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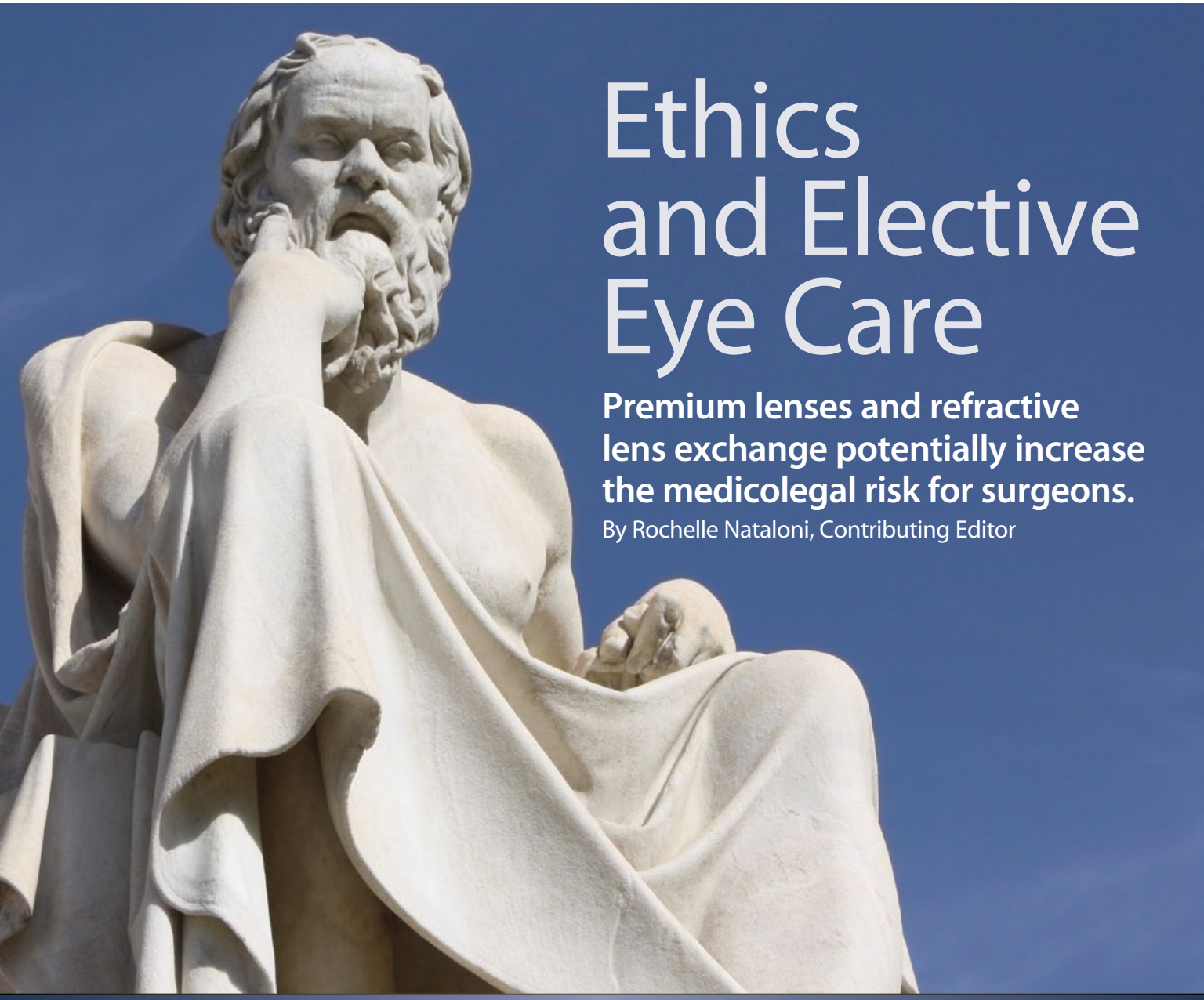

Ethics and Elective Eye Care

Premium lenses and refractive lens exchange potentially increase the medicolegal risk for surgeons.

