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Dry Eye Workshop II Committee Members

Dear ,

It has been nearly a decade since the Tear Film and Ocular Surface Society (TFOS) published *The Report of the International Dry Eye Workshop* (DEWS). That impressive body of work introduced Dry Eye as an “under-recognized clinical condition whose etiology and management challenge clinicians and researchers alike.” In 2016, despite advances in diagnosis and treatment, Dry Eye continues to be a vexing problem not only for clinicians and researchers, but more importantly for the patients who suffer with Dry Eye, sometimes with symptoms so debilitating that lives are ruined.

Now, TFOS is undertaking the challenge of updating the body of knowledge about Dry Eye. We, the board of the Not A Dry Eye Foundation (who are all Dry Eye patients ourselves) encourage all DEWS II committee members to adopt the proven approach in health care that embraces the patient perspective in all aspects of disease management, from research and diagnosis, to treatment and training.

The mission of our foundation is raising awareness of Dry Eye syndrome, to improve patient education and advocacy, and to effect positive outcomes. We believe that through combining increased involvement from patients like ourselves with the very important work of DEWS II, advances in Dry Eye disease management, which for us is a primary goal, will be accelerated, more outcomes will be positive, and fewer patients will retreat into oblivion with the quality of their lives destroyed.
In the spirit of patient participation, earlier this year we contacted TFOS Executive Director Amy Gallant who assured us that there are many Dry Eye patients already participating on the various DEWS II committees. Our own examination of the list of committee members uncovered only two patients. Although many others on the committees may also suffer from Dry Eye, we believe that unbiased patient representation - unaffiliated with clinical, pharmaceutical, or research organizations - will better serve your cause as well as ours.

**Patient Perspectives and Committee Discussions**

Because Ms. Gallant declined our offer to participate on DEWS II committees, and because there is no DEWS II committee focusing specifically on the patient’s perspective, we are taking this opportunity to communicate directly with the committees where we feel the patient’s voice would contribute to or advance the discussion on the topic. In this way, we aim to add the “patient perspective” to these committees’ thoughtful discussions and published papers. The comments are compiled from conversations and interviews with patients in 2015-16.

Each comment or discussion point is presented as a separate paragraph under a heading with the name of the subcommittee to which it applies. The order of subcommittees mirrors the order listed on the TFOS website.

Under each subcommittee heading our thoughts and comments are presented in no particular order of importance, and may overlap several subcommittees. However, for the purpose of brevity, we are not repeating comments that might apply to more than one subcommittee. Therefore, we suggest reading the document in its entirety.

We conclude with a section titled *What’s Missing*, where we take the opportunity to comment on Dry Eye Syndrome on a variety of additional related topics.

Please note that we are distributing this letter broadly (see cc: list below) to bring awareness to this disease that is neither well understood by many doctors nor widely recognized by patients.

**Definitions and Classifications Subcommittee**

From our perspective, *seeing* (vision/blindness) and *looking* (keeping eyes opened as long as necessary to see) are fundamentally different acts. Therefore, a distinction is required between visual *acuity* and visual *ability* impaired by eye discomfort. Dry Eye patients often complain of difficulty reading, driving, or performing other activities that demand focus because these activities exacerbate pain or other eye discomfort. These patients have no vision problems per se, but they are unable to use their eyes normally (for vision) because of pain. This distinction
will help to change the dialogue between patients and providers regarding severity of the disease and its impact on Quality of Life (QOL), and anyone evaluating a Dry Eye patient for disability.

**Epidemiology Subcommittee**

Although we applaud all efforts by various researchers to *estimate* the incidence and prevalence of the disease, it is time to begin tracking *actual* disease incidence and prevalence internationally to better understand its impact on QOL and populations.

Disease tracking to include at a minimum:

- Severity or stage of disease
- Impact on QOL
- Causes and co-morbidities

**Iatrogenic Dry Eye Disease Subcommittee**

*Primum non nocere.* First do no harm. In good faith, we trust that our doctors follow this principle. But we understand that sometimes harm is unavoidable; Dry Eye as a side effect of chemotherapy is just one of many examples. However, other iatrogenic conditions are avoidable, such as chronic Dry Eye when refractive surgery is performed on patients who are not qualified candidates for the procedure.

Providers will continue to dismiss the risks of surgery for some patients without reliable primary data on the incidence of Dry Eye induced by refractive surgery to support anecdotal reports of post-surgical pain and discomfort that can lead to permanent disability.

Isotretinoin (Accutane) used for acne treatment has long been known to contribute to decreased meibomian gland function (Cornea, 1991). Beta blockers and other medications are known to contribute directly to Dry Eye disease or symptoms. Prescribing physicians (e.g., dermatologists, psychiatrists) must be made aware that adverse side effects of these medications can be severe and disabling.

