

OPHTHALMIC PIONEER ROBERT SINSKEY, MD, PASSES AWAY

"True happiness is not a feat lightly achieved, but I can honestly say that through my adventures, experiences, and relationships—thick and thin—I have found it."

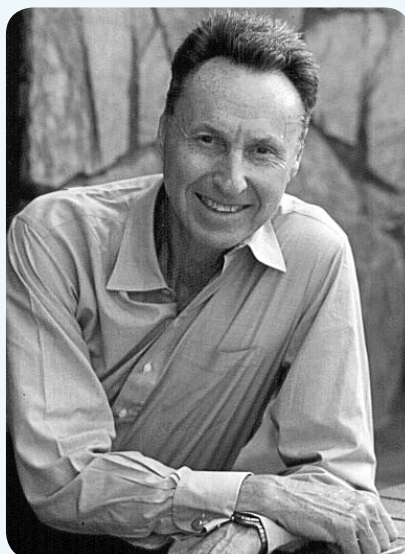
—A Life in Focus, Robert M. Sinskey, MD

World-renowned cataract surgeon Robert M. Sinskey, MD, passed away on June 22, 2015. Dr. Sinskey was an ophthalmic pioneer who played an important role in the development and acceptance of phacoemulsification.

Dr. Sinskey was the first to perform posterior chamber phacoemulsification and the first to recommend early surgery for children. His research in the 1950s in Hiroshima, Japan, contributed to the current understanding of radiation-induced cataracts and how they differ from other types of lenticular opacities.

Beginning in the 1970s and continuing for more than 20 years, Dr. Sinskey and Richard Kratz, MD, personally trained over 3,500 early adopters of phacoemulsification. Dr. Sinskey also patented his internationally popular modified J-loop IOL and invented several surgical instruments, including his widely used Sinskey hook.

"Bob Sinskey was a true pioneer in the advancement of phacoemulsification and lens implant surgery," Jack M. Dodick, MD, professor and chairman of the Department of Ophthalmology at New York University, told *CRST*. "He taught us how to make small-incision cataract surgery easier and safer, and he travelled worldwide sharing his



knowledge. Bob was instrumental in propelling acceptance of lens implants at a time when mainstream ophthalmology was skeptical of this device. We are in a better place because of his efforts."

Born in 1924, Dr. Sinskey received his medical degree from and performed his ophthalmology residency at Duke University School of Medicine. He served as medical director emeritus of the Southern California Lion's Eye Institute, was clinical professor of ophthalmology at the Jules Stein Eye Institute at UCLA, and was on the staff at St. John's Health Center in Santa

Monica, California. He served as president of the American Society of Cataract and Refractive Surgery (ASCRS) from 1999 to 2000 and was inducted into the organization's hall of fame in 2005.

Known for the high-quality charitable eye care Dr. Sinskey brought to Ethiopia, the ASCRS Foundation's Robert Sinskey Eye Institute is now the largest charitable eye hospital in the capital city of Addis Ababa. The facility treats over 16,000 patients annually and helps to train the next generation of Ethiopian surgeons, according to a news release from the ASCRS.

Dr. Sinskey served as guest faculty and surgeon for more than 100 symposia and had more than 200 speaking engagements around the world. He published more than 30 journal articles and textbook chapters as well as a revised monograph on phacoemulsification. In 2010, Bryn Mawr Communications published his autobiography, *A Life in Focus*, in which Dr. Sinskey shared stories from his family life and provided a medical history of phacoemulsification.

Outside the medical profession, Dr. Sinskey was well known for his award-winning winery, Robert Sinskey Vineyards, which sits on approximately 200 acres in the Napa Valley.

Imprimis Acquires Proprietary Compounded Conscious Sedation Formulations

Imprimis Pharmaceuticals has acquired the rights to novel proprietary sedation and analgesia/anesthesia formulations that are administered sublingually to block pain and sedate patients undergoing ocular and other surgical procedures, according to a news release. After completing its intellectual property diligence process and filing a patent application with the US Patent and Trademark Office, Imprimis executed an invention assignment agreement to acquire the rights to commercialize these formulations.

A team of ophthalmic surgeons is conducting a patient-specific clinical evaluation to support the commercialization of these formulations. The company said they may be available for prescription and dispensing sometime during the fall of this year.

