NEARLY 95% OF AMERICANS AT RISK FOR DIGITAL EYE STRAIN WITH INCREASED DEVICE USE

A new report by The Vision Council finds nearly 95% of Americans spends 2 or more hours every day on digital devices. The report found a lack of awareness about how this use affects eyes and vision health, according to a news release.

"On average, we look at our mobile phones more than 100 times a day, yet people aren't making the connection how this constant use of technology is impacting vision health," said Dora Adamopoulos, OD, medical adviser to The Vision Council. "Digital eye strain is likely to continue to grow as a health concern. However, there are tools and products that can alleviate or even prevent the onset of symptoms as well as protect the eyes."

Digital eye strain is characterized as temporary physical discomfort felt after 2 or more hours in front of a digital screen and is associated with the close to midrange distance of digital screens. It is marked by symptoms such as redness, irritation or dry eyes, blurred vision, eye fatigue, back and neck pain, and headaches. Several environmental factors can contribute to fostering the condition, including the small size of the text on screens; time spent staring at devices; posture; computer setup; existing, untreated vision issues; and the blue light emitted from digital screens and lighting.

The report also highlights emerging research on blue light overexposure, also referred to as *high-energy visible* or *HEV* light. Blue light is emitted from backlit displays of devices, LED and fluorescent light bulbs, and even the sun, and it is an increasing cause for concern among eye care providers who are worried about the potential long-term impact on vision health, according to the report. Because blue light can reach deeper into the eye than ultraviolet light, specific wavelengths may damage the retina.

Although the issue is nascent, recent evidence points to a possible link between exposure to blue light and long-term vision issues such as age-related macular degeneration and cataracts. Yet, most adults (72%) are not aware of the potential damage caused by blue light overexposure and do not know that digital devices emit blue light.

Imprimis Expanding Portfolio With Less Drops

Imprimis Pharmaceuticals announced its plans to introduce proprietary triamcinolone acetonide and moxifloxacin hydrochloride (Tri-Moxi) and prednisolone acetate and moxifloxacin hydrochloride (Pred-Moxi) combination eye drop formulations for patients following laser refractive surgery, including LASIK and PRK, cataract, and other ocular surgeries, according to a company news release.

The current treatment regimens following LASIK, cataract, and other ocular surgeries include two or more daily self-administered topical eye drops for up to 4 weeks. It is well documented that current eye drop regimens can be confusing to patients, creating noncompliance issues and incorrect dosing, according to Imprimis. For some high-volume ocular surgeries, like PRK and LASIK, the company estimates that its combination Tri-Moxi and Pred-Moxi topical eye drop formulations can require up to 50% fewer drops to be administered by patients and may cost up to 75% less than current postsurgery drop regimens.

Importantly, Imprimis' topical compounded drops may be eligible for reimbursement to patients covered by both public and private insurance plans, the company says. A prospective evaluation of de-identified quality assurance data of the Tri-Moxi and Pred-Moxi topical formulations for patients following LASIK surgery enrolled in the fall of 2014 at the Cleveland Eye Clinic. Imprimis expects the results of this research to be announced by the end of January 2015.

Imprimis also announced it has appointed Richard L. Lindstrom, MD, to its board of directors. Dr. Lindstrom is a board-certified ophthalmologist and internationally recognized leader in corneal, cataract, refractive, and laser surgery. He has been at the forefront of ophthalmology's evolutionary changes throughout his career as a recognized researcher, teacher, inventor, writer, lecturer, and highly acclaimed physician and surgeon, according to Imprimis. Dr. Lindstrom is founder and an attending surgeon of Minnesota Eye Consultants, Adjunct Clinical Professor Emeritus at the University of Minnesota Department of Ophthalmology, and visiting professor at the UC Irvine Gavin Herbert Eye

Institute. He serves as an advisor to numerous companies throughout the world.

2014 New Drug Approvals Hit 18-Year High

The FDA approved a total of 44 drugs in 2014. That is the most since the industry's all-time record in 1996, when 55 "new molecular entitites" were given the green light.

According to the FDA's report, AstraZeneca received the most approvals with four, Lilly received three approvals, and Abbvie saw its blockbuster hepatitis C treatment, Viekira Pak, gain the FDA's okay. The lone eye care agent to gain approval was Hetlioz (Vanda Pharmaceuticals) for the treatment of non-24-hour sleep-wake disorder, which occurs almost exclusively in blind patients.