Conventional Dry Eye treatments themselves can exacerbate symptoms or co-morbid conditions (e.g., lid massage and even warm compresses can exacerbate symptoms when there is obstructive meibomian gland dysfunction).

Approaches to treatment that exacerbate symptoms or co-morbid conditions may be traced to insufficient diagnosis or outdated conventional wisdom regarding the contribution of obstructive meibomian gland dysfunction that may lead to damaged conjunctival tissue.
The consequences of doing nothing, or doing not enough, can be just as bad as causing harm. Prescribing treatments to patients that will be largely ineffective prolongs suffering and delays the administration of effective treatment. Of note are patients with moderate to severe Dry Eye who are prescribed treatments appropriate for those with mild Dry Eye (e.g., lubricating drops, lid wipes, warm compresses, and lid massage). Similarly, prescribing Restasis, with its limited efficacy and long treatment horizon (Restasis Product Information, Allergan), while scheduling follow-up appointments in three months or more, can delay the administration of better or more targeted treatments, thus prolonging patient suffering.

Treatment with anesthetizing drugs (e.g., gabapentin, pregabalin) may alleviate symptoms temporarily, but underlying causes are left untreated. When treatment stops, symptoms return. Treatment with these drugs can cause serious side effects, including suicidal thoughts. Some Dry Eye patients, who are without hope, may already be considering suicide. Prescribing these drugs can have serious, possibly fatal, side effects.

Patients are largely unaware of the adverse effects of long-term use of topical or OTC lubricating eye drops that contain benzalkonium chloride (BAK). Patients require counseling and guidance to avoid products containing BAK for long-term treatment, even if safer alternatives are more expensive.

In good faith, patients put the care of their eyes into the hands of their doctors and have every right to expect safe, competent care that improves, rather than exacerbates, their condition.

**Sex, Hormones, Gender**

Even if many Dry Eye sufferers are menopausal women, it is still important to treat each patient individually and not rely too heavily on population statistics or disease risk when diagnosing and treating patients. Men can get Dry Eye. Men and women sitting in front of a computer screen for long hours are at risk for Computer Vision Syndrome. Young women undergoing refractive surgery can get Dry Eye. Hormones and gender are of little consequence in these cases (Dry Eye in the Beaver Dam Offspring Study, 2014).

Normal aging and the hormonal changes that take place over time are not diseases even if hormones alter tear secretions.

**Management and Therapy**

Management of Dry Eye and therapies prescribed must align with diagnoses of all co-morbid conditions. Individual patients benefit little from population therapy or treatments that relieve
symptoms in small numbers of patients. Dry Eye patients require treatments that will relieve their specific symptoms.

Pharmaceutical companies and medical device manufacturers, with regulatory oversight, must design tests that screen for patients who will benefit from their specific therapies and not expect patients to purchase drugs or treatments based on generalizations from population health.

When symptoms are moderate or severe, doctors must adjust treatment plans for these patients. All too often patients with increasingly severe symptoms seek care from different doctors each of whom presents the same limited protocol (i.e., lubricating drops/ointments, lid wipes, warm compresses, lid massage). Patients require treatment plans that take into account all co-morbidities and severity of symptoms. Treating severe Dry Eye with stage 1 therapies only causes patients to lose trust in their doctors.

Patients need training and guidance as they begin their treatment plan. Providers must not assume that patients know how to safely and hygienically do the following:

- Instill drops
- Instill ointments
- Massage their lids
- Apply warm compresses
- Use moisture chamber goggles
- Treat themselves with any regimen or therapy performed at home or work

Patients have little patience. If treatment does not alleviate symptoms, the treatment, and possibly the doctor who prescribed it, will be abandoned.

Doctors need to maintain open communication channels with their patients, letting them know that if their condition does not improve or worsens, they should make an appointment to be seen. Doctors need to assure patients that they will be seen promptly and communicate accordingly (e.g., if a follow-up appointment is scheduled in three months but there is no relief after two weeks, the patient should make an appointment to see the doctor sooner).

Companies marketing therapies that are only effective for small populations (e.g., 10% of all patients) and that concurrently do not take effect for months, not only increase costs to patients and insurers, but also delay the administration of more effective treatment to the vast majority of patients while prolonging their suffering needlessly.

Dry Eye patients sometimes skip follow-up appointments when they experience little or no relief of their symptoms. While some doctors may assume that patients do not return for follow-up care because symptoms have improved, the opposite may be the case.

Treatment and management practice guidelines must steer doctors toward better and more specific diagnoses that are then explained to patients (e.g., obstructive meibomian gland
dysfunction or demodicosis instead of the less specific “blepharitis”). If patients understand their co-morbidities, they will be better educated and more motivated to manage their symptoms.