By Rochelle Nataloni, Contributing Editor

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Premium Practice Today is a monthly feature section in **CRST** providing articles and resources to assist surgeons and their staff in the pursuit of premium practice development to facilitate exceptional experiences for patients and business success.

Ethics and Elective Eye Care

Premium lenses and refractive lens exchange potentially increase the medicolegal risk for surgeons.

BY ROCHELLE NATALONI, CONTRIBUTING EDITOR

Physicians are under attack. In the past months, several articles have appeared in The New York Times *decrying the compensation of dermatologists in one and ophthalmologists in the other; the spotlight being placed on specialty physicians is unlikely to disappear anytime soon.*

This month's timely topic deals with the ethics of self-pay health care in the context of premium implants. Ideally, there would be no ethical dilemma facing physicians. The "three Cs" that govern the doctor-patient relationship: choice, communication, and confidence (in the surgeon's recommendation), would be the foundation of the discussion and lead to the right decision being made. As we have seen in recent press, however, there are bad actors among surgeons including ophthalmologists, one of whom has notoriously billed Medicare nearly $21 million in 2012 … after being found to have overbilled by nearly $9 million in 2009. Clearly, we have a problem here. Although the law will eventually catch up with such behavior, no law can dictate common sense.

Drs. Zacks and Hovanesian provide enlightened commentary that reminds us what side of the line all surgeons need to stand on when it comes to patient care. Whether the service is reimbursed or elective is not the core issue. "Patient first" is the mantra that must dictate regardless of who is paying the bill. As we have already seen, the trend is and will continue to shift more of the financial burden to the patient. At some point, it will make sense for patients to pay directly for nearly all services via self- or secondary insurance beyond what the Affordable Care Act will cover. Other nations such as Australia who have gone to a two-tier system are finding that 40% of the population participates in this "above-and-beyond" system where they are responsible for their own care. My only question is, what's taking us so long?

—Section Editor Shareef Mahdavi

Premium IOLs and laser cataract surgery, as well as other elective and semielective advances, provide additional benefits to patients but also additional costs. For the surgeon, these developments offer the opportunity to better satisfy patients and grow his or her practice, but they also pose unique challenges that can blur the ethical boundaries that were once clearly etched.

Charles M. Zacks, MD, a member of the American Academy of Ophthalmology's Ethics Committee from 1994 to 2010, points out a problem with wording. He explains, "The term 'premium lens' is very well established, but from an ethics point of view, it already assigns a value to these lenses that may or may not apply for an individual patient. *Premium* is defined as 'of exceptional quality or greater value than others of its kind; of higher price or cost.' It is a commercial term, not a medical one. It would be more objective to refer to these lenses as *special purpose, specialty, or noncovered* to avoid the impression that we are indiscriminately selling this technology." Dr. Zacks is a partner at Maine Eye Center in Portland and specializes in cornea and external disease with a special interest in corneal transplantation surgery.

PATIENTS COME FIRST

When using special purpose implants, Dr. Zacks says it is important to remember that the patient's needs come first. "Special purpose implants are not for every patient," he emphasizes. "We need to avoid using spin to convert patients who might otherwise appropriately use a conventional implant. As for any treatment recommendation, [a] proposal of noncovered lenses should be made primarily with each individual patient's best interests and preferences in mind—not the interests of the surgeon. With additional IOL options, the advantages and disadvantages of each IOL choice for that patient must be considered."

"An example of an ethical dilemma unique to noncovered lenses is a patient with significant myopic astigmatism who might seem a 'good candidate' for a toric IOL, but the patient expresses no interest in avoiding glasses, even stating, 'I understand what it (the toric lens)

can do, but I've always worn glasses; people would not recognize me without them,'" Dr. Zacks notes. "Even the surgeon's strong impression that the patient 'should' have a toric lens—because it's in his 'best interest'—should not result in any coercion or biased discussion to change the patient's informed decision. This would violate the patient's autonomy to make his [or her] own choices."