A summary of the approvals shows that 15 of the agents approved were orphan drugs (the most since the Orphan Drug Law passed in 1983), 57% had priority review, and 37% were fast tracked. The FDA reports that it shortened its median approval time for expedited drugs: 6.5 months in 2014 versus 7.9 months in 2013.

NovaBay Rebrands Its i-Lid Cleanser as Avenova

NovaBay Pharmaceuticals announced the rebranding of its i-Lid Cleanser with Neutrox as Avenova with Neutrox, according to a company news release. This name change, effective immediately, helps NovaBay differentiate prescription Avenova from other products marketed as eye cleaners, in particular over-the-counter (OTC) products not intended for continuous daily use.

According to the company, Avenova is the only eye care product to contain Neutrox, NovaBay's pure hypochlorous acid, which is a naturally occurring substance produced by white blood cells to fight microbial invaders. Laboratory tests show it has potent antimicrobial activity in solution yet is nontoxic to mammalian cells; it also neutralizes bacterial toxins, according to the news release.

"Avenova is uniquely suited for daily use by the millions of Americans who suffer from chronic eye conditions like blepharitis and dry eye," Glenn Moro, NovaBay's vice president for sales and marketing, said in the news release. "Yet far too many ophthalmologists and optometrists have confused prescription Avenova with OTC surfactant lid cleaners. While those OTC products are effective for their intended uses, none is designed for continuous daily eyelid hygiene."

"Avenova is a real breakthrough in eye care," said Terrence P. O'Brien, MD, director of the Refractive Surgery Service, Bascom Palmer Eye Institute at Palm Beach Gardens, Florida. "This product fills a medical need not being met by current products."

"Historically, eye care specialists have brought relief to patients who present with conditions like blepharitis, where *Staphylococci* bacteria grow on eyelids and cause swelling, redness, inflammation, irritation, and a crusty build-up," Art Epstein, OD, director of the Dry Eye & Ocular Surface Disease Center and director of clinical research at Phoenix Eye Care, said in the news release. "While Avenova is effective as part of the regimen for managing those conditions, regular use of Avenova may prevent such problems before they occur, much as daily flossing helps to prevent dental problems."

Avenova was cleared by the FDA as a prescription medical device through the 510(k) process. As previously announced, NovaBay signed a distribution agreement with McKesson, the largest pharmaceutical distributor in North America, making Avenova available to the 45,000 pharmacies it services across the United States. In addition, Avenova is now available to the members of the Vision Source Independent Optometry Network. Vision Source is the largest independent optometry network in the country, representing 2,800 independent optometrist offices.

Drs. O'Brien and Epstein are members of NovaBay's advisory board.

Mitosol Receives Key Reimbursement Assurance for 2015

Mobius Therapeutics has received a renewal of reimbursement for the Mitosol (mitomycin) kit for ophthalmic use in 2015, according to a company news release. After reviewing the final Outpatient Prospective Payment System/Ambulatory Surgery Center rule from the Centers for Medicare & Medicaid Services (CMS) regarding 2015 reimbursement, Mitosol will continue to receive a separate, pass-through reimbursement at 106% of the average sales price. The full updated CMS reimbursement schedule for hospital outpatient prospective payment can be found online at www.cms.gov.

"As Mitosol remains the only approved formulation of mitomycin C bearing an ophthalmic indication, this continuation of reimbursement supports federal regulatory guidance related to the use of approved formulations," Ed Timm, president and CEO of Mobius Therapeutics, said in the news release. "When regulatory guidance and economics align, patients and providers win. As Medicare payment remains unchallenged, we are seeing broad adoption of this same payment policy from private payors. This reaffirmation will assure existing and new Mitosol patients and providers economic security. Access to Mitosol will meet their ongoing needs, both clinical and financial."

CRST NEWS

Phase 2 Trial Initiated for Macular Edema Associated With Noninfectious Uveitis

Clearside Biomedical announced the enrollment of the first patient in a phase 2 randomized, controlled, masked, multicenter clinical trial for the treatment of macular edema associated with noninfectious uveitis using Clearside's proprietary formulation of triamcinolone acetonide, CLS-TA, administered via suprachoroidal injection using Clearside's proprietary microinjector, according to a company news release.

