Within the last year, industry groups such as the Advanced Medical Technology Association (AdvaMed) and the Pharmaceutical Research and Manufacturers of America (PhRMA) have dramatically overhauled their codes of ethics. The Academy also is engaged in a comprehensive review of appropriate relationships between ophthalmologists and industry. This activity reflects the stark reality that the old rules covering physician-industry relationships are no longer acceptable to the public, to the government . . . even to the profession itself.

“All ophthalmologists—residents and those in practice, academicians and those in the clinic—should familiarize themselves with these codes of conduct. They constitute the new ‘rules of the road’ governing professional relationships in the office, at meetings and in consulting relationships,” said David W. Parke II, MD, executive vice president and CEO of the Academy.

Lessons Learned From Orthopedists

The Academy’s Ethics Committee chairman, Charles M. Zacks, MD, states that physicians may come under renewed scrutiny, and he’s not exaggerating. He pointed to recent events in the orthopedic field as a cautionary tale of how the physician-industry relationship can cross ethical boundaries. In a federal investigation that began in 2005 and was closely covered by The New York Times, the five leading manufacturers of artificial joints paid hundreds of millions of dollars in penalties in 2007 to settle federal charges that they used kickback payments and fake consulting agreements to persuade surgeons to use their products.

But the story does not stop there. According to The New York Times, at the 2008 annual meeting of the American Academy of Orthopedic Surgeons, hundreds of doctors heard some words of warning from Lewis Morris, Esq., the chief counsel at the Department of Health & Human Services’ Office of Inspector General (the office that pursues civil
complaints of Medicare fraud). He said that the government would next turn its focus on physicians who solicit kickbacks. While the five investigated companies were required by the U.S. Department of Justice to create disclosures lists, they did not distinguish potentially questionable kickback deals from legitimate research grants and licensing agreements. The American Academy of Orthopedic Surgeons has called on the companies to provide a detailed breakdown of payments made to surgeons to help clear up any suspicions.

This dramatic and well-publicized investigation has played a part in the reintroduction of legislation that would require device and drug makers to report all financial links with physicians on a federal Web site. In the Senate, this bill is known as the Physician Payments Sunshine Act, and a parallel effort is under way in the House of Representatives.

These developments over the last few years, combined with a variety of other political and economic factors, have led the industry and physicians to become proactive—taking the initiative to regulate themselves before the government or other outside forces step in. “Physicians are realizing that the status quo is not good for patients nor is it good for their own interests in the long run,” Dr. Zacks said.

He also noted that for many years, the Academy has developed and maintained its comprehensive Code of Ethics, which encompasses issues relating to appropriate management of conflict of interest. The Academy also realizes that physician cooperation with industry is absolutely essential. “We need them and they need us—especially in a field like ophthalmology,” Dr. Zacks said. “We depend on sophisticated devices and new drugs, and these cannot be developed without physician input.”

PhRMA Guidelines
PhRMA was the first industry organization out of the gate with revised guidelines. Its latest Code on Interactions with Healthcare Professionals was introduced in July 2008 and went into effect in January 2009. “We always have been firmly committed to ethics,” said Diane E. Bieri, JD, PhRMA executive vice president and general counsel. “We had our last revision of the code in 2002. After six years, it was time to look at the code again with fresh eyes to enhance the provisions that address the current interactions between physicians and industry.”

The organization asked companies to publicly sign the code, and, as of April, more than 47 companies had done so. Some of the changes include:

• Prohibits distribution of noneducational items such as pens and mugs adorned with a company or product logo.

• Prohibits company sales representatives from inviting health care professionals to restaurants but allows reps to provide occasional meals in health care professionals’ offices in conjunction with informational presentations.

Other additions to the code include more detailed standards regarding the independence of continuing medical education, principles on the responsible use of nonpatient identified prescriber data and additional guidance for speaking and consulting arrangements with health care professionals. The full code is available by selecting the “PhRMA Code” box at www.phrma.org.

AdvaMed Guidelines
The board of directors of AdvaMed on Dec. 18, 2008, unanimously approved a major update of its Code of Ethics on Interactions with Health Care Professionals. The revisions will go into effect July 1 of this year. “The revised code represents the product of a comprehensive review and expansion of the industry’s existing code,” said Christopher L. White, JD, AdvaMed executive vice president and general counsel. “We brought together 80 lawyers from member companies, including those involved in ophthalmic equipment and medical devices.”

Mr. White said the revisions were made in response to new business practices and types of collaboration driven by the very rapid advancement in technology. “Because of the highly interactive nature of devices and the advances in technology produced by collaborative exchange between physicians and industry, it is necessary to preserve the beneficial industry-physician relationships,” Mr. White said. “Our code of ethics distinguishes those beneficial relationships that foster collaboration and innovation from improper marketing tactics.”

Mr. White said AdvaMed’s revised code expands into several new areas, including:

• Guidelines that allow for companies to enter into royalty arrangements with health care professionals in exchange for substantial contribu-
tions that improve medical technologies.

• A new section titled Evaluation and Demonstration Products that sets forth appropriate parameters under which companies may provide products intended to educate both health care professionals and patients on newer or improved medical technologies.

The code also provides greater clarity and rigor in areas such as consulting agreements, company-conducted training and education for health care professionals, and research and educational grants. The AdvaMed code of ethics can be found at www.advamed.org/MemberPortal/About/code.

Academy Guidelines

Dr. Zacks said the Academy is working on its own guidelines and policies, and will continue to review and update its policy statements such as Gifts to Physicians from Industry, which was created in 1991 as an adoption of the AMA’s statement with the same title. In fact, new revisions of this policy statement were approved by the Academy’s board of trustees this past January.

The revised statement on gifts states that ophthalmologists must avoid any appearance of impropriety; disclose potential conflicts to patients, the public and colleagues; and take the high road to avoid unintended influence by industry. This statement can be found at www.aao.org/about/policy.

Hidden Dangers of Influence

Dr. Zacks notes that some practicing ophthalmologists may be tempted to view this focus on ethical guidelines as an overreaction to recent industry events. Yet research has shown that even small gift items and seemingly inconsequential relationships can affect physician behavior, such as choice of devices and prescribing habits. Mr. White referred to an article in the Journal of the American Medical Association that cites social science research showing that the impulse to reciprocate even for small gifts is a powerful influence on the way people behave. It goes on to say that people who receive gifts, large or small, often cannot remain objective. In addition, people who purport to give gifts with “no strings attached” still have an expectation that they will receive something in return.

Potential Impact on Residents

One worry for residency programs across the country is the decrease in unrestricted educational grants. “Resident education is an unfunded mandate, and even in state institutions we get very little money for resident education and are forced to skim funds from the clinical enterprise,” Dr. Oetting said. “We don’t know how these new rules will play out yet at the University of Iowa, but we do worry how we are going to provide the same level of CME courses and residency education events.”
The study also cites research showing that physicians have positive attitudes toward pharmaceutical representatives who give them gifts. The authors recommend more stringent regulation around gifts, pharmaceutical samples, drug formularies, CME, funds for physician travel, speakers bureaus and ghostwriting, and consulting and research contracts. “This research confirms the need for a common set of principles concerning industry relations with physicians,” Dr. Parke said.

Time to Get Up to Speed
Dr. Zacks strongly suggests that ophthalmologists, read up on the ethics code revisions and become familiar with current ethical guidelines on managing conflicts arising from relationships with industry. “We face the specter of either self-regulating or being regulated. The game is changing, and everyone should become familiar with the new rules,” Dr. Zacks said.