Some say that offering specialty or premium IOLs and laser cataract surgery complicates the informed consent process. Dr. Zacks explains that the essentials of the process remain the same. "The patient is entitled to receive objective, unbiased information and disclosures regarding the rationale, risks, benefits, and alternatives for the proposed surgery, including the option of continued observation and its consequences," he says. "Additional disclosures relating to the 'premium' IOL generally include a higher risk of secondary procedures such as correcting an off-axis toric lens or surgery to correct biometry errors with a multifocal lens as well as side effects unique to the lens itself such as glare and decreased contrast sensitivity of multifocals. Disclosures of the additional fees over use of conventional lenses and what they include should be disclosed, and if comanagement is proposed with another provider, the possibility of incurring charges that are not covered by insurance that might not otherwise be charged should also be included in the consent process."

Refractive cataract surgeon John Hovanesian of Harvard Eye Associates, Laguna Beach, California, says that, although the ethics should remain the same whether one is recommending a premium lens or a conventional lens—or any other medical treatment or service—the issue will rear its head increasingly as patient-shared responsibility expands. "We faced this more than 10 years ago when the presbyopia-correcting lenses came on the market, and we faced it in 2005 when Centers for Medicare & Medicaid Services [CMS] ruled that presbyopia-correcting lenses are a patient-shared expense, and we are facing it more and more with so many new technologies. Ultimately, we physicians are in a tough position, because we have to decide whether a costly upgrade or a costly new treatment is in the patient's best interest."

Dr. Hovanesian adds, "It's very easy to feel comfortable recommending an expensive treatment to a patient if some faceless third party is footing the bill, but increasingly, we are seeing services that are paid for out of the patient's pocket. Honestly, the ethics are the same because it really should not matter who is paying for the service. However, we are face to face with the patients to whom we have to explain the charge and whose lives are affected by the cost when we recommend something that's self pay, and that makes the ethics of the decision a little more poignant."

Although the ethics remain the same, Dr. Hovanesian concedes that the lines appear to be somewhat blurred with respect to elective upgrades. "We all want to do the right thing for the patient, but our practices depend upon seeing and treating a certain volume of patients, and so there is inherently a conflict of interest," he acknowledges. "How much profit there is depends upon how [the practices] charge and what their costs are. There certainly is more being offered to the patient and more being paid to the practice. Whether it's real or not, there's a perception of increased benefit to the practice."

Part of behaving ethically in the patient-pay arena means being clear about what a patient wants and what a patient needs "That means not giving a patient who has no visual potential an expensive lens option," says Dr. Hovanesian. "Part of it is how we present it to the patient. It's OK to make value judgments and say, for example, with presbyopia-correcting lenses, that this is a better treatment, but it's not OK to say that, if you choose a conventional lens, that you are opting for inferior care." He adds, whether it is a new diagnostic technique or a new surgical procedure, unless there is clear evidence that a patient is short-changing him- or herself by opting for the traditional instead of the advanced offering, he would feel unethical saying, "This is better for your eye; this is better for your health."

DO NO HARM

It is frequently said that patients are savvier than ever because of online access to medical information. Dr. Hovanesian points out, however, that no matter how sophisticated their knowledge base is, "patients trust us to make the best recommendation for them. We know so much more about the treatments we offer than our patients do, so they are in no position to question us if we tell them that the safer, better treatment is what they have to do. We have to wield that power with great care so that we don't cheapen the practice of medicine and make it into something like selling a used car."

Dr. Zacks adds, "If you are practicing with these specialty lenses or in a cataract practice in general, you should clearly understand the delegation of services and comanagement. Appropriate fee arrangements, in particular, should be tracked. Both good professional ethics and [the] law require that fees paid must be commensurate with services actually provided and must not include any consideration (financial

ETHICAL CONSIDERATIONS WITH PREMIUM IOLs

Charles M. Zacks, MD, former long-time member of the American Academy of Ophthalmology's Ethics Committee, addresses ethical considerations regarding specialty IOLs.

