Markus Hardt, PhD
Assistant Member of the Staff, Department of Applied Oral Sciences, The Forsyth Institute

Research Project Title

Identification of proteolytic profiles diagnostic of Sjögren's

Lay Abstract

The disease process of Sjögren's involves inflammation and destruction of the tear and salivary glands. Enzymes that breakdown the tissue structure are part of this process. Breakdown products, so called peptides, could be early indicators of the disease. We developed new analytical technologies that allow us to detect and characterize these breakdown products in unprecedented molecular detail. We will use this approach to gain unique insights into the disease process. We anticipate that this knowledge will help us to identify patients who are in the early stage of the disease when interventional therapy is most promising.

One Committee member highlighted that Dr. Hardt's research utilizes "great new technology," and "…could lead to the development of a non-invasive test for Sjögren's."

Petros Papagerakis, DDS, PhD
Assistant Professor of Dentistry, Orthodontics & Pediatric Dentistry, University of Michigan

Research Project Title

Clinical Significance of Circadian Rhythms Disruption in Sjögren's Pathogenesis

Lay Abstract

The circadian clock is an endogenous mechanism that regulates our body's functions such as sleep/wake status, saliva flow, metabolism, and hormone release. Several autoimmune diseases are caused, at least in part, by malfunction of circadian clocks. Our aim is to achieve a better understanding of the causes that result in Sjögren's, the second most common autoimmune rheumatic disease in the U.S., in which immune cells attack and destroy the glands that produce saliva and tears. Sjögren's patients suffer greatly by the lack of saliva (dry mouth) and tears (dry eye) and the current therapeutic options are not satisfactory. We found that in patients with Sjögren's, the salivary gland circadian clock does not work properly. We propose to study how changes in our circadian clock initiate and/or control progression of Sjögren's. Our goal is to provide a foundation for better diagnostic markers and novel treatment modalities for these patients.

The SSF Research Review Committee members highlighted that this "is a novel approach by a young investigator into an important area," and that the research should yield "interesting results."

It is thanks to the generous support of our members, patients and friends that the SSF is able to award grants to such talented researchers. Our goal is to nurture the investigators of tomorrow, help keep those in Sjögren's focused on Sjögren's, and encourage new ways of thinking about this disease. The SSF also expresses its deep gratitude to the many expert volunteers who review research applications for the Foundation and whose donation of time, knowledge and experience is immeasurable. The SSF will continue to update you on exciting discoveries in Sjögren's research. ■

2016

National Patient Conference

April 8-9, 2016

Hilton Seattle Airport &
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Save The Date

"The Sjögren's Journey"

This April we invite you to join with fellow Sjögren's patients, their families, medical experts, the SSF staff and industry/ product exhibitors for our 2016 National Patient Conference, "The Sjögren's Journey," at the Hilton Seattle Airport & Conference Center (Seattle, Washington).

Sjögren's is not the same for every person diagnosed, which is why educating yourself on the most up-to-date information and treatment options is so important. Attending the SSF National Patient Conference is one way you can gain information from many different sources while also meeting fellow patients.

This year's Conference will include opportunities to:

- Hear from national Sjögren's experts, researchers and SSF staff
- Find new products and receive free samples at our exhibitor hall
- Learn from your fellow patients
- Browse Sjögren's resources at the SSF Book Table
- Become inspired during the Conference's Awards Banquet Dinner

We encourage you to take this opportunity and travel "The Sjögren's Journey" with us. This two-day educational experience will give you the tools to take control of your health and learn how to manage and understand your Sjögren's symptoms and complications.

Watch for your conference brochure coming in January or visit www.sjogrens.org to see updated Conference information.

Presentation topics will include:

- Sjögren's Overview
- Dry Skin and Dermatological Issues
- Oral & Ocular Manifestations of Sjögren's
- Examining Sjögren's – Case by Case
- Tips for Your Sjögren's Journey
- Gynecological Issues with Sjögren's
- An Inside Look at Sjögren's and Gluten-Free Diets
- Sjögren's – Where Are We in Drug Development?

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If you would like to receive this newsletter but are not currently an SSF Member, please contact us! 800-475-6473

Shopping for Sjögren's

As the husband of a Sjögren's patient, I see the struggles that my wife experiences each and every day and I want nothing more than for her disease to be non-existent. This holiday season, I hope you will celebrate the spirit of generosity with us by shopping with one of our retail partners below and help give back to the Sjögren's Syndrome Foundation.

While there are many ways that you can support the Foundation, I have found that by using the links on the SSF website when shopping for holiday items, as well as everyday items, is one easy way to accomplish this. Together we can make a difference because a portion of every purchase you make goes back to the Sjögren's Syndrome Foundation, which in turn allows us to fight this disease.

Please help us keep our momentum alive as we strive to transform the future for those living with this debilitating disease by simply "Shopping for Sjögren's!" It is because of your continued support that the SSF is able to focus on changing the way Sjögren's is treated, managed and monitored.

Thank you and have a healthy, safe and enjoyable Holiday Season.

Ken Economou, *Chairman of the SSF Board*

Anne and Ken Economou

"Simplify your holiday shopping by using these links and having your gift delivered directly to you, while also supporting the SSF!"

Shop to benefit the Sjögren's Syndrome Foundation

The Sjögren's Syndrome Foundation has partnered with online retailers who will donate a portion of your purchase to the SSF, so shopping online is now an easy way to contribute to Sjögren's!

Just visit **www.sjogrens.org/shopforsjogrens** and click through the links provided so that your purchases will benefit the SSF. Some of our partners include:

- **Amazon.com** is one of the most popular online stores in the world, offering a wide variety of products. Up to 10% of the value of your purchase is donated back to the Foundation.
- **Drugstore.com** is a leading online provider of health, beauty, vision, and pharmacy products. The website allows you to shop as if you were at your local drug store, and you can get instant savings while 8% of your purchase benefits the SSF.
- **iGive.com** offers exclusive deals with over 700 brand name stores you know and love, with a specified percentage of each purchase coming back to the SSF. Be sure to select "Sjögren's Syndrome Foundation" as your charity of choice. Whenever you return to iGive.com and log in, any shopping you do will benefit the SSF! It's that simple.