The True Cost of Transparency

Why some physicians are speaking out against a new code of conduct.

BY STEPHEN DAILY, NEWS EDITOR

After several high-profile, corporate corruption scandals that shook the global economy, medical specialty societies and physician groups are under increased pressure by politicians, regulators, and the public to disclose financial relationships with industry. Some physicians, however, are claiming that the new rules being adopted are unfair, are counterintuitive, and could impede scientific discovery, which they argue has traditionally relied on relationships with industry.

The debate has intensified in recent months as 13 medical specialty societies, including the American Academy of Ophthalmology (AAO), have agreed to formally adopt a new code of conduct approved in April by the Council of Medical Specialty Societies (CMSS). Altogether, the member organizations of the CMSS represent more than 650,000 American physicians.

The voluntary "Code for Interactions with Companies" sets forth guidelines for interactions between medical societies and key leaders of those societies and pharmaceutical and medical device companies.[1] Physicians who responded to inquires from *Cataract & Refractive Surgery Today* overwhelmingly oppose the policies set forth in the CMSS code, and they claim several of the included measures could stifle innovation and ultimately hurt patients.

A PUSH FOR INCREASED DISCLOSURE

Norman Kahn, MD, executive vice president of the CMSS, told *CRSToday* that the council decided to develop the code of conduct 2 years ago because there was a gap in the existing codes.

"There was no code that governed the relationships of specialty societies with industry, and since that was one of our strategic priorities—professionalism—we decided that it was our responsibility to create such a code," Dr. Kahn said.

The CMSS code was also influenced by much-publicized reports in April 2009, published by the Institute of Medicine and the *Journal of the American Medical Association*, in which a doctor-led expert panel called for stricter management of financial conflicts. The panel concluded that the current policies of professional medical associations were not uniform and often lacked stringency.[2]

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"We already had our task force at that time, but we took a look at that report, and we said, 'That's a pretty good table of contents for our code.' So, that helped us focus the eventual code for the medical societies," Dr. Kahn said.

In an interview with *CRSToday*, David W. Parke, MD, chief executive officer of the AAO, said the Academy decided to adopt the CMSS code to increase its level of transparency and integrity.

"I think it's critical that our profession—ophthalmology—and the American Academy of Ophthalmology, as the umbrella premier ophthalmic organization, be viewed by all the important stakeholders as demonstrating integrity, trust, and true professionalism," Dr. Parke said. "And by stakeholders, I mean patients, the media, Congress, policymakers, and our own members. Our members should have great faith that the Academy is acting in a highly professional fashion as it pertains to its financial relationships to industry."

The AAO has its own long-standing code of ethics, and it is the only code in all of medicine approved by the Federal Trade Commission, Dr. Parke said. In several areas, the AAO's code is more specific than the CMSS code, and in those situations, the Academy's code trumps the CMSS code, he added.

"We are going to be compliant with both, but the [AAO] is even more rigorous," Dr. Parke said.

DOCS: CMSS CODE OVER THE TOP

The stated purpose of the CMSS code is to ensure independence, transparency, and the advancement of medical care for the benefit of patients and population groups. The 28-page code sets forth 10 key principles for member societies' interactions with industry, along with annotations that explain the CMSS' current interpretation of certain key principles.

Among the main areas addressed in the code is the recommendation that societies publicly disclose donations and support received from for-profit companies in the health sector, along with board members' financial and uncompensated relationships with companies. It also calls for societies to develop and make publicly available policies and procedures that ensure that educational programs, advocacy positions, and research grants are developed independent of industry supporters. Also, the code does not allow industry-sponsored "reminder" items, such as tote bags and note pads, to be dispensed at society meetings.

Such measures have some physicians questioning the unintended consequences of such restrictions.

"I think we are beginning to see some potentially concerning change that right now is limited to key AAO leaders," Ronald R. Krueger, MD, medical director of the Department of Refractive Surgery, Cole Eye Institute, Cleveland Clinic Foundation, told *CRSToday*. "What used to be disclosure is now going to divesture. For the sake of transparency, key AAO leaders (president, CEO, and editor-in-chief of the AAO journals) have to divest of everything that they own, any kind of relationship or stock ownership they have with a company. Although of noble intention, this is somewhat prohibitive for those aspiring to these positions and could become especially prohibitive if it begins to filter down to other leadership positions or policy-making committees. If so, it would restrict the most innovative individuals who contribute to new technology from having a voice in the education and expansion of our field."

"People need to be worried that it does not muzzle useful and appropriate conversation, and [AAO society leaders] should not lose sight of the fact that we cannot serve our patients without industry," said Lisa Brothers Arbisser, MD, of Eye Surgeons Associates, Iowa and Illinois Quad Cities, and adjunct associate clinical professor at the John A. Moran Eye Center of the University of Utah in Salt Lake City. "We need to be partners in medicine and industry, particularly with government having so little input at this point, financially, for granting and so on. I

think it is really important that we are able to communicate about advances."

Dr. Parke, however, maintains that the CMSS code does not stifle innovation or break up physicians' relationships with industry.

"I like to emphasize that the [CMSS] code does not constrain clinical trials, it does not prohibit individual ophthalmologists from financial relationships, it does not prohibit ophthalmologists from serving as consultants to companies, and it does not prohibit them from presenting that material as speakers at Academy events," Dr. Parke said. "It simply says that, as long as an ophthalmologist receives direct financial payments from industry, he or she cannot serve in a few key positions where those payments could lead the organization, and the policy positions that it takes, as being untrustworthy."

Another aspect of the code some physicians are questioning is its policy on continuing medical education (CME) programs. The code calls for specialty societies to adhere to the Accreditation Council for Continuing Medical Education's (ACCME) standards for commercial support and to clearly distinguish between the accredited CME courses, industry-sponsored satellite symposia, and nonaccredited programs offered at the meetings.