What new ethical challenges do premium IOLs present to surgeons with respect to recommending the appropriate lens for a given patient?

- The need for more complex and comprehensive disclosures
- Extra time to provide a careful description of the pros and cons of each choice
- Avoidance of bias or nonobjective discussion intended to coerce or inappropriately direct a patient's decision
- Disclosure of more complex financial arrangements, including what is covered in the additional fees and what is not

How can a surgeon avoid bias when recommending a specialty lens?

- Stay objective.
- Remain scrupulously factual about pros and cons, risks, side effects, and benefits.
- Exercise self-restraint against a "sales job." Every surgeon should know when he or she is "selling."
- Remember that, as surgeons, we are almost, but not completely, in control of outcomes. An unhappy postoperative patient who felt he or she was coerced to pay more could become a significant liability.
- Your good reputation for patient care is more important than booking one more specialty lens that day.

Why is it important to distinguish between side effects and potential complications when explaining specialty IOL options?

- A complication is something that could happen if something goes wrong (eg, vitreous loss).
- A side effect is something that will happen, even if everything goes right (eg, glare with a multifocal lens).
- If a patient confuses the two, he or she may be left with the impression that a side effect will not happen to him or her and be disappointed or angry when it does.

How can a practice ensure that advertising/marketing remains fair and not economically motivated?

- Information and claims in communications to the public should be objective and free of false, deceptive, or misleading statements, which can include significant omissions as well as express claims.
- Avoid claims that either appeal to patients' anxiety or lead a reasonable reader to form unrealistic expectations.
- Claims regarding surgeons' credentials must be truthful and must not contain claims of superiority that cannot be substantiated.

Suggested Reading
American Academy of Ophthalmology. AAO Code of Ethics. http://www.aao.org/about/ethics/code_ethics.cfm. Accessed April 8, 2014.
Silverman J. Should doctors change the Hippocratic oath? Discovery Health. http://health.howstuffworks.com/medicine/healthcare-providers/hippocratic-oath1.htm. Accessed April 10, 2014.
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or nonfinancial) as an inducement for referrals. Keeping records of any exchange of fees and the services they cover would be essential to defending an allegation of improper comanagement relationships or kickback arrangements."

Cataract surgery is the most frequently performed ophthalmic procedure in the United States and the source of the majority of medical malpractice claims reported to Ophthalmic Mutual Insurance Company. The addition of premium lenses and refractive lens exchange (RLE) potentially increases the medicolegal risk for surgeons, and sources say this warrants heightened attention to the informed consent process. Adhering to strict informed consent rules and following through on careful chart documentation can help. A sample informed consent form for RLE containing the minimum information that the surgeon should personally disclose to the patient has been developed by Ophthalmic Mutual Insurance Company and is accessible here: www.omic.com/refractive-lens-exchange-consent-form.

With RLE, the beneficiary is responsible for the charge that exceeds that of a conventional IOL. Patients should be given the Notice of Exclusion from Medicare Benefits and should know that CMS will only pay for one pair of glasses or contact lenses if needed after the implantation of a presbyopia-correcting IOL. The patient should also be informed that, if the lens needs to be removed due to complications, CMS will cover the insertion of a conventional IOL as a replacement and that private insurance may or may not cover costs associated with an RLE. ■

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Suggested Reading
Centers for Medicare & Medicaid Services. Notice of Exclusion from Medicare benefits. www.cms.hhs.gov. Accessed April 8, 2014.
Chang D. Presbyopia-correcting intraocular lenses: everyday ethical issues. In: Hovanesian J, ed. *Premium Cataract Surgery: A Step-by-Step Guide*. Thorofare, NJ: Slack; 2012.
Zacks C. Informed consent for multifocal and accommodative intraocular lenses. In, Chang D, ed. *Mastering Refractive IOLs – The Art and Science*. Thorofare, NJ: Slack; 2008.