Reforms Proposed to Limit Conflicts of Interest

BY MARY ANN MOON
Contributing Writer

The relationship between physicians and the makers of pharmaceuticals and medical devices now is so fraught with conflicts of interest that broad reforms regulating their interactions are essential, according to a group of medical ethics experts.

Industry-sponsored events, the dispensing of free samples and other "gifts" by detail people and drug reps, and lucrative "consultation" agreements are unmistakable ploys by drug and device makers to promote the use of their products. These practices have intensified in recent years to the point that they pose a "serious threat" to both physician integrity and patient welfare, Dr. Troyen A. Brennan of Harvard Medical School, Boston, and his 10 coauthors noted.

Existing guidelines of such groups as the American Medical Association, the American College of Physicians, and the Accreditation Council for Continuing Medical Education "are not sufficiently stringent" and allow both professionalism and patient care to be undermined. "The profession itself must exert much tighter control over the relationships between manufacturers and physicians," Dr. Brennan and his associates said (JAMA 2006;295:429-33).

The group, whose work was sponsored by the American Board of Internal Medicine Foundation and the Institute on Medicine as a Profession, called for academic medical centers to take the lead in:

► Prohibiting all gifts to physicians including free samples, meals, payment for travel, and payment for time spent at meetings.

► Strictly regulating industry support of continuing medical education and prohibiting direct funding of CME meetings.

► Strictly regulating industry support of research.

► Strictly regulating hospital purchases of drugs and medical devices.

► Prohibiting faculty from serving on manufacturers' speakers bureaus and from publishing material ghostwritten by industry employees.

Of these proposed reforms, the prohibition of gifts such as drug and device samples may have the greatest effect on physicians in private practice, if it is enacted.

Most physicians believe that detailers' gifts don't influence their prescribing behavior. But pharmaceutical companies would hardly spend some 90% of their $21 billion marketing budget on these and other practices if the strategies weren't successful in promoting their products, Dr. Brennan and his associates said.

"An overwhelming majority of interactions [with drug and device makers] had negative results on clinical care" in a recent review of the literature, the authors wrote. Prohibiting detailers' visits to physicians' offices will deprive manufacturers of "foot in the door" access that unduly influences physicians' choices of treatment, they added. But regardless of whether sampling should be eliminated, what goes on in a private practice is beyond the control of academic medical centers and the AMA, commented Dr. Prakash Deedwania, professor of medicine at the University of California, San Francisco, and chief of the cardiology section at the Veterans Affairs Medical Center in Fresno. And the practice simply doesn't exist in many academic institutions, such as UCSF, which neither accepts samples nor allows pharmaceutical representatives in the offices, he added.

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Regarding pay for physicians' travel expenses to medical meetings, the editorial writers are ignoring the fact that trainees don't get financial support from their institutions as they once did, and that those institutions don't have the money to send them, Dr. Deedwania said.

Also unrealistic is the notion that CME can survive without industry support, said Dr. John Flack, professor and interim chair of the department of medicine and chief of the division of clinical epidemiology and translational research at Wayne State University, Detroit.

"Without industry support, CME will become a thing of the past, because few entities can afford to pay for it," Dr. Flack said.

Nonetheless, many in the academic community have had a more positive response to the proposals, said Dr. Jordan J. Cohen, one of the JAMA report's coauthors and president of the Association of American Medical Colleges, Washington. The reforms will, of course, meet with resistance because they "represent a big change in practices that have been very widely accepted over a significant time, and frankly there's a significant amount of money in play here. I won't suggest that it would be at all easy to implement these changes, but it is looking possible," he said.

The proposals "will at least inspire a good deal more conversation about, and examination of, current policies and their unintended consequences, which are not in the best interests of the public. It will allow the medical community to find other ways of supporting activities that are now dependent on the health care industry," he said.

Dr. David L. Coleman, interim chair of internal medicine at Yale University, New Haven, Conn., applauded Dr. Brennan's group for "stepping forward with a very bold set of recommendations." Yale has already implemented strict guidelines prohibiting any gifts from industry representatives, any meals funded by industry, and any payment for attending CME meetings. The Yale guidelines are detailed in a report published in February (Acad. Med. 2006;81:154-60).

