ACC and Others Pledge Disclosure Transparency

BY ALICIA AULT

The American College of Cardiology is one of several medical specialty societies that have signed a voluntary pledge to be more transparent in dealings with pharmaceutical and medical device manufacturers and other for-profit health care companies.

The pledge, issued by the Council of Medical Specialty Societies (CMSS), capped a year of negotiations, said Dr. Allen S. Lichter, chair of the CMSS Task Force on Professionalism and Conflict of Interest and the CEO of the American Society of Clinical Oncology.

'Properly managed partnerships with industry are absolutely critical to maintaining scientific progress in cardiology and other specialties.'

"CMSS is committed to encouraging and supporting a culture of integrity, voluntary self-regulation, and transparency," said Dr. James H. Scully Jr., CMSS president and chief executive officer of the American Psychiatric Association. "This code provides a clear benchmark for maintaining integrity and independence."

The societies adopting the CMSS Code for Interactions With Companies agree to establish and publish conflict of interest policies as well as policies and procedures to ensure separation of program development from sponsor influence. They must disclose corporate contributions and board members' financial relationships with companies, and must prohibit financial relationships for key association leaders.

"Properly managed partnerships with industry are absolutely critical to maintaining scientific progress in cardiology and other specialties," Dr. Jack Lewin, CEO of the ACC said in a statement. "This code is a step in the right direction for specialty societies and reaffirms our commitment to the highest ethical standards as we continue to move toward responsible, transparent relationships that will allow us to maintain quality education and research in cardiovascular medicine."

The ACC noted that it posts funding sources as well as disclosures for all trustees, committee chairs, and state chapter governors on its Web site.

Other signers include the American Academy of Family Physicians, American Academy of Neurology, American Academy of Pediatrics, American College of Emergency Physicians, American College of Obstetricians and Gynecologists, American College of Physicians, American Society for Radiation Oncology, American Society for Reproductive Medicine, American Society of Clinical Oncology, and the Society of Critical Care Medicine.

Dr. Lichter called the code a "very important milestone" because it will create consistency where there has been none and because it is a public undertaking.

The code represents a minimum set of guidelines. Some organizations may choose to be more restrictive, he said.

According to the CMSS, the code was developed by a 30-member task force. More of the 32 members of the CMSS plan to adopt the code in the next few months. ■

The code is available at www.cmss.org/codeforinteractions.aspx.

Patients Want Researchers To Disclose Financial Ties

BY JANE ANDERSON

FROM THE ARCHIVES OF INTERNAL MEDICINE

Physicians, patients, and study participants believe researchers' financial ties to industry decrease the quality of evidence, and patients say that such ties influence professional behavior and should be disclosed, a review of studies has found.

For some, knowledge of the researchers' financial ties to industry would affect their willingness to participate in studies, wrote Dr. Cary Gross of Yale University, New Haven, Conn., and colleagues (Arch. Intern. Med. 2010;170:675-82).

"When any financial tie was disclosed, there was a reduction in the perceived quality of research" among participants and physicians, they reported. Patients believed that financial ties decreased the quality of clinical care and affected prescribing behavior.

The investigators reviewed 11 original quantitative studies of the views of patients, research participants, and journal readers about financial ties and perceptions of quality.

In studies of patient perception of cost, 26%-76% said they believed that gifts to physicians increase the cost of care; fewer patients thought professional gifts were a problem.

"In a 2009 study of 903 patients contacted by telephone, 9% disapproved of physicians receiving free drug samples and 16% disapproved of free medical texts, compared with disapproval rates of 55% and 68%, respectively, for paid dinners and golf tournaments," Dr. Gross and his colleagues wrote.

In other studies, when asked to rate disclosure statements, respondents said researchers with financial ties were less trustworthy and less important than were those without such ties.

For some potential trial participants, disclosure of financial ties affected their willingness to participate. "Three studies reported that prospective research participants were least willing to participate in a hypothetical clinical trial when a researcher equity ownership was disclosed," wrote Dr. Gross and his colleagues. "Of note, the participants also reported less trust in researchers after disclosure of financial ties."

In an editorial, Eric Campbell, Ph.D., of Harvard University, Boston, said public disclosure seems like a likely first step toward a more active government and health care institution role in evaluating and managing physician-industry relationships (Arch. Intern. Med. 2010;170:667).

"This will likely be seen by some physicians as a direct assault on their sense of professional identity and autonomy," he wrote. But the transparency "will help prevent the further erosion of public trust in the medical profession."

The review was funded in part by a Doris Duke Clinical Research Fellowship. Dr. Gross and a coauthor disclosed ties to Genzyme Corp. Dr. Campbell did not report any financial disclosures.

FDA Issues Guidance on Waivers, Conflicts of Interest

BY JANE ANDERSON

The Food and Drug Administration has released draft guidance to provide more information on conflicts of interest involving members of its advisory committees and the waivers that allow them to participate in specific meetings.

The guidance aims to bring agency policy in line with standard conflict-of-interest practice in the academic community, where medical journals require disclosures to be specific and thorough, said Jill Hartzler Warner, acting associate commissioner for special medical programs at the FDA.

"When final, the guidance will increase transparency of the waiver process so that the public can understand the nature of the potential conflict," Ms. Warner said.

The FDA has 49 advisory committees with a total of more than 600 positions that provide advice on specific regulatory decisions, such as drug and device approvals, and general policy matters, such as regulations.

For highly technical subjects, the FDA often must choose from a small pool of potential advisers who frequently have conflicts of interest, she said.

Federal law allows the FDA to grant waivers so experts with conflicts of interest can participate in advisory committee meetings, but the waiver and disclosure process has been controversial. The FDA acknowledged that its decisions could be viewed as tainted if it relies too heavily on experts with conflicts.

When a waiver is granted, federal law requires the FDA to disclose the type, nature, and magnitude of the conflict on its Web site. Ms. Warner said that the law limits the number of waivers to about 13% of all members participating in committee meetings, and in practice the agency grants waivers to fewer than 5%.

Currently, when the FDA decides to grant a waiver, it discloses whether the interest involved is associated with the sponsor, a competitor, or another affected firm. Under the draft guidance, the nature of the waiver granted and name of the company involved would be posted online prior to committee meetings.

As a part of this effort, FDA Commissioner Margaret Hamburg advised senior FDA staff in an April letter to take three steps to minimize conflicts:

► Consider the nature of the conflict before granting a waiver. A researcher whose institution receives grants from an affected company but who does not personally participate in the studies has a more tangential relationship to the conflict than does one who conducts studies for the company directly.

► Weigh the advisory committee meeting issues. Waivers may be more appropriate for meetings to consider broad policy issues and less appropriate for specific product considerations.

► Explain why the individual's participation is needed, and provide information on the search for equally expert advisers without conflicts. ■

View the draft guidance at www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM209201.pdf. Public comment will be accepted through June 20.

INDEX OF ADVERTISERS

Accumetrics VerifyNow	11	**Otsuka America Pharmaceuticals, Inc.** Samsca	3-4
Bayer HealthCare LLC Aspirin	32	**sanofi-aventis U.S. LLC** Multaq	24a-24d, 25-26
Daiichi Sankyo, Inc. and Lilly USA, LLC. Effient	17-19	**University Nuclear & Diagnostics** Corporate	21
Forest Laboratories, Inc. Bystolic	13-16	**University of Pittsburgh Medical Center** Corporate	23
Gilead Sciences, Inc. Ranexa	8-10		