

## UK Ophthalmologists Object to Government Efforts to Privatise Care

The British Royal College of Ophthalmology (RCO) is continuing a campaign against the outsourcing of cataract surgery to private treatment centres. At the end of 2005, there were 80 Independent-Sector Treatment Centres in operation in the United Kingdom, with more than 223,000 patients having been treated since the start of the program in 2003, according to British government figures.

The treatment centres were started by the British government as a way of reducing waiting lists for medical treatment in the United Kingdom. The government targeted reduced waiting lists to a maximum of 6 months by the end of 2005. The target is 18 weeks by 2008. The treatment centres are run either by the National Health Service (NHS) or can be commissioned by primary care trusts from private-sector health care providers. Primary care trusts are local government authorities that operate the hospital system in a particular area.

In the case of cataract surgery, the British Department of Health claims the waiting time for cataract surgery has been reduced to 3 months since the introduction of a mobile chain of cataract treatment centres, as well as one fixed centre.

All well and good, according to RCO President, Nick Astbury, FRCS, FRCOphth, FRCP, but the group believes that the government should be putting emphasis and investment into the existing NHS ophthalmology departments. The RCO is also not happy with government

claims that the independent centres are the reason patients now only wait 3 months before having cataract surgery.

"I must take issue with your statement that treatment centres have reduced cataract waiting times from 3 years to 3 months," Mr. Astbury wrote in a letter to Patricia Hewitt, the UK secretary of health. "It is simply not true and gives no credit to the staff in the eye departments around the country." According to the RCO, in the time that 10,000 cataract operations were carried out in the private centres, surgeons at public hospitals performed 400,000 operations. The cataract operations were carried out in addition to the surgeons performing other types of ophthalmic surgery and training residents, said Mr. Astbury.

"The college is all for shorter waiting times, but there have been concerns raised over issues of patient safety, continuity of care, impact on training and the viability of local units that have been impacted by the treatment centres," said Mr. Astbury.

On its Web site, the Department of Health states: "Treatment centres have already made a positive contribution to patients, having reduced waiting times for thousands of patients with painful and debilitating conditions. This success has been achieved by increasing the number of spaces available for surgery outside of the emergency setting, making the treatment more efficient and convenient, while maintaining high levels of care."

## British Parliament Looks to Regulate Refractive Laser Surgery

The British House of Commons intends to place greater regulation on laser refractive surgery and the ophthalmologists who perform the procedures.

A bill that will be considered this year would require refractive surgeons to be registered and institutes a cool-

ing-off period between when a patient consents to have surgery and when he or she undergoes it. Anyone performing laser refractive surgery without being registered could face penalties and fines.

The proposed regulation stems from a series of hearings held by a House committee, as well as negative media coverage about laser refractive surgery in the United Kingdom.

If approved sometime later this year, the RCO would be required to develop and maintain the registration list,

along with providing training for ophthalmologists and guidance documents for patients, optometrists and referring general practitioners.

In a statement issued following the first reading, Mr. Astbury said the group welcomes the interest shown by Parliament, but noted that the General Medical Council has responsibility of regulating the medical profession.

"Our role is to uphold the professional standards in ophthalmology. The Modernising Medical Careers initiative has required a review of all specialist training beginning in 2007," stated Mr. Astbury. "We have taken the review as an opportunity to expand the proposed Ophthalmic Specialists Training curriculum to include elements of refractive surgery." The RCO is also developing a stand-alone test on refractive surgery.

The bill is scheduled for consideration in May.

## Tekia Receives CE Mark for Accommodating IOL for Presbyopia

Tekia Inc (Irvine, California) has received a CE Mark approval from the European Union for its accommodating IOL. The accommodating IOL is for the treatment of presbyopia.

"The artificial lens is designed to utilize the eye's ocular structures to shift the lens forward, enabling a person to see close up, and then shift back to the resting position so the person will see distant objects," said Gene Currie, president and COO of Tekia, in a news release. "The lens could be used during cataract surgery to restore near vision and at the same time correct for other visual disorders, such as farsightedness. It could also be used in precataract patients with presbyopia to restore near and intermediate vision, replacing corrective glasses or contact lenses."

William C. Huddleston, CEO and CFO of Tekia, said: "Later in 2006, the company expects to submit to the US Food and Drug Administration [FDA] an investigational device exemption for the accommodating IOL to initiate clinical studies in the United States as the first step in obtaining FDA approval. The FDA approval process is costly. The company expects to pursue financing options and/or a strategic partner to provide additional resources for this important step in our development."

Tekia currently distributes its Kelman Duet Refractive

IOL in the EU and some South American countries. The Kelman Duet IOL was codeveloped by Tekia and Charles D. Kelman, MD, and is designed for the treatment of myopia and hyperopia in noncataract patients.