"I think banning food and gifts makes things a lot easier, frankly," he said. "It's so nice to walk into a conference and not have to have that awkward conversation with a drug rep, and not have to feel squeamish about possible conflicts of interest."

He acknowledged that the proposed reform central to most physicians in private practice—banning free samples and other gifts from detail people—is not likely to be adopted any time soon. At Yale, "we considered banning free samples for patients, because it clearly encourages the use of more expensive medications. Even worse, it is a poorly regulated process, so these drugs can end up in the hands of patients who are not followed adequately. But it was finally decided that free samples could not be prohibited until some other system for delivering free samples to needy patients is in place."

Yale did ban the use of free samples by physicians and their families, a measure that has had an unexpectedly large effect. "There has been some grumbling," but the response to the strict guidelines from Yale physicians as well as outsiders has been overwhelmingly positive, Dr. Coleman said.

Another dissenting note was sounded by Ken Johnson, senior vice president of Pharmaceutical Research and Manufacturers of America, Washington, who noted that sales representatives are technically well trained and provide crucial information to doctors about the way drugs work and their side effects. Most detailers already follow PhRMA's voluntary guidelines and focus on ensuring that medicines are used correctly, he said.

Most physicians interviewed agreed heartily with one proposed reform: ghostwriting. This should be controlled or eliminated, because some companies do influence the wording in research manuscripts, and busy investigators may go along with it, Dr. Deedwania said. ■

Worries About Genetic Testing for Cancer Called Misplaced

BY BRUCE JANCIN
Denver Bureau

SAN ANTONIO — The specter of discrimination based on genetic test results has turned out to be greatly overblown, Dr. Kenneth Offit said at a breast cancer symposium sponsored by the Cancer Therapy and Research Center.

"It's a topic we've heard a lot about. Maybe too much," added Dr. Offit, chief of the clinical genetics service at the Memorial Sloan-Kettering Cancer Center, New York.

"Forty percent of our patients come in saying that this is their major concern, not medical issues. They're worried they'll lose their insurance and that employers will discriminate against them. This is a profound concern," he noted.

Yet this concern has neither been borne out in the more than 4,000 patients at Sloan-Kettering who have undergone genetic testing nor in the 600 known cancer mutation carriers who are being followed there on a regular basis.

"We've asked them, and not one of them has had an episode of genetic discrimination in the workplace or their insurance," the oncologist continued.

Similarly, a careful seven-state survey conducted a few years ago found no cases of genetic discrimination (Am. J. Hum. Genet. 2000;66:293-307).

"Yet the press and the media still harp on the issue of genetic discrimination," Dr. Offit said.

"Insurance companies in North America are paying for genetic testing, they're paying for counseling, and they're paying for preventive surgery. And in one of the least-told stories around, companies like Blue Cross/Blue Shield and Aetna in New York don't require that genetic test results even go back to them," Dr. Offit said.

Patients are 'worried they'll lose their insurance and that employers will discriminate against them.'

DR. OFFIT

Two federal statutes protect patients from genetic discrimination: the Americans with Disabilities Act and HIPAA. There is also a federal precedent in the form of a Burlington Northern and Santa Fe Railway Company settlement with the Equal Employment Opportunity Commission that helps protect the medical confidentiality of genetic test results.

Moreover, in 2003 the U.S. Senate unanimously passed a bill banning discrimination in employment or health insurance based on genetic testing. The bill hasn't passed in the House of Representatives simply because genetic discrimination is no longer seen as a priority concern there, he said.

Yet genetic discrimination continues to be a high-visibility worry in the eyes of the public—and this overblown concern can have destructive consequences.

For instance, in a 384-patient study, 14% of women who were at risk for hereditary breast cancer declined BRCA mutation testing because of concern about insurance discrimination, and based on testing of other women in the study, one-half of those who declined testing would have been expected to be BRCA positive (Cancer Epidemiol. Biomarkers Prev. 2002;11:79-87).

"The folks that most need the testing are the ones most worried about it," Dr. Offit observed. ■