Ocular Therapeutix Begins Enrollment for Phase 3 Clinical Trial for Dextenza

Ocular Therapeutix announced enrollment of the first patients in a phase 3 clinical trial to evaluate the safety and efficacy of Dextenza (sustained-release dexamethasone, 0.4 mg) for the treatment of allergic conjunctivitis, according to a company news release. Dextenza is administered by a physician as a bio-resorbable intracanalicular depot for drug release to the ocular surface for up to 30 days.

This prospective, multicenter, 1:1 randomized, parallel-arm, double-masked, vehicle-controlled study based in the United States is enrolling subjects who exhibit chronic signs and symptoms of allergic conjunctivitis. This is the first of two phase 3 studies, and it will evaluate Dextenza versus a placebo vehicle punctal plug using Ora's modified Conjunctival Allergen Challenge (Ora-CAC) model, which accounts for the longer therapeutic effect of a sustained-release drug product administered one time. The study is designed to assess the effect of Dextenza compared with placebo on allergic reactions using three series of successive allergen challenges over a 30-day period. Dextenza or placebo will be administered 48 to 72 hours after final confirmatory exposure to the allergen, and the primary endpoints to be evaluated are ocular itching and conjunctival redness 7 days after insertion. The secondary efficacy measures for both itching and redness will be assessed 14 days after insertion and on days 27 to 30 after insertion.

"When my patients are experiencing more frequent or more severe symptoms, I often consider a steroid since they block most mediators of inflammation and work effectively in the acute phase of allergic conjunctivitis," Carolyn Repke, MD, principal investigator at Philadelphia Eye Associates and first enroller in the study, said in the news release. "With Dextenza, I will be

able to offer my patients enduring relief against these symptoms with one-time administration and a release profile that avoids the peaks and valleys associated with topical dosing."

Allergan to Acquire Aesthetic Drug Maker for \$2.1 Billion

Allergan and Kythera Biopharmaceuticals, a company focused on the discovery, development, and commercialization of novel prescription products for the aesthetic medicine market, announced that they have entered into a definitive agreement under which Allergan has agreed to acquire Kythera in a cash and equity transaction valued at \$75 per Kythera share, or approximately \$2.1 billion, subject to the fulfillment of certain customary conditions summarized hereafter, according to a company news release.

The fixed-value transaction consideration will be payable as 80% in cash and 20% in new Allergan shares issued to Kythera shareholders. Allergan's 2015 earnings-per-share forecast provided on May 11, 2015, is unchanged as a result of the acquisition, which is expected to break even in 2016 and accretive thereafter. The company remains committed to de-levering to below 3.5x debt to adjusted earnings before interest, taxes, depreciation, and amortization by the end of the first quarter of 2016.

The acquisition of Kythera immediately enhances Allergan's global facial aesthetics portfolio, which includes Botox, Juvederm XC, Juvederm Voluma XC, Latisse, and Skinmedica, with the addition of Kybella (deoxycholic acid) injection. Kybella is reportedly the first and only FDA-approved nonsurgical treatment for contouring moderate to severe submental fullness, commonly referred to as *double chin*, according to Allergan. Kybella injection is also being developed for potential introduction into international markets; Kythera has submitted Kybella injection for regulatory approval in Switzerland, Canada, and Australia, with other market applications to follow. The acquisition will also add Kythera's development product setipiprant (KYTH-105), a novel compound for the prevention of male pattern baldness, as well as other candidates in the early stages of development.

Alcon Receives European Approval for New Trifocal IOL

Alcon has received CE Mark approval in Europe for its AcrySof IQ PanOptix trifocal IOL, according to a company news release (product not available in the United States). The IOL is indicated for adult patients with and without presbyopia undergoing cataract surgery who desire near, intermediate, and distance vision with increased spectacle independence.

"Today's patients undergoing cataract surgery are more likely to seek vision correction options to address various lifestyle tasks such as reading books, using electronic tablets, working on computers, and performing outdoor activities without the

need for glasses or contact lenses,” Richard Packard, MD, FRCS, FRCOphth, director and senior ophthalmologist, Arnott Eye Associates, London, United Kingdom, said in the news release. “The AcrySof IQ PanOptix trifocal IOL is an important option that should provide these patients with a full range of vision and thus significantly reduced dependence on glasses.”