Dry Eye patients often do not understand the multi-factorial nature of the disease, expecting instant results and instant relief. Many doctors never venture beyond treatment for mild cases. This results in a disconnect between doctors and their patients.

Doctors have a choice when presented with patients who do not respond to treatment or for whom pain or other discomfort persists. Doctors can choose to alleviate the symptoms with beta blockers and/or anesthetizing drugs, or they can choose to delve deeper into the patient’s symptoms, diagnose further to determine which co-morbidities are causing the symptoms, and then treat these co-morbidities. Most patients, given a choice, would understand that treating the underlying co-morbidities is the better option.

**Clinical Trials**

Dry Eye patients have experiences that extend beyond the research and clinical setting. Embracing patient needs and perspectives will give clinicians and researchers a better understanding of the challenges we face while informing the projects they undertake.

**Tear Film**

There are many factors that contribute to tear film health and disease. Any diagnosis or treatment of the tear film must include diagnosis and treatment of all these factors.

A treatment that improves a specific aspect of the tear film (e.g., mucous layer) should be prescribed only to those patients who have had a specific diagnosis (e.g., mucous deficiency or disease).

**Diagnosis**

Undiagnosed or misdiagnosed co-morbidities are a common phenomenon among Dry Eye patients. Sometimes even aqueous deficiency is missed. Often conjunctivochalasis and superior limbic keratoconjunctivitis are missed.

Misdiagnoses and missed co-morbidities are a form of iatrogenic Dry Eye disease, because these delay the administration of effective treatment and prolong patient suffering.
Patients, especially those with severe Dry Eye, may see many doctors who do not diagnose many of their co-morbidities. As a result, limited treatment is usually prescribed with little efficacy and patients continue to suffer, sometimes with unbearable pain. These patients can become desperate for help while losing hope in the medical profession.

Providers have little insight into the number of doctors a patient with severe Dry Eye typically sees before finding one who diagnoses all of their co-morbidities.

When treatment is ineffective, signs or symptoms persist, further diagnosis is warranted. Resorting to neuropathic diagnoses misses the underlying etiology.

Doctors require clear guidelines for administering Schirmer Tests and interpreting results (e.g., Schirmer Test 1 with numbing drops to test for aqueous deficiency; Schirmer Test 1 without numbing drops to test for Sjogren’s Syndrome).

Test results can be altered after emotional or reflexive tears.

Any underlying co-morbid systemic conditions contributing to Dry Eye require diagnosis and treatment. Patients should be referred to their primary care physician or appropriate specialists.

Include patients in the development of questionnaires to improve patient-doctor communications. Strive to better understand symptoms and their impact on QOL.

**Pain and Sensations**

The name of this committee would have been more descriptive had it been *Pain and Other Discomfort*, because as sufferers we can attest that the only truly comfortable state for the eye is one in which there are no sensations. Any other sensation in the eyes eventually, if not immediately, becomes discomfort.

A growing trend in Dry Eye research and literature attributes Dry Eye pain and discomfort to non-specific neuropathic pain which cannot be attributed to a specific cause or is not revealed in various tests. We suspect that this is exceedingly rare. Instead, doctors should examine patients with persistent symptoms for other co-morbid conditions that affect nerves, such as conjunctivochalasis and SLK. All too often, patients have been told, “It’s all in your head.”

Co-morbid conditions that are completely different can cause the exact same pain and discomfort.

Expand the list of “common” symptoms (e.g., burning, gritty, dry) to include all of the symptoms experienced by patients. Our website (www.notadryeye.org) includes a more comprehensive list that continues to grow as patients submit their symptoms.
Surgeries, procedures, topical medications, and treatments can all cause pain and other discomfort.

When symptoms persist, patients do not always seek additional care from their doctor. Instead they seek care elsewhere or after seeing many doctors, they simply lose hope. They can lose trust not only in their Dry Eye doctor, but in the medical professional as a whole. Once that trust, an essential component of the patient-doctor relationship, is broken, it is very difficult to rebuild.

To assess the magnitude of the devastation caused by persistent pain and discomfort due to Dry Eye, measure health-related disability, QOL, and the economic impact on individuals and families.

Patients need to understand that moderate or severe symptoms of a specific co-morbidity can mask symptoms of other co-morbidities. When one symptom is effectively treated, another symptom or similar symptom may emerge, indicating another condition that requires treatment.

Public Awareness

In order to engage patients and build trust, public awareness campaigns need unaffiliated patient involvement in their design and delivery.

What’s Missing

In addition to Pain and Discomfort, the committees should discuss and include in their published report the behaviors displayed by Dry Eye patients. These behaviors indicate severity of the disease and should be included in Dry Eye questionnaires to aid in diagnosis and staging (e.g., inability to read, loss of social contacts, thoughts of suicide). Our website includes a list of behavioral signs displayed by Dry Eye patients that may be referenced.