## WaveLight Broadens Ophthalmic Portfolio

On the heels of the merger between Visx Inc (Santa Clara, California) and Advanced Medical Optics Inc (AMO; Santa Ana, California), another ophthalmic company is working to deepen its product portfolio. Wavelight Laser Technologie AG (Erlangen, Germany) announced plans toward the end of last year to acquire AcriMed GmbH (Berlin), as well as a 30% stake in Medical Device Production BV (MDP), (Eerbeek, Netherlands).

The move signals Wavelight's plans to offer a more comprehensive ophthalmic product line. Wavelight currently offers a wide range of lasers and diagnostic equipment for refractive surgery. With the acquisition of Acrimed and the interest in MPD, Wavelight's product portfolio will include silicone, polymethylmethacrylate and acrylic IOLs; capsular tension rings; viscoelastics; surgical instruments, insertion devices and knives; and vitreoretinal products.

Acrimed is a family-owned company founded in 1995 by Dr. Frank Klemm that employs 24 people at its Berlin facility. MDP was founded in 1974 and employs 15 people at its facility in the Netherlands.

In a news release announcing the deals, the company said: "The acquisition of Acrimed and the investment in MDP are an important precondition for rapid entry into the cataract surgery market. With it, Wavelight is systematically expanding its recently launched Intraocular Surgery Business Unit."

The total cost of the two deals is €5.2 million.

In addition to ophthalmology, Wavelight develops and manufactures laser systems for aesthetic surgery, urology and industrial applications.

## AMO Awarded \$213.9 Million USD in Infringement Case

Late last year a US District Court judge upheld a jury decision and awarded AMO \$213.9 million USD in damages resulting from willful infringement by Alcon

Manufacturing Ltd (Fort Worth, Texas).

According to an AMO news release, the two patents that Alcon was found guilty of infringing upon were for phacoemulsification equipment. The judge in US District Court for the District of Delaware concluded that "the jury was presented with clear and convincing evidence that Alcon intentionally copied" the occlusion mode and the fluidics system from AMO's Sovereign machine.

The complaint was originally filed in US District Court on Dec. 3, 2003.

Alcon shares dropped more than 5% following the statement that the manufacturer would book the charge in the fourth quarter of 2005. Alcon said it would appeal the judgment, however it was still required to record a charge for the entire amount.

The judge granted a permanent injunction against Alcon prohibiting the company from selling equipment that infringed on the AMO patents. The injunction has been stayed pending an appeal, according to Alcon.

## Pfizer Exercises Option on New-technology Drug Compound

Pharmaceutical manufacturer Pfizer (New York) has announced plans to move ahead with development of a novel compound that apparently makes drugs more effective. The company announced at year-end plans to exercise an option to acquire an exclusive worldwide license to nitric oxide-donating compounds developed by a French company, NicOx (Sophia Antipolis). As part of the agreement, Pfizer has paid NicOx €2 million.

NicOx creates patentable new compounds by taking an existing drug and grafting a nitric oxide-donating molecule. According to the company's Web site, nitric oxide plays a critical role in a number of biochemical processes in the human body, such as acting as a messenger molecule and regulating certain cellular processes.

Pfizer and NicOx were jointly responsible for this research project, in which a number of nitric oxide-donating compounds were synthesized and submitted to an extensive series of preclinical tests. Several com-

pounds successfully fulfilled a number of key criteria and demonstrated superior activity, compared with reference compounds, in established in vivo eye disease models. Pfizer has selected a candidate compound and will now be responsible for the remaining development of this compound.

The research, option, development and licensing agreement between Pfizer and NicOx was signed in August 2004 and granted Pfizer an option to acquire a worldwide license to the nitric oxide-donating compounds under study, with exclusive development and commercialization rights. Including the recently announced payment, NicOx will have received €4 million from Pfizer in connection with this agreement and stands to receive a further €33 million, plus royalties, if the collaboration results in the successful commercial development of a product.

Neither company has indicated for what treatment area the new compound is intended, but Pfizer currently markets xalatan (Latanoprost) for glaucoma and Visine, a product line for dry eyes, in Europe.

## Ista Seeks European Marketing Approval for Vitragan

The European Medicines Evaluations Agency (EMA) has accepted for review an application from Ista Pharmaceuticals Inc (Irvine, California) seeking European market approval of ovine hyaluronidase (Vitragan) for the treatment of vitreous hemorrhage.

Vitragan is known in the United States as Vitrase. "Vitreous hemorrhage is a serious and debilitating eye condition that delays the diagnosis and treatment of the underlying problem, and, if left unchecked, can lead to blindness," stated Vicente Anido Jr, PhD, president and CEO, in a news release.

"ISTA has accumulated a wealth of clinical data demonstrating that Vitrase can have a meaningful impact on reducing hemorrhage density and improving [BCVA] after only a single dose of treatment," he continued.

"Based on a recent notification from the EMA, we expect that the review process will most likely result in a decision by the first half of 2007." ■