Approximately 30 patients will be randomized 1:1 to receive either a single 4-mg dose or a single lower dose of 0.8 mg of CLS-TA, according to the news release. The 4-mg dose is a commonly used amount when triamcinolone acetonide is dosed intravitreally. The trial is designed to explore safety and efficacy information on suprachoroidal injection of each of these doses of CLS-TA.

The primary efficacy endpoint of the phase 2 trial will be the mean change from baseline in retinal thickness at 2 months after treatment. Secondary efficacy endpoints will include visual acuity improvements at 1 month and 2 months after treatment, measured by the mean change in BCVA from baseline. Safety measures will be monitored over the 2-month observation period and will include the incidence of adverse events and serious adverse events, including increases in IOP.

Noninfectious Anterior Uveitis IND Submitted

Aldeyra Therapeutics submitted an investigational new drug (IND) application to conduct phase 2 clinical testing of NS2 for the treatment of noninfectious anterior uveitis, according to a news release. NS2 is designed to trap free aldehydes.

"The submission of an IND for NS2 [for] the treatment of noninfectious anterior uveitis is a major milestone for Aldeyra and is another step forward in the execution of our development strategy," Todd C. Brady, MD, PhD, president and CEO of Aldeyra, said in a news release. "NS2 has the potential to reduce or eliminate the use of steroids in the treatment of this disease, which we believe would significantly enhance the treatment options for these patients and improve their long-term ocular health. We remain focused on advancing NS2 through its planned clinical program as we prepare to initiate the phase 2 trial early next year."

WHAT'S THE BUZZ?

MEDICAL NEWS BY THE NUMBERS

5,492 **TOTAL NUMBER OF LABORATORY-CONFIRMED INFLUENZA-ASSOCIATED HOSPITALIZATIONS REPORTED THROUGH THE INFLUENZA HOSPITALIZATION SURVEILLANCE NETWORK (FLUSURV-NET) SINCE OCTOBER 1, 2014**

- This translates to a cumulative overall rate of 20.1 hospitalizations per 100,000 population.
- A total of 26 influenza-associated pediatric deaths have been reported for the 2014-2015 season at this time.

Clinicians should prescribe antivirals for hospitalized, severely ill, and high-risk patients with flu symptoms without waiting for lab confirmation, the Centers for Disease Control and Prevention announced.

Source: *Centers for Disease Control and Prevention*

PERCENTAGE OF INDIVIDUALS AGED 18 TO 29 WHO HAVE USED A COMMERCIAL TANNING BED IN THE PAST YEAR, DESPITE ITS BEING LINKED TO MELANOMA AND NONMELANOMA SKIN CANCER **20%**

- Use by teenage girls is 40%.
- Estimates are that 1 million people use tanning beds daily despite their placement in the highest cancer risk category and use's being restricted in many states.

Because indoor tanning is associated with increased morbidity and mortality, the availability of devices to certain demographics may have significant public health consequences.

Source: *JAMA Dermatology*

15 MILLION **NUMBER OF PEOPLE IN THE UNITED STATES WHO HAVE FOOD ALLERGIES**

- 6 million are children.
- About 90% of food allergies are caused by eight foods: milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans.
- Peanuts are the most common trigger of food-allergic reactions in the United States.

In the 10% of 436 study participants who were most sensitive to food allergens, between 1.6 to 10.1 mg of hazelnut, peanut, and celery protein needed to be consumed to trigger an allergic reaction, whereas 27.3 mg of fish and 2.5 g of shrimp protein were required to produce a response.

Source: *Journal of Allergy and Clinical Immunology*

NUMBER OF HYSTERECTOMIES PERFORMED THAT MAY BE UNNECESSARY **1 in 5**

- About 68% of hysterectomies for benign conditions are done to treat abnormal uterine bleeding, uterine fibroids, and endometriosis.
- Rates of hysterectomy in the United States are falling, with one study reporting a 36.4% reduction in the number of hysterectomies carried out between 2003 and 2010.