CDC Report: Severe Vision Loss Linked to Poverty, Southern Geography

Rates of severe vision loss (SVL) are linked to poverty rates and a southern geographic location, according to a *Morbidity and Mortality Weekly Report* issued by the US Centers for Disease Control and Prevention (CDC).¹

The CDC analyzed data from the American Community Survey to estimate the prevalence of SVL on the county level. Patients who were blind or had serious difficulty seeing even while wearing glasses were considered to have SVL. Among counties in the highest quartile of SVL prevalence ($\geq 4.2\%$), 77.3% were located in the South; 11.7%, 10.7%, and 0.3% were in the West, Midwest, and Northeast, respectively.

Researchers also found a link between poverty and the prevalence of SVL. Among counties in the top quartile of percentage of population living below the poverty line, 74.5% were in the South; 13.1%, 11.5%, and 0.9% were located in the Midwest, West, and Northeast, respectively.

Researchers identified 437 counties in the top quartiles for both SVL and percentage of those living below the poverty line, 83.1% of which were in the South, followed by 9.1% in the West and 7.8% in the Midwest. No county in the top quartile for both SVL and percentage of those living below the poverty line was in the Northeast.

1. Kirtland KA, Baaddine JB, Geiss LS, et al; US Centers for Disease Control and Prevention. Geographic disparity of severe vision loss: United States, 2009–2013. *Morb Mortal Wkly Rep*. 2015;64:514–517.

QLT to Acquire InSite Vision in All-Stock Deal

QLT has signed a definitive agreement to buy InSite Vision for \$0.178 per share in an all-stock deal. QLT says the merger will create a diversified, pure-play, late-stage ophthalmic pharmaceutical company well equipped to advance QLT’s existing phase 3–ready retinoid program and the multiple additional late-stage assets acquired in the deal, according to a company news release.

Under the deal, InSite Vision shareholders will receive 0.048 common shares of QLT for each common share of InSite Vision they own, which equates to a value of \$0.178 per InSite Vision share based on QLT’s closing share price of \$3.71 on June 5, 2015.

The newly formed company will be incorporated in Canada and led by a combined InSite Vision and QLT

leadership team. With operations in Alameda, California, and Vancouver, British Columbia, and headquarters in Vancouver, the new company will retain the name of QLT and will continue to trade on NASDAQ under the ticker “QLTI” and on the Toronto Stock Exchange under the ticker “QLT.”

InSite Vision said it plans to promptly file a new drug application later this week with the FDA for marketing approval of BromSite (0.075% bromfenac ophthalmic solution), which is indicated to reduce postoperative inflammation and prevent pain after cataract surgery. The company continues progression of a phase 3 clinical trial of QLT091001, QLT’s orphan drug and FDA fast-track designated retinoid product candidate for the treatment of inherited retinal diseases in the first half of 2016. The merged companies expect to file a second new drug application for InSite Vision’s DexamSite (0.1% dexamethasone) for the treatment of blepharitis in 2016.

The combined company expects to have approximately \$70 million in cash after the closing of the transaction and completion of other investments and dividends announced by QLT, all of which dividends will be effected after the completion of the merger and include distributions to prior InSite shareholders as new QLT shareholders.

Increased Calcium Consumption Linked to Prevalence of AMD

Patients who reported higher than usual supplementary calcium consumption were at higher risk of developing age-related macular degeneration (AMD), according to research published in *JAMA Ophthalmology*.¹

Researchers reviewed data from participants ($n = 3191$) in the 2007 to 2008 National Health and Nutrition Examination Survey. All participants were at least 40 years old. They were questioned regarding their use of dietary supplements and antacid consumption during the month prior to the interview and were evaluated for the presence or absence of AMD using fundus photography.

In total, 248 participants (7.8%) were diagnosed with AMD. The mean age of those with AMD was 67.2 years; that of those without AMD was 55.8 years. Investigators found that participants who reported consuming more than 800 mg per day of supplementary calcium had higher odds of an AMD diagnosis than those reporting less than 800 mg per day (odds ratio [OR], 1.85; 95% CI, 1.25–2.75). The association between higher calcium consumption and the presence of disease was stronger in older patients (OR, 2.63; 95% CI, 1.52–4.54), leading researchers to speculate that the association may be linked to the longer duration of calcium supplementation in this group.

The investigators wrote that “the findings [suggest] a threshold rather than a dose-response relationship.” ■

1. Kakigi CLM, Singh K, Wang SY, et al. Self-reported calcium supplementation and age-related macular degeneration [published online ahead of print April 9, 2015]. *JAMA Ophthalmol*. doi:10.1001/jamaophthalmol.2015.0514.