Depression may be a co-morbid condition, but it is not the cause of Dry Eye for many patients. However, when a patient’s life is ruined by the disease, when a patient is unable to find relief and has lost all hope, a patient may become depressed and even entertain thoughts of suicide or enucleation.

Any diagnosed mental disorder must be verified by a qualified mental health professional before any treatment is prescribed. These patients must be monitored by a psychiatrist or other mental health care professional during the course of their treatment. The alarming 63% increase in the suicide rate among middle-aged women over the past 15 years in the U.S. must be taken into account (NCHS Data Brief No. 241, April 2016).
Given the severity of pain, the potential for suicidal ideation and disability due to moderate or severe Dry Eye, PTSD is a potential co-morbidity that must be monitored by a professional clinician.

Patients, having put trust in their doctors in good faith, deserve, and are entitled to, competent and inquisitive doctors who are committed to understanding and resolving their patients’ co-morbidities. The multi-factorial nature of Dry Eye may be difficult to diagnose and treat, but that is why we hold our doctors to such high standards – so they can solve this very difficult problem.

Advances in DNA testing and stem cell research may provide new insights into disease etiology and treatment options.

**Conclusion**

We would like to thank TFOS and all of the committee members in advance for taking time to participate and contribute to the Dry Eye body of knowledge. As patients, we gratefully recognize that we will continue to be the recipients of the work you do today.

Although we all know there is still much to be learned about Dry Eye, it is encouraging to see the expanded focus of committees in this decade’s DEWS II meetings. Knowing that the complexities of this condition are being examined by leaders in the field, gives hope to each of us - and thousands of patients like us, worldwide.

We prepared this document to contribute the patient perspective to the DEWS II committee discussions and publications focused on various aspects of Dry Eye and related co-morbidities. The Not A Dry Eye Foundation fully anticipates and welcomes your feedback to this correspondence.

Sincerely,

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(Note: this correspondence was sent only via email or electronic submission)

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*Dr. Chantal Couderc, Directeur des Affaires Médicales, Horus

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Dr. Diane Houtman, Vice President, Professional Relations, Akorn

*Dr. Jami R Kern, Vision Care Franchise Head, Global Medical Affairs, Alcon

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Maria Grazia Mazzone, Head of Project Management, SIFI Pharma

*Robert J Meyering, Vice President, Global Medical Relations and Operations, Bausch & Lomb

*Dr. Christine Purslow, Head, Medical Affairs, UK & Ireland, Laboratoires Théa

*Julie Speed, Vice President, Global Marketing, TearLab

Dr. Edward R Truitt III, (Lμbris), CEO

*Dr. Tawnya J Wilson, Principal Research Optometrist, Johnson & Johnson Vision Care

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Dr. Belinda Seto, Deputy Director, NEI

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Dr. Cheri L Wiggs, Groups Leader, Low Vision & Blindness Rehabilitation, Myopia and Refractive Error, NEI

Dr. Hemin R. Chin, Group Leader, Glaucoma and Optic Neuropathies, NEI

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Anna Harper, Media Relations, NEI

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Dr. Vivek H. Murthy, Surgeon General

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Dr. Jeff Brady, Director, Center for Quality Improvement and Patient Safety (CQuIPS), AHRQ

Dr. Arlene S Bierman, Director, Center for Evidence and Practice Improvement (CEPI), AHRQ

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*Dr. Marla B Sultan, Industry Liaison, Dermatologic and Ophthalmic Drugs Advisory Committee, FDA

Dr. Geoffrey G Emerson, Dermatologic and Ophthalmic Drugs Advisory Committee, FDA

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Dr. Jennifer L Coyle, Historian, Cornea, Contact Lenses and Refractive Technologies Section, American Academy of Optometry

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Dr. Timothy B Edrington, Immediate Past Chair, Cornea, Contact Lenses and Refractive Technologies Section, American Academy of Optometry

Dr. Douglas P Benoit, Diplomate, Cornea, Contact Lenses and Refractive Technologies Section, American Academy of Optometry

Dr. Louise A Sclafani, Case Reports, Cornea, Contact Lenses and Refractive Technologies Section, American Academy of Optometry

Dr. Michael D Twa, Editor, Optometry and Vision Science

Dr. Anthony J Adams, Associate Editor, Optometry and Vision Science

Dr. Alan Sugar, Editor-in-Chief, Cornea: The Journal of Cornea and External Disease

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New York Times

Wall Street Journal

Washington Post

LA Times

Boston Globe

New Yorker

ABC News

CBS News

NBC News
CNN

MSNBC

Fox News

PBS News Hour

60 Minutes

Medical News Today

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