More than 400,000 hysterectomies are carried out in this country every year, and some researchers at the University of Michigan Medical School note that concerns about the appropriateness of hysterectomy remain.

Source: *American Journal of Obstetrics & Gynecology*

Aldeyra said it intends to initiate a phase 2 trial of NS2 for noninfectious anterior uveitis in 2015, pending the FDA's review of the IND. High levels of proinflammatory free aldehydes are associated with noninfectious anterior uveitis and other ocular and systemic diseases. Aldeyra said by trapping free aldehydes, NS2 may reduce inflammation, fibrosis, and tissue damage associated with inflammatory ocular diseases and may be a safe and effective alternative to corticosteroids.

Report: Some Top-Selling Eye Vitamins Do Not Match AREDS

A study evaluating the top-selling ocular nutritional supplements finds that they contain the same ingredients as the Age-Related Eye Disease Study (AREDS) and AREDS 2 formulas but that not all contained the same doses.[1] The study, published online in the journal *Ophthalmology*, also called into question whether manufacturers' claims were based on evidence.

The researchers, based at Yale-New Haven Hospital-Waterbury Hospital, Penn State College of Medicine, Providence VA Medical Center, and Warren Alpert Medical School of Brown University, identified the five top-selling brands based on market research (tracked by SymphonyIRI) collected from June 2011 to June 2012 and analyzed the brands' 11 products. The brands include PreserVision and Ocuvite (Bausch + Lomb), ICaps and ICaps AREDS (Alcon), and EyeScience Macular Health Formula (EyeScience). The ingredients of the supplements were compared with those contained in the AREDS and AREDS2 formulas.

The study found that all of the ocular vitamins contained the ingredients from the AREDS or AREDS2 formula but that only four (36%) of the supplements contained equivalent doses of AREDS or AREDS 2 ingredients. Another four contained lower doses of all the AREDS or AREDS2 ingredients. Four of the products also included additional vitamins, minerals, and herbal extracts that are not part of the AREDS or AREDS2 formulas.

All the individual supplements claimed to "support," "protect," "help," or "promote" vision and eye health, but none specified that there is "no proven benefit in using nutritional supplements for primary prevention of eye disease," according to the study. In a statement to *Cataract and Refractive Surgery Today*, Bausch + Lomb said it was pleased with the results.

"Of the 11 supplements examined in the study, only four of the products were found to include the same ingredients and in the same concentrations as used in the AREDS and AREDS2 studies, and of those four products, three are from the company's vitamin and mineral supplement portfolio," a portion of the statement read.

The researchers concluded that the findings underscore the importance of ophthalmologists' educating patients that they should only take the proven combination of nutrients and doses for age-related macular degeneration. ■

1. Yong J, Scott I, Greenberg P. Ocular nutritional supplements: are their ingredients and manufacturers' claims evidence-based? [published online ahead of print November 20, 2014]. *Ophthalmology*. doi: http://dx.doi.org/10.1016/j. ophtha.2014.09.039.

LETTERS

The following reader-author exchange refers to "The Literature" column that appeared in our September 2014 edition.

In their discussion of the relative benefits of the glued IOL technique, Waisbren and colleagues decry the complications of anterior chamber IOLs (ACIOLs) by saying, "All of these mechanical complications relate to the anatomical position of the lens." To support this statement, they cite a 1987 article on closed-loop ACIOLs, which, of course, are no longer available. To my knowledge, there is still no study showing that modern open-looped ACIOL outcomes are inferior to any other choice in the setting of no capsular support. Though I concur that other options are viable and may ultimately prove superior in some circumstances and in experienced hands, the discussion section of this article does a disservice to the reader, who may not notice the statement's antiquated and irrelevant source.

Lisa Brothers Arbisser, MD

While ACIOLs are certainly acceptable in some situations, it has been our experience that ACIOLs are often placed under duress, after the surgeon has broken the capsule. In our collective experience, frequently, they are misplaced or sized incorrectly, or vitreous is present in the anterior chamber, which further complicates the situation. These untoward complications may lead to chronic inflammation, corneal endothelial cell loss, and subsequent corneal failure. Based on this, it is generally agreed upon that a posteriorly placed IOL is preferable to one in the anterior chamber. Perhaps the lack of recent literature illustrates the trend away from ACIOLs.

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