Dr. Parke said the AAO complied with ACCME standards before the CMSS code was adopted, and he said that doctors who consult for industry will continue to be allowed to give talks at meetings that include CME hours.

Although the subject matter covered by the CMSS code generally overlaps that addressed in the Pharmaceutical Research and Manufacturers of America Code, Advanced Medical Technology Association (AdvaMed) Code, and ACCME standards, the CMSS code is more stringent than its predecessors in several respects, according to a report by Sidley Austin LLP (Chicago, IL), a global law firm that deals with litigation and regulatory matters.[3]

"For example, the CMSS Code requires member societies to disclose to its members and the public the names of any companies providing support for CME, corporate sponsorships, charitable contributions, and research grants," the report states.

"Clearly, some reform was needed, as some CME programs had begun to resemble extended commercials for the sponsoring companies' products," said Robert K. Maloney, MD, director of the Maloney Vision Institute in Los Angeles in an interview with *CRSToday*. "However, I

think the reforms went too far. These rules will have the effect of disqualifying some of the most knowledgeable speakers from speaking and disqualifying some of the most capable leaders from leading," he added. "As a result, I predict a move to non-CME courses for physicians who want the latest, most innovative educational programming."

One of the most highly contentious areas for doctors who spoke with *CRSToday* is the CMSS' stance on independent leadership, which prohibits societies' leaders—including presidents, CEOs, and editors-in-chief of societies' journals—from having direct financial relationships with relevant for-profit companies in the health care sector. It would also, for the first time in history of the AAO, prevent individuals on clinical guideline committees from having ties with industry.

J. Michael Gonzalez-Campoy, MD, PhD, serves on the steering committee of the Association of Clinical Researchers and Educators, an advocacy group that defends physician-industry collaboration. He said the leadership policy of the code will remove the most qualified individuals from the most important roles.

"The problem is that most of the people who are at the cutting edge of [a] specialty are the ones who are doing clinical research and educating their peers," Dr. Gonzelez-Campoy said. "If you prevent those people from having leadership positions in their organizations that are part of CMSS, you have basically prevented the most expert, the most wise individuals in their specialty from having leadership positions in their organizations. You are going to have specialty organizations being led by individuals that are not the most expert, which is going to hurt medicine in a big way."

Drs. Krueger and Maloney pointed to the recent resignation of George O. Waring III, MD, who stepped down in July after 20 years as editor-in-chief of the AAO's *Journal of Refractive Surgery*, as an example of why they object to the updated CMSS code. Dr. Waring resigned because of a commercial relationship he held.

Dr. Parke discounts the argument that the independent leadership policy will eliminate cutting-edge physicians from the leadership roles and cites the vast pool of talent.

"At the Academy, we have 30,000 members, and there are more than just a handful of people who are qualified for leadership positions," Dr. Parke said. "So, to say that all 500 of the leadership-qualified individuals are going to choose their personal finance over the organization just has proven to be not true. There are some medical organizations that have had this rule for years, and in speaking with their leaders, they have not really had a problem. In the end, those leaders who really want to be leaders in their profession, and be the voice of their profession, are going to choose the organization over a financial payment from industry."

TREND TOWARD MORE SCRUTINY

The introduction of the CMSS code is the latest in what have been repeated efforts over the past year to shine a light on potential conflicts of interest taking place behind closed doors.

Included in the enactment of the federal health care reform act in March was the Physician Payment Sunshine Act [H.R. 3590, section 6002] that will require manufacturers, starting in 2013, to disclose any "in kind" payments made to physicians or teaching hospitals in the form of compensation, food, entertainment or gifts, travel, consulting fees, honoraria, research funding or grants, education or conference funding, stocks or stock options, ownership or investment interest, royalties or licenses, charitable contributions, and any other transfer of value as described by the secretary of the Department of Health and Human Services.

In addition, in May, directors of the National Institutes of Health proposed new rules that would lower the dollar threshold at which researchers funded by the Institutes would have to disclose their financial ties with industry to the university at which they work.[4]

As the move toward greater disclosure continues, stakeholders will continue to debate the issue of protecting the integrity of the ophthalmic profession versus the potential to impede relationships that lead to scientific discovery.

"I think it's really important that we are able to communicate about advances without being so restricted in our rules that we can't teach and learn," Dr. Arbisser said. "I do think [the CMMS Code] has the potential for stifling innovation, and there's no real incentive for a company to develop things if doctors don't learn and implement them."

"You might say, '[One] should not be forced to make a choice [between society leadership or ties with industry],'" Dr. Parke said. "The reality is, in the world in which we live, our board felt unanimously that [it] was critical that we be able to hold ourselves out to our members and to the public as being free from any conflicts of interest that might impair our ability to make critical decisions."

The full code, and the list of signers who have adopted it thus far, is available on the CMSS' Web site at http://www.cmss.org/codeforinteractions.aspx. ■

1. Code for interactions with companies. Council of Medical Specialty Societies. http://www.cmss.org/codeforinteractions.aspx. Accessed July 29, 2010.
2. Collins F, Rockey S. Managing financial conflicts of interest in biomedical research. *JAMA*. 2010;303(23):2400-2402.
3. Sidley Austin LPP. Council of Medical Specialty Societies issues voluntary code for interactions with pharmaceutical and medical device industry. Published May 12, 2010. http://www.sidley.com/sidleyupdates/Detail.aspx?news=4414. Accessed July 29, 2010.
4. Rothman D, DeAngelis C, Hale R, et al. Professional medical associations and their relationships with industry. A proposal for controlling conflict of interest. *JAMA*. 2009;301(13):1367-1372.