

# A Singularly Focused Company Blazes a Path

An industry consultant to Eyeonics predicts the market will grow in terms of the company's premium channel and the first and only FDA-approved accommodating IOL.

BY SARA E. SMITH, MANAGING EDITOR

The premium channel of lenses, which includes accommodating, multifocal, and toric IOLs, will experience growth similar to that of LASIK, according to Jim Largent, a former executive of Allergan, Inc. (Irvine, CA), and currently a consultant to ophthalmic medical device companies. Mr. Largent led the IOL industry coalition in the 1990s that produced the reimbursement regulations for advanced technology IOLs. As a consultant to Eyeonics, Inc. (Aliso Viejo, CA), he led the company's lobbying effort that resulted in the Centers for Medicare & Medicaid Services' (CMS) ruling that allows patients to pay out of pocket for IOLs that correct presbyopia. In an interview with *Cataract & Refractive Surgery Today*, Mr. Largent discussed the history of the premium channel of lenses as well as the current market, the development of the Crystalens (Eyeonics, Inc.), and the growth of Eyeonics.

## HISTORY AND FUTURE OF REFRACTIVE IOLs

The option for patients to pay privately for presbyopic treatments was first approved by the CMS in May 2005. Industry analysts estimated that presbyopia-correcting IOLs would penetrate 20% of the cataract surgery market within 3 years, according to Mr. Largent, who added that actual penetration is only estimated at 4% to 5% after 2 years.<sup>1</sup> Despite surgeons' and manufacturers' best efforts, the first generation of accommodating and multifocal lenses did not always deliver outcomes that thrilled patients. Disappointment in the actual postoperative results was amplified, because patients who pay out of pocket for the presbyopia-correcting technology have much higher expectations than those who undergo cataract surgery with a conventional IOL. Although some outcomes were quite good, enough patients were dissatisfied to cause the market to slow temporarily. Some patients placed such high demands on the

practices that offered presbyopia-correcting IOLs for higher levels of service and the best possible vision postoperatively that they overwhelmed these practices and disrupted their operations. Even though the market has not expanded as many had hoped, however, baby boomers remain unmatched in their purchasing power. The premium channel market will grow as surgeons and technologies improve to meet these individuals' demanding expectations, according to Mr. Largent.

By 2010, about 30% of Americans (approximately 80 million) will be over 55 years of age. The CMS will strain to cover the growing number of retirees. Roughly 46% of healthcare dollars, however, are currently spent on Medicare/Medicaid per year, according to Mr. Largent. Cataract procedures are the number-one reimbursed procedure within Medicare, so they will continue to have the attention of the CMS' budgetary managers. Mr. Largent predicted that, for cataract surgery with conventional IOLs, patients' options will be reduced and cataract surgeons' reimbursement will continue to decrease, a situation underscoring why premium lens procedures are an important option for their practices. Baby boomers have demonstrated a willingness to pay out of pocket for elective procedures as they strive to maintain an active lifestyle.<sup>2</sup> He explained that, during the fourth quarter of 2006, the FDA approved 10 medical devices, the majority of which were in the cosmetic sector.<sup>3</sup> This market is driven by what patients want, he says, and device manufacturers are targeting this population with rejuvenating technologies.

## THE CMS' RULING

Prior to the CMS' recent ruling, patients basically could not choose a premium lens, because, under the previous regulations, providers were not allowed to bill a patient extra for a covered service beyond the amount of the centers' reimbursement for that service. Furthermore, patients

## AN IMPOSSIBLE VISION REALIZED

**By John F. Doane, MD**

We ophthalmologists have been conditioned over the last 20 years to believe that our choice of a profession is devolving, principally because our reimbursement from third-party payers has been on a downswing. As I have mentioned multiple times to the readership of *Cataract & Refractive Surgery Today*, I believe that the US is now in the midst of a socialized-welfare death spiral. The desires of the recipients now far outweigh the contributions made by the taxpayers.

Fortunately for ophthalmology, 9 years ago, J. Andy Corley joined forces with Stuart Cumming, MD, to launch a small IOL company that would become Eyeonics, Inc. (Aliso Viejo, CA). The plan was to start clinical studies on Dr. Cumming's new lens and, if it proved effective, to convince the Centers for Medicare & Medicaid Services (CMS) to allow physicians to charge extra for the implantation of the accommodating IOL. Andy maintained that this strategy would return control of cataract surgery to the surgeon. Just about everyone he shared his plan with wished him well but thought he was a dreamer. When was the last time the CMS made a change that could be viewed as a positive for surgeons (or industry)?

As the CEO of Eyeonics, Andy showed he believed in his long-term strategy by insisting that the Crystalens stay outside the CMS' reimbursement system, thereby giving up the opportunity for the company's lens to be used for any Medicare patients. For a small start-up company, this was not a sensible path.

With the help of his local congressman and others, Andy convinced the CMS that Medicare beneficiaries should not be prevented from receiving presbyopia-correcting IOLs but that the CMS should not have to pay for these services as elective upgrades. He felt that patients should be allowed to access the technology by paying for it themselves.

On March 10, 2005, Andy's impossible vision became reality. The CMS began to allow patients to choose presbyopia-correcting IOLs over conventional IOLs. Earlier this year, the centers passed a similar policy in regard to toric IOLs.

Andy Corley's unwavering persistence and leadership have changed the face of cataract surgery, and we all owe him a great deal of gratitude.

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were not allowed to pay extra, even if they were willing and able to do so. "If a patient opted for a premium-channel IOL, they had to leave the Medicare system entirely for 2 years," Mr. Largent said. "That patient had to find a surgeon who is not a Medicare provider because, if that provider agreed to accept the extra payment, he would be breaking the law and could lose his ability to participate as a provider. Finding an ophthalmologist who is not a Medicare provider is virtually impossible." Because the cost of the Crystalens was over \$650 more than the CMS' reimbursement allowed for an IOL, providers could not afford to use the product, and Medicare beneficiaries were blocked from accessing the technology.

In the case of accommodating and multifocal IOLs, a unique feature created a powerful argument for why the CMS should treat them differently. These premium IOLs have two indications—one that is covered by the CMS (cataract procedure) and one that is not (correction of presbyopia). The CMS' ruling allows surgeons to treat presbyopia privately, while allowing the patient's relationship with Medicare for covered services to remain undisturbed. In essence, the CMS still pays the same amount for the covered service (ie, the cataract), and patients are responsible for the additional charges related to correcting their presbyopia.

The people who truly understand the value of modern-day cataract removal are the patients, according to Mr. Largent. During the last 20 years, they were completely removed from the value proposition. "Prior to CMS' ruling, we only had one buyer—Medicare—and they ultimately set the pricing for not only Medicare recipients, but all patients, since private insurers pretty much followed the Medicare standard," Mr. Largent commented. "You had one buyer making all the rules, and their focus was to reduce their costs because of pressures that the Medicare budget faced as the numbers of beneficiaries grew and the array of available treatments and technologies grew. Medicare got to name the price, which was not going to increase, no matter how much the procedure and associated technologies improved." He explained that the saving grace of the CMS' decision was that the value proposition was returned to the patient. Surgeons benefit, because they may now charge the market rate for their presbyopia-correcting services.

"Industry is again invigorated with numerous new technologies targeting the baby boomer population," Mr. Largent added. "Venture capital is again flowing into IOL development, something that had completely stopped during the 1990s."

According to Mr. Largent, the two individuals who were

instrumental in achieving the CMS' ruling were Chris Cox, the 28<sup>th</sup> Chairman of the Securities and Exchange Commission and formerly California's Congressman in Eyeonics' district, and Leslie Norwalk, Esq, the Deputy Administrator for the CMS. "Chris Cox is the gentleman that fought the battle and is ophthalmology's best friend," he said. "Leslie Norwalk was the government official that recognized the logic of providing Medicare beneficiaries with the same rights to access the new technology as those patients who are under 65 years old. She championed the policy change within [the] CMS and got the new policy issued."

### THE PREMIUM LENS MARKET

In this market, patients expect the highest possible quality of vision postoperatively. Ultimately, surgeons are more likely to offer the lenses that deliver the best outcomes, and their usage will continue to grow.

In the premium segment, the recent inclusion of toric lenses under the CMS' policy allows patients to pay out of pocket for the new technology. Although fewer than 10% of cataract patients have 1.50 D of astigmatism or more, this segment still represents a large number of patients. According to Mr. Largent, one could expect that the CMS' new policy will increase patients' access to toric IOLs and will lead to the growth of this category of lenses.

Mr. Largent noted that, in the presbyopia-correcting IOL segment, multifocal lenses captured the largest share of the sector initially, and their use continues to grow. In the first quarter of 2007, Advanced Medical Optics, Inc. (Santa Ana, CA), and Alcon Laboratories, Inc. (Fort Worth, TX), both noted ongoing strong growth for their premium IOL products. The use of Advanced Medical Optics' refractive lenses grew by 25.3%.<sup>4</sup> The utilization of Alcon's Acrysof Restor and Acrysof Toric lenses grew by 19.1%.<sup>5</sup>

The race between multifocal IOLs and accommodating IOLs is not over, Mr. Largent stated. The Crystalens' popularity is growing rapidly and will capture a greater share of the presbyopic segment from the multifocal products. According to a company press release, Eyeonics' first-quarter sales for this year were up 45%.

### THE CRYSTALENS AND EYEONICS

Eyeonics' strong growth in 2007 was spurred by the recent introduction of its third-generation accommodative IOL, the Crystalens Five-O. Mr. Largent said this model is a further improvement on the previous model (45SE). The Crystalens Five-O has a 5-mm optic and improved refractive predictability. Surgeons' ability to hit their refractive target more reliably has enhanced the near vision patients have achieved postoperatively.

The Crystalens' growing popularity also reflects the changing competition and marketing dynamics of the pres-

byopic segment. Following the CMS' ruling, Alcon and Advanced Medical Optics captured the greatest share of this category. With much larger sales forces than that of Eyeonics, these two companies used their reputations as the established market leaders to strengthen the image of their multifocal technologies. These products were the first lenses approved to treat presbyopia and had a long clinical track record. Conversely, these companies positioned the Crystalens as new technology, thus reinforcing natural questions that surgeons had about how the lens would perform in the long term. "With fewer sales representatives and a new technology, Eyeonics' ability to penetrate the market was slowed. Surgeons understandably opted to use the older technologies and wait until the Crystalens had a longer clinical track record to prove that patients would be happy and that there wouldn't be 'surprises' that caused unhappy patients," Mr. Largent said.

Time has given the market more experience with the accommodating IOL. This experience combined with the introduction of the Crystalens Five-O are now encouraging more surgeons to adopt the Crystalens as either their presbyopia-correcting lens of choice or at least as an option, according to Mr. Largent.

Mr. Largent concluded that which ever technology wins the race to control the presbyopic market will ultimately be determined by the outcomes that patients and their surgeons achieve. Ophthalmologists can expect that the three current players will continue to develop innovative technologies and improve their products. Additionally, new companies are likely to enter the market with their own designs. As clinicians gain experience and designs are improved, the market for presbyopia-correcting IOLs will continue to grow, and this expansion should accelerate as surgeons become increasingly confident about recommending these technologies to their patients. The new reimbursement policy allows patients to decide how they value the available technologies and their associated outcomes. "In the end, patients, physicians, and the companies will all benefit from the new technologies that deliver on the promise of the best quality of vision," Mr. Largent